

Volume VIII

Part 2. Biospecimen Collection and Transport Procedures



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Overview

Biospecimens will be collected in the home, clinic, or birth setting and will be transported to a local Specimen Processing and Shipping Center (SPSC) for temporary storage before shipping to a central National Children's Study (NCS) repository or histology laboratory. An overview of the types of biospecimens that will be collected from study participants over the course of the NCS is presented in Table 1-1 in Part 1 of this volume.

Before a data collector may obtain biospecimens from a study participant during a data collection visit, the participant must sign a biological and environmental sample collection informed consent document. This consent form need be signed only once for each participant during the first visit when biospecimens are to be collected. The visit coordinator will use the Field-Administered Collection Environment (FACE) to launch the consent instrument to administer the biological and environmental sample consent. If the participant declines to sign the consent form, biospecimens may not be collected from the participant. Detailed procedures for administering the biological and environmental sample collection consent are found in Volume I.

Part 2 describes step-by-step procedures for the collection and transport of all NCS biospecimen types except blood, which is covered in Part 4. This includes general instructions for the documentation of collection and transport activities using FACE. Detailed specifications for administering each collection instrument in FACE are found in volume Appendix VIII-A. If FACE is unavailable at the time of biospecimen collection, the appropriate hard copy backup forms should be used to document collection data until data can be entered in the system. Participant collection instructions and data collection forms are located in the appendices at the end of each chapter where they are referenced. Frequently Asked Questions (FAQs) that may be asked by participants regarding biospecimen collection activities are located in Appendix I-F in General Resource Documents of Volume I.

The procedures presented in Part 2 are organized by chapters according to biospecimen type. Every chapter contains all the information needed to collect and transport specimens for all study events. The procedures do not distinguish between event types if the procedures are the same



(i.e., “T3” may refer to either a T3 first or a T3 prior study event if there is no difference between the collection procedures for these event types). When specific events require additional procedures or modifications, the event-specific information is displayed in a box. Refer to the event-specific parts in Volume V for more detailed information about specific biospecimen activities for each event type.

Collection and transport procedures for the following types of biospecimens can be found in the following chapters. The study events during which each biospecimen type is collected are indicated.

Chapter 2	Urine Collection and Transport Procedures
2.1	Adult Urine (P1, T1 mother, T1 father, T3)
2.2	Pregnancy Testing and Pregnancy Urine (P1)
2.3	Infant Urine (6-Month, 12-Month)
Chapter 3	Vaginal Swab Collection and Transport Procedures (P1, T1 mother, T3)
Chapter 4	Saliva Collection and Transport Procedures
4.1	Adult 2-Day Saliva (T1 mother, T3, 6-Month)
4.2	Adult Blood Not Collected (BNC) Saliva (P1, T1 mother, T1 father, T3)
Chapter 5	Hair Collection and Transport Procedures
5.1	Adult Hair (P1, T1 father, T3)
5.2	Child Hair— <i>Forthcoming</i>
Chapter 6	Toenail Collection and Transport Procedures (T1 father, T3)
Chapter 7	Birth Biospecimen Collection and Transport Procedures
7.1	Overview
7.2	Maternal Blood Collection and Transport Procedures
7.3	Cord Blood Collection and Transport Procedures
7.4	Placenta and Umbilical Cord Collection and Transport Procedures
7.5	Infant Blood Spot Collection and Transport Procedures
7.6	Meconium Collection and Transport Procedures
Chapter 8	Breast Milk and Infant Formula Collection and Transport Procedures (1 month, 6-Month)

Urine Collection and Transport Procedures

2.1 Adult Urine

Adult urine specimens will be collected at the P1 mother, T1 mother, T1 father, and T3 mother study events. Adult urine specimens will be analyzed to obtain information about physiological conditions and environmental exposures.

A participant may provide a urine specimen at any time during a specified visit. However, for visits during which both urine and vaginal specimens are collected, it is preferred that the participant self-collects the vaginal specimens at the same time (i.e., during the same bathroom visit) as the urine specimen.

Note: These collection procedures are for Group 1 *only*. For Group 2 T3 urine collection, please refer to Part 2 Addendum A (at the end of this part).

2.1.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to collect and transport adult urine:

- Adult Urine Collection Kit (kit contents are in the next list)
- Specimen collection tray
- Disposable laboratory coat
- Gloves
- Hand sanitizer
- Biohazard waste bag
- Biospecimen transport cooler
- Dry ice

- Dry ice glove
- Computer tablet with bar code scanner
- Computer keyboard cover.

The Adult Urine Collection Kit contains the following items:

- One prelabeled urine collection container with lid
- One biohazard transport bag
- Two absorbent pads
- Two paper towels
- Adult Urine Collection Instructions
- One adhesive label for Biospecimen Transmittal Form (TM label)
- One adhesive label for hard copy backup Adult Urine Data Collection Form (DC label)
- Three additional adhesive labels for collection container (EX labels).

The following form is required to collect and transport adult urine specimens:

- Event-specific Biospecimen Transmittal Form (see volume Appendices VIII-B through VIII-G for forms and field-by-field instructions).

Urine collection data will be documented in the Biospecimen instrument in the Field-Administered Collection Environment (FACE). If FACE is not available, then the appropriate hard copy backup Adult Urine Data Collection Form must be used to document collection data (see Appendices 2-A and 2-B for form and field-by-field instructions). Once the system becomes available, data must be entered in the system from the backup form. Instructions for entering data from backup forms into FACE can be found in the document *Guide to FACE Data Entry From Backup Biospecimen Data Collection Forms: Prenatal Data Collection* (located on the NCS Collaboration Portal).

2.1.2 Step-by-Step Procedures for Adult Urine Collection

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following procedures are to be used for adult urine collection. For general guidance on how to use FACE for data collection activities, refer to the FACE User's Guide. For detailed question-by-question specifications for administering the Biospecimen instrument, refer to the appropriate section in volume Appendix VIII-A.

1. Put on a disposable laboratory coat.
2. Place the computer keyboard cover on the keyboard if you have not already done so. This will prevent the keyboard from contamination when handling specimens during the visit. One keyboard cover will be used for the duration of the biospecimen collection.
3. Launch the Biospecimen Data Collection instrument (Module 1) of FACE on the tablet. If FACE is not available, the hard copy backup Adult Urine Data Collection Form should be used.

P1 Mother, T1 Mother, T3 Mother

Follow the prompt in FACE to give the participant the option of collecting the vaginal swabs at the same time she is collecting the urine specimen (i.e., during the same bathroom visit).

4. Read the urine collection questions to the participant from FACE and enter the responses. If FACE is not available, read the collection questions in Part B of the hard copy backup Adult Urine Data Collection Form and record the responses.

P1 Mother, T1 Mother, T3 Mother

If both urine and vaginal swabs are to be collected during the same bathroom visit, FACE will prompt the user to ask the vaginal swab collection questions at this time. If FACE is not available read the collection questions in Part B of the hard copy backup Vaginal Swab Data Collection Form and record the responses.

5. Locate the Adult Urine Collection Kit and event-specific Biospecimen Transmittal Form.

P1 Mother, T1 Mother, T3 Mother

If both urine and vaginal swabs are to be collected during the same bathroom visit, also locate the Vaginal Swab Collection Kit. Follow the procedures in Chapter 3 of this part and volume to provide the participant with the Vaginal Swab Collection Kit and instructions simultaneously with the urine kit and instructions.

6. Wand the collection kit bar code into FACE and validate the kit type and expiration date.
7. If the kit type is valid and the kit is not expired, open the kit and remove the urine collection container, instructions, and labels.
8. Give the prelabeled urine collection container to the participant for collection.
9. Instruct the participant in the urine self-collection procedures using the Adult Urine Collection Instructions (see Appendix 2-C). The participant may refer to the collection instructions when collecting the specimen.
10. While the participant is in the bathroom collecting the specimens, do the following:
 - a. Place the TM label on the Biospecimen Transmittal Form.
 - b. If FACE is not available during the collection procedures, the hard copy backup Adult Urine Data Collection Form should be used. Place an extra subject label (from the visit coordinator's supplies) in the appropriate place on the form and place the DC label in the appropriate place on the form.
 - c. Put on gloves.
11. Place the specimen collection tray on a flat surface.
12. When the participant returns with the specimen:
 - a. Thank the participant for providing the specimen and ask him or her to place it on the specimen collection tray, and
 - b. Check the lid of the urine collection container to make sure it is securely closed.

2.1.3 Documenting Adult Urine Collection

1. Record the urine collection status in FACE and wand the bar code label on the urine collection container.

2. Place the urine specimen in the biohazard transport bag with the absorbent pad and seal the bag. Wearing the dry ice glove, immediately place the sealed bag on dry ice in the transport cooler.
3. Record any comments pertaining to the urine specimen collection in FACE (up to a 250-character limit) or on the hard copy backup Adult Urine Data Collection Form. If using the backup form, ensure the form is complete.
4. Record the urine collection status on the Biospecimen Transmittal Form.
5. If an incident occurs during the urine collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

2.1.4 Clean-Up Procedures

- After completing the urine collection procedures, make sure the work area is clean and reusable.
 - The work area is reusable if contamination, such as a spill, has *not* occurred.
 - If a spill has occurred, clean the tray with a bleach wipe. Discard items in the biohazard waste bag.
 - If the urine specimen is the last biospecimen collected at the visit, remove the computer keyboard cover, clean the work area and pack all collection supplies.
- After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer. Be sure to pack the biohazard waste bag appropriately for transport so that it is not visible upon leaving the site of data collection. The biohazard waste bag must be disposed of properly at the Specimen Processing and Shipping Center (SPSC).

2.1.5 Transport Procedures

Urine specimens will be transported to the SPSC in the dry ice chamber of the biospecimen transport cooler.

- Ensure the Biospecimen Transmittal Form is complete. If this is the last biospecimen type collected at the visit, place the completed form in the zippered document pouch inside the lid of the transport cooler along with any unused labels.

- Secure the biohazard transport bag containing the urine container in the dry ice and confirm the cooler is properly closed for transport.

2.2 Pregnancy Testing and Pregnancy Urine

At the P1 mother data collection visit, the data collector will collect a urine specimen from the study participant. At the same visit, participants in the High Tryer Pregnancy Probability Group¹ will receive a Pregnancy Test and Urine Collection Kit. The kit contains materials and instructions for performing pregnancy tests and for collecting and storing a urine specimen after a positive pregnancy test.

Pregnancy urine specimens will be analyzed to obtain information about physiological conditions and environmental exposures.

2.2.1 Providing Participant with Pregnancy Test and Urine Collection Materials (P1 Study Event)

2.2.1.1 Equipment, Supplies, and Forms

The following equipment, supplies and forms are required:

- Pregnancy Test and Urine Collection Kit (kit contents are in the next list)
- Prelabeled Pregnancy Test and Urine Data Collection Form. This is a self-administered questionnaire (SAQ) to be completed by the participant at the time of collection (see Appendices 2-D and 2-E). The form must be prelabeled with the subject label.
- Computer tablet with bar code scanner.

The Pregnancy Test and Urine Collection Kit contains the following items:

- Five First Response[®] pregnancy tests

¹ Information from the Pregnancy Screener is used to assign study participants to one of five pregnancy probability groups. At the P1 data collection visit, FACE will prompt the data collector to give the participant a Pregnancy Test and Urine Collection Kit if she has been assigned to the High Tryer Pregnancy Probability Group. Participants in the other groups *will not* receive this kit at the P1 data collection visit. For detailed information regarding assignment of participants to pregnancy probability groups, refer to Chapter 5 of Part 2, Volume III.

- Five plastic cups
- NCS Pregnancy Test Instructions (see Appendix 2-F)
- First Response manufacturer pregnancy test instructions
- An inner bag containing the following:
 - One prelabeled urine collection container with lid
 - One biohazard transport bag
 - Two absorbent pads
 - Two paper towels
 - Adult Urine Collection Instructions
 - One adhesive label for Biospecimen Transmittal Form (TM label)
 - One adhesive label for Pregnancy Test and Urine Data Collection Form (DC label)
 - One additional adhesive label for collection container (EX label).

2.2.1.2 Procedures for Providing Participant with Pregnancy Test and Urine Collection Materials

For study participants in the High Tryer Pregnancy Probability Group, pregnancy tests and pregnancy urine collection materials are given to them during the P1 data collection visit.

For general guidance on how to use FACE for data collection activities, refer to the FACE User's Guide. Detailed instructions for administering the Biospecimen instrument are found in Appendix VIII-A.

1. Locate the Pregnancy Test and Urine Collection Kit and Pregnancy Test and Urine Data Collection Form. Launch the Biospecimen instrument from FACE on the tablet.
2. Wand the collection kit bar code into FACE and validate the kit type and expiration date. If FACE is not available, validate the kit type and expiration date manually.
3. If the kit type is valid and the kit is not expired, open the kit.

4. Instruct the study participant in the pregnancy test procedures using the NCS Pregnancy Test Instructions. After reviewing the instructions, review the relevant contents of the kit with the participant. The participant may refer to the NCS Pregnancy Test Instructions when performing the pregnancy tests.
5. Explain to the study participant that if she has a positive pregnancy test, she then will be asked to self-collect a urine sample. The urine should be collected the following morning after the positive pregnancy test and should be stored in the participant's freezer until it can be picked up by study staff. If the participant learns of her pregnancy from a healthcare provider without using a home pregnancy test, she is asked to collect a urine sample the following morning after learning about the pregnancy.

If a study participant does not have a home freezer, the data collector should request that the participant store the urine specimen in the refrigerator until it can be picked up by study staff. If a study participant does not have a refrigerator, the data collector should request that the participant store the urine specimen at room temperature until it can be picked up by study staff. Information about storage temperature in the participant's home should be recorded appropriately on the Pregnancy Test and Urine Data Collection Form at the time of pick-up.

6. Instruct the study participant in the pregnancy urine collection instructions using the Adult Urine Collection Instructions. After reviewing the instructions, review the contents of the kit with her. The participant may refer to the Adult Urine Collection Instructions when performing the pregnancy urine collection.
7. Verify that the participant's subject label is affixed to the Pregnancy Test and Urine Data Collection Form. If not, place the subject label in the appropriate place on the form.
8. Open the inner bag and remove the adhesive labels. Place the DC label in the appropriate place on the Pregnancy Test and Urine Data Collection Form.
9. Place the remaining labels (TM and EX labels) inside the biohazard transport bag. Ask the study participant to keep the remaining adhesive labels in the biohazard transport bag when storing the urine specimen.
10. Review the Pregnancy Test and Urine Data Collection Form with the study participant, emphasizing the following instructions:
 - The morning after a positive pregnancy test, she should collect a pregnancy urine specimen using the collection kit.
 - She should place the urine specimen inside the biohazard transport bag and freeze the specimen immediately in her home freezer.
 - She should contact the Study Center to inform the Study Center about her pregnancy and to schedule a pick-up for the urine specimen.

11. Give the Pregnancy Test and Urine Collection Kit and labeled Pregnancy Test and Urine Data Collection Form to the study participant.

2.2.2 Mailing the Participant Pregnancy Test and Urine Collection Materials (Post-P1)

After the P1 collection visit, study participants will receive follow-up calls from the Site Office. During these telephone contacts, or if a study participant contacts the Site Office at another time to request additional pregnancy tests, the Site Office may mail an additional Pregnancy Test and Urine Collection Kit to participants in the High Tryer group.

2.2.2.1 Supplies and Forms

The following supplies and forms should be mailed to the study participant:

- Pregnancy Test and Urine Collection Kit
- Prelabeled Pregnancy Test and Urine Data Collection Form. This SAQ is to be completed by the participant at the time of collection (see Appendices 2-D and 2-E). The form must be prelabeled with the subject label *and* the collection kit label (DC label).

2.2.2.2 Procedures for Mailing the Participant Pregnancy Test and Urine Collection Materials

For detailed instructions regarding mailing pregnancy test and urine collection materials to study participants, refer to Volume II.

2.2.3 Pick-Up and Transport of Pregnancy Urine

After a study participant has a positive pregnancy test, she is instructed to collect a pregnancy urine specimen and to contact the Study Center to inform them about her pregnancy. The Site Office then will schedule a date and time to pick up the urine specimen within 7 days (preferably within 7 days of collection, depending on when the study participant contacts the Study Center).

The pregnancy urine specimen will be picked up from the participant's home by study staff and transported to the SPSC.

2.2.3.1 Equipment, Supplies, and Forms

The following equipment, supplies, and forms are required to pick up pregnancy urine from a participant's home and to transport the specimen to the SPSC:

- Specimen collection tray
- Disposable laboratory coat
- Gloves
- Hand sanitizer
- Biohazard waste bag
- Biospecimen transport cooler
- Dry ice
- Dry ice glove
- P1 Mother Biospecimen Transmittal Form (see volume Appendices VIII-B and VIII-G for form and field-by-field instructions).

2.2.3.2 Step-by-Step Procedures for Pick-Up of Pregnancy Urine

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

A computer tablet is not required to pick up pregnancy urine specimens from the study participant's home. Pick-up of pregnancy urine specimens will be documented on the hard copy data collection form and the P1 Mother Biospecimen Transmittal Form.

1. Ask the participant to retrieve the urine specimen from the freezer and the Pregnancy Test and Urine Data Collection Form.
2. Locate the P1 Mother Biospecimen Transmittal Form.

3. Put on a laboratory coat and gloves.
4. Place the specimen collection tray on a flat surface.
5. When the participant returns with the specimen, do the following:
 - Thank the participant for providing the specimen and ask her to place the biohazard transport bag containing the specimen on the specimen collection tray.
 - Remove the TM label from the biohazard bag and place it on the Biospecimen Transmittal Form.
 - Check the lid on the collection container to make sure it is securely closed and then seal the biohazard bag.
6. Wearing the dry ice glove, immediately place the sealed bag on dry ice in the transport cooler.

2.2.4 Documenting Pick-Up of Pregnancy Urine

1. Review the Pregnancy Test and Urine Data Collection Form for legibility and completeness and verify that the DC label from the collection kit is affixed to the form. If the DC label was not affixed to the form and is no longer available, manually record the collection kit ID with the suffix “DC01” onto the form (e.g., “AB1234567-DC01”). The kit ID is the nine-digit sequence before the item ID. Because the form is a Teleform, this information should be written in block letters above the label box.
2. Record the following data on the back of the form in the “For Data Collector’s Use” box:
 - Data collector ID
 - Date of pick-up
 - Sample condition at pick-up
 - Time placed in cooler.
3. Record the pregnancy urine collection status on the Biospecimen Transmittal Form.
4. If an incident occurs during the urine pick-up procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

2.2.5 Clean-Up Procedures

After completing the pregnancy urine pick-up procedures, make sure the work area is clean.

- The work area is clean if contamination, such as a spill, has *not* occurred.
- If a spill has occurred, clean the tray with a bleach wipe. Discard the wipe in the biohazard waste bag.
- Clean the work area and pack all supplies.

After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer. Be sure to pack the biohazard waste bag appropriately for transport so that it is not visible when leaving the site of data collection. The biohazard waste bag must be disposed of properly at the SPSC.

2.2.6 Transport Procedures

Pregnancy urine specimens will be transported to the SPSC in the dry ice chamber of the biospecimen transport cooler.

1. Ensure that the Biospecimen Transmittal Form is complete. Place the completed form in the zippered document pouch, inside the lid of the transport cooler along with any unused labels.
2. Secure the biohazard transport bag containing the urine container in the dry ice and confirm the cooler is properly closed for transport.

The Pregnancy Test and Urine Data Collection Form will be transported to the Site Office.

2.3 Infant Urine

Infant urine specimens will be collected for the 6-Month and 12-Month data collections. These specimens will be analyzed to obtain information about physiological conditions and environmental exposures.

The parent will be told at the beginning of the visit that the visit includes collecting a urine sample from the child. If the parent agrees to the collection, the data collector will place a urine collection bag on the child towards the beginning of the visit. The urine collection bag will remain on the child while the data collector proceeds with other data collection activities and periodically checks to see if urine has collected in the bag. The urine collection bag should remain on the child for at least 1 hour and 15 minutes to allow for urine to collect in the bag, but as soon as the child has urinated, the bag should be removed. The data collector will then transfer the sample from the urine collection bag into the urine collection container and prepare the specimen for transport to the SPSC.

2.3.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to collect and transport infant urine using the urine collection bag method:

- Infant Urine Bag Collection Kit (kit contents are in the next list)
- Pediatric urine collection bag for demonstration
- Specimen collection tray
- Chux pads
- Soap cleansing towelette
- Disposable laboratory coat
- Gloves
- Hand sanitizer
- Biohazard waste bag
- Biospecimen transport cooler
- Dry ice
- Dry ice glove
- Computer tablet with bar code scanner
- Computer keyboard cover.

The Infant Urine Bag Collection Kit contains the following items:

- One sterile pediatric urine collection bag, prescreened
- One sterile prelabeled urine collection container with lid
- One adhesive remover wipe
- One biohazard transport bag with absorbent pads
- Two paper towels
- One diaper
- Infant Urine Bag Collection Instructions
- One adhesive label for Biospecimen Transmittal Form (TM label)
- One adhesive label for hard copy backup Infant Urine Data Collection Form (DC label)
- One additional adhesive label for collection container (EX label).

The following form is required to collect and transport infant urine specimens:

- Event-specific Biospecimen Transmittal Form (see appendices at the end of this volume for forms and field-by-field instructions).

Infant urine collection data will be documented in the Biospecimen instrument in FACE. If FACE is not available, then the appropriate hard copy backup Infant Urine Data Collection Form must be used to document collection data (see Appendices 2-G and 2-H, respectively, for form and field-by-field instructions). Once the system becomes available, data must be entered in the system from the backup form. Instructions for entering data from backup forms into FACE can be found in the document *Guide to FACE Data Entry From Backup Biospecimen Data Collection Forms: Postnatal Data Collection* (located on the NCS Collaboration Portal).

2.3.2 Step-by-Step Procedures for Infant Urine Collection

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following procedures are to be used for infant urine collection using the urine collection bag method. For general guidance on how to use FACE for data collection activities, refer to the FACE User's Guide. For detailed question-by-question specifications for administering the Biospecimen instrument, refer to the document *Instructions for Documenting Biospecimen Collection in FACE* (see Appendix VIII-A).

2.3.2.1 Application of the Urine Collection Bag

1. Put on a disposable laboratory coat.
2. Launch the Biospecimen instrument of FACE on the tablet. If FACE is not available, the hard copy backup Infant Urine Data Collection Form should be used.
3. Review the infant urine bag collection procedures with the parent, using the Infant Urine Bag Collection Instructions as a guide (see Appendix 2-I).
 - Be sure to emphasize that the parent must be present during both the application and the removal of the urine collection bag.
 - Inform the parent that the adhesive on the bag may cause mild skin irritation upon removal of the bag.
 - Show the parent the demo pediatric urine collection bag from the Biospecimen Auxiliary Bag supplies when explaining the procedures.
 - If the parent objects or is uncomfortable with the data collector cleansing the child's diaper area and applying the urine collection bag, the parent may perform these procedures with guided instruction from the data collector.
4. If the parent refuses to allow the collection, document the refusal in FACE or on the Infant Urine Data Collection Form.
5. Read the infant urine collection questions to the parent from FACE and enter the responses. If FACE is not available, read the collection questions in Part B of the hard copy backup Infant Urine Data Collection Form and record the responses.
6. Place the specimen collection tray on a flat surface.
7. Locate the Infant Urine Bag Collection Kit and Biospecimen Transmittal Form.
8. Wand the collection kit bar code into FACE and validate the kit type and expiration date.

9. If the kit type is valid and the kit is not expired, open the kit and place the kit contents on the tray.
10. Place the TM label on the Biospecimen Transmittal Form.
11. If the hard copy backup Infant Urine Data Collection Form is being used during the collection procedures, place the DC label in the appropriate place on the form and place an extra subject label (from the visit coordinator's supplies) in the appropriate place on the form.
12. Select an appropriate location in the participant's home to perform the urine bag application. The child will need to be lying on his or her back while the procedures are being performed. A changing table is ideal for this purpose, but dependent on the circumstances, a changing pad, Chux, or other suitable absorbent material may be placed on a flat surface. If the bag application will be performed in another room, use the specimen collection tray to transport the necessary materials to the selected location.
13. Cleanse your hands and put on gloves.
14. Lay the child on his or her back on a changing table or other suitable flat surface. Do not leave the child unattended at any time during these procedures to avoid accidental falls.
15. Remove the child's diaper. If preferred, the parent may remove the child's diaper.
16. If the parent will perform the procedures, instruct the parent on the procedures for cleansing the genital area and placing the collection bag on the child (steps 17-25), using the Infant Urine Bag Collection Instructions as a guide.
17. The child's genital area will need to be cleaned based on how the parent responds to the question regarding product use in the Biospecimen instrument (or Question 3 in Part B of the hard copy backup Infant Urine Data Collection Form). The four products asked about are
 - Diaper cream or ointment,
 - Vaseline,
 - Infant lotion, and
 - Baby oil.

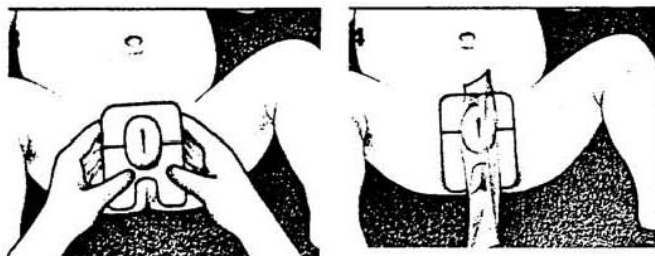
If the parent indicated that any of the products were used on the child's diaper area in the past 24 hours, then perform the following two steps to cleanse the child's genital area:

- First cleanse the area from front to back with a soap towelette to remove any product residue.
- Follow by cleansing the area from front to back with the water and/or wipe provided by the study.

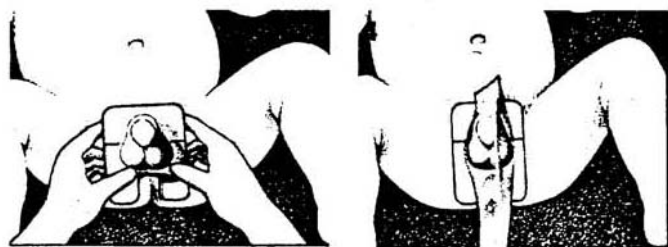
If the parent indicated that none of the four products were used on the child's diaper area in the past 24 hours, cleanse the area from front to back only with the water and/or wipe provided by the study. Do not cleanse the area with a soap towelette.

If the parent did not know whether any of the four products were used in the past 24 hours, or if the parent refused to answer the question, then perform the following two steps to cleanse the child's genital area:

- First cleanse the area from front to back with a soap towelette to remove any product residue.
 - Follow by cleansing the area from front to back with the water and/or wipe provided by the study.
18. Allow the newly cleansed area to air dry. Do not wipe the area to speed drying. The skin must be completely dry before applying the collection bag.
 19. Remove the paper backing from the bottom half of the adhesive patch. Leave the top half of the adhesive covered until the bottom section has been applied to the skin.
 20. Open the child's legs to expose the genital area.
 21. Begin application of the adhesive on the tiny area of skin between the genitals and the anus, smoothing any folds of skin if necessary.
 22. For girls, it is best to apply the adhesive so that the urethral opening is at the top of the bag opening (see following image).



23. For boys, the adhesive can be placed on or below the scrotum. Ensure that the penis is inside the opening of the collection bag (see following image).



24. Press the adhesive firmly against the skin, avoiding wrinkles. When the bottom section of the adhesive is in place, remove the paper backing from the upper portion of the adhesive patch. Work upward to complete application of the bag.
25. After the collection bag is securely in place, carefully place a diaper on the child over the collection bag. A diaper is provided in the collection kit, or if preferred, the parent may use one of the child's own diapers. If the diaper that was removed is not soiled, the diaper can be re-used.
26. Remove your gloves and cleanse your hands.
27. Record in FACE that the urine collection was initiated.
28. On the next FACE screen break off the FACE session by selecting "Break Off" and click on the End Exam button () at the top of the screen. Select "Planned Break" at the End of Section screen.

After placement of the collection bag is complete, the data collector may proceed with other data collection activities and should periodically check the collection bag to see if urine has collected in the bag. If preferred, the parent may check the child's diaper periodically instead of the data collector. The urine collection bag should remain on the child for at least one hour and 15 minutes to allow for urine to collect in the bag, but as soon as the child has urinated, the bag should be removed.

If the child has a bowel movement while the bag is in place, if the bag leaks, or if the bag is pulled off by the child, promptly remove the bag and follow the procedures to transfer any collected urine to the collection container if possible.

If a second urine collection bag will be applied to the child, ask the parent if he or she agrees to a second application before repeating the procedure with a new collection bag from the Biospecimen Auxiliary Bag supplies.

2.3.2.2 Removal of the Urine Collection Bag and Transfer of Urine

The urine collection bag should be removed from the child by the data collector as soon as possible after the child has urinated. If the parent objects or is uncomfortable with the data collector removing the urine collection bag, the parent may perform this procedure with guided instruction from the data collector. The data collector will then transfer the urine from the collection bag into the urine collection container and prepare the specimen for transport to the SPSC.

1. Put on a disposable laboratory coat.
2. Place the computer keyboard cover on the keyboard if you have not already done so. This will prevent the keyboard from contamination when handling specimens during the visit.
3. Launch the Biospecimen instrument of FACE on the tablet. If FACE is not available, the hard copy backup Infant Urine Data Collection Form should be used.
4. Continue the FACE session by selecting “Collect Specimen.”
5. Select an appropriate location in the participant’s home to perform the urine bag removal. The child will need to be lying on his or her back while the bag removal procedure is performed. A changing table is ideal for this purpose, but depending on the circumstances a changing pad, Chux, or other suitable absorbent material may be placed on a flat surface.
6. To prepare the transfer of the urine, place the specimen collection tray on a flat surface and gather the materials needed (i.e., paper towels, urine collection container with lid). Unfold a paper towel on the specimen collection tray.
7. Cleanse your hands and put on gloves.
8. Lay the child on his or her back on a changing table or other suitable flat surface.
9. Remove the child’s diaper. If preferred, the parent may remove the child’s diaper.
10. If the parent will perform the bag removal procedure, instruct the parent on the procedures for removing the collection bag from the child (steps 11 and 12) using the Infant Urine Bag Collection Instructions as a guide.
11. Carefully remove the urine collection bag from the child, being careful not to spill the bag contents. Slowly remove the adhesive from the skin, beginning at the top of the adhesive patch and working downward. Avoid discomfort to the child by pushing the skin away from the adhesive rather than pulling the adhesive from the skin.

12. If necessary, use the adhesive remover wipe to aid in removing the adhesive patch from the skin.
13. Re-diaper or ask the parent to re-diaper the child after the urine collection bag has been removed.
14. As soon as possible after removing the urine collection bag, perform the following steps to transfer the urine into the sterile prelabeled urine collection container provided in the Infant Urine Bag Collection kit:
 - Unscrew the lid from the empty collection container and place the lid face down on the paper towel.
 - Tilt the collection bag so the urine is away from the blue tab.
 - Remove the blue tab and carefully drain the contents of the urine collection bag into the collection container, being careful not to touch the inside of the sterile container or the lid.
 - Immediately replace the lid on the collection container and close it securely.
 - Dispose of the empty urine collection bag in the biohazard waste bag.

2.3.3 Documenting Infant Urine Collection

1. Record the urine collection status in FACE and record the required collection information by following the prompts.
2. Wand the bar code label on the urine collection container.
3. Place the urine specimen in the biohazard transport bag with the absorbent pads and seal the bag. Wearing the dry ice glove, immediately place the sealed transport bag on dry ice in the transport cooler.
4. Record any comments pertaining to the infant urine collection in FACE (up to a 250-character limit) or on the hard copy backup Infant Urine Data Collection Form. If using the backup form, ensure the form is complete.
5. Record the urine collection status on the Biospecimen Transmittal Form.
6. If an incident occurs during the urine collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

2.3.4 Clean-Up Procedures

1. After completing the infant urine collection procedures, make sure the work area is clean and reusable.
 - The work area is reusable if contamination, such as a spill, has *not* occurred.
 - If a spill has occurred, clean the tray with a bleach wipe. Discard items in the biohazard waste bag.
 - Remove the computer keyboard cover, clean the work area, and pack all collection supplies.
2. After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer. Be sure to pack the biohazard waste bag appropriately for transport so that it is not visible upon leaving the site of data collection. The biohazard waste bag must be disposed of properly at the SPSC.

2.3.5 Transport Procedures

Infant urine specimens will be transported to the SPSC in the dry ice chamber of the biospecimen transport cooler.

- Ensure the Biospecimen Transmittal Form is complete. Place the completed form in the zippered document pouch inside the lid of the transport cooler along with any unused labels.
- Secure the biohazard transport bag containing the urine container in the dry ice and confirm the cooler is properly closed for transport.

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Part 2

Appendix 2-A

Adult Urine Data Collection Form

Appendix 2-A. Adult Urine Data Collection Form

	National Children's Study Adult Urine Data Collection Form	T1-1 st , T1-Prior, P1, T3-1 st , T3 Prior, T1 Dad

(Only for use when FACE is not available)

Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office Time collection kit opened: : ☐ a.m. ☐ p.m. h h m m Place Adult Urine Collection DC Label Here	Collection Status (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for Not Done/Partial (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient ☐ Defective collection kit ☐ Slide broken ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other-specify: _____
Part B: Adult Urine Collection Questions	
1. When did you last urinate? ¿A qué hora orinó por última vez? : ☐ a.m. ☐ p.m. h h m m ☐ Refused ☐ Don't know	
2. When was the last time you had anything to eat or drink other than water? ¿A que hora comió o bebió algo por última vez, aparte de agua? : ☐ a.m. ☐ p.m. h h m m ☐ Refused ☐ Don't know	

Subject Label

Assignment ID,
Subject ID, Event Type

ADUCPT02.00DU

Appendix 2-A. Adult Urine Data Collection Form (continued)

3. The last time that you ate, how much of what you ate was beef, pork, cod, tuna, or salmon? <i>La última vez que comió, ¿qué tanto de lo que comió era carne de res, cerdo, bacalao, atún o salmón?</i> ☐ None / Nada ☐ Less than one quarter of the meal / Menos de un cuarto de la comida ☐ One quarter to one half of the meal / De un cuarto a la mitad de la comida ☐ Less than three quarters of the meal / Menos de tres cuartos de la comida ☐ Three quarters to all of the meal / De tres cuartos a toda la comida ☐ All of the meal / Toda la comida ☐ Refused ☐ Don't know	
4. Do you take creatine supplements? <i>¿Toma suplementos de creatina?</i> ☐ Yes ☐ No ☐ Refused ☐ Don't know	
Part C: Adult Urine Collection	
UR01 or UR02 Urine collection container	Collection Status (Mark one.) ☐ Collected (END) ☐ Not collected Reason not collected (Mark one.) ☐ Quantity not sufficient ☐ Other-specify: _____ ☐ Refused
UR03 Urine collection container For Urine 2 Cup Kit Only	Collection Status (Mark one.) ☐ Collected (END) ☐ N/A ☐ Not collected Reason not collected (Mark one.) ☐ Quantity not sufficient ☐ Other-specify: _____ ☐ Refused
Comments:	

Data collector ID for field QC:

Date entered into FACE: / /

m m d d y y y y

ID of data collector who entered the form:

Part 2

Appendix 2-B

Adult Urine Data Collection Form: Field-by-Field Instructions

Appendix 2-B.
Adult Urine Data Collection Form: Field-by-Field Instructions

ADULT URINE DATA COLLECTION FORM: FIELD-BY-FIELD INSTRUCTIONS

This form is only to be used when the Field-Administration Collection Environment (FACE) is not available and should be completed by the biospecimen data collector at the P1 mother, T1 mother, T1 father and T3 mother data collection visits. Instructions for completing each item on the form are provided in this field-by-field.

After Completing the Form

- Within 2 hours of the visit, the form should be checked to make sure that it is accurate, legible, and complete.
- Make sure that all of the appropriate boxes are completely filled. Comments should be limited to the area provided.
- The biospecimen data collector who checks the form for completion should write her data collector ID in the space provided at the bottom of the last page.
- The data collector who enters the data in FACE should record the date of data entry and her data collector ID in the spaces provided on the last page of the form.



National Children's Study Adult Urine Data Collection Form

T1-1st, T1-Prior, P1, T3-1st, T3 Prior, T1 Dad

(Only for use when FACE is not available)

Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office	Collection Status (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for Not Done/Partial (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient ☐ Defective collection kit ☐ Slide broken ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other-specify: _____
Time collection kit opened: : ☐ a.m. h h m m ☐ p.m. Place Adult Urine Collection DC Label Here	
Part B: Adult Urine Collection Questions	
1. When did you last urinate? : ☐ a.m. h h m m ☐ p.m. ¿A qué hora orinó por última vez? ☐ Refused ☐ Don't know	
2. When was the last time you had anything to eat or drink other than water? : ☐ a.m. h h m m ☐ p.m. ¿A que hora comió o bebió algo por última vez, aparte de agua? ☐ Refused ☐ Don't know	

ADUCPT02.00DU

Subject Label

Assignment ID,
Subject ID, Event Type

Part A: Administrative Section

- *Date*—Record the date that the adult urine collection was completed or attempted. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002). The date of collection should not be recorded in advance of the participant’s study visit.
- *Data Collector ID*—Record the data collector ID of the person who completes the form.
- *Visit location*—Mark the box corresponding to the location of the visit.
- *Collection status (Select one)*—Mark the box that corresponds to the status of the adult urine collection.
 - “Complete”—Mark this box to indicate that the specimen was collected.
 - “Partial complete”—Mark this box to indicate that the urine collection was attempted but the participant did not collect any urine.
 - “Not done”—Mark this box to indicate that the participant did not provide a urine specimen. When this box is marked indicate the reason that the urine specimen was not collected.
- *Reason for Not Done/Partial (Mark one)*—Mark the box that corresponds to the choice that best explains why the urine specimen was not done or was partially completed. If the reason is determined prior to giving the Adult Urine Collection Kit to the participant, complete this section and the items in Part A as described; however, do not open the Adult Urine Collection Kit or complete Parts B and C.
 - “Participant refusal”—Mark this box to indicate that the participant was unwilling to provide a urine specimen.
 - “Participant Ill/emergency”—Mark this box to indicate that the participant became ill during the visit and was unable to provide a urine specimen. This box also is marked if the participant has an emergency that requires termination of the visit prior to the collection of the urine specimen. Record a brief description of the nature of the emergency or illness in the Comments section of Part C.
 - “No time”—Mark this box to indicate that the urine specimen was not collected because the visit is ended ahead of schedule. Record a brief description of the reason that the visit was ended in the Comments section in Part C.

	National Children's Study Adult Urine Data Collection Form
T1-1 st , T1-Prior, P1, T3-1 st , T3 Prior, T1 Dad	

(Only for use when FACE is not available)

Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office Time collection kit opened: : ☐ a.m. h h m m ☐ p.m. Place Adult Urine Collection DC Label Here	Collection Status (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for Not Done/Partial (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient ☐ Defective collection kit ☐ Slide broken ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other-specify: _____
Part B: Adult Urine Collection Questions	
1. When did you last urinate? : ☐ a.m. <i>¿A qué hora orinó por última vez?</i> h h m m ☐ p.m. ☐ Refused ☐ Don't know	
2. When was the last time you had anything to eat or drink other than water? : ☐ a.m. <i>¿A que hora comió o bebió algo por última vez, aparte de agua?</i> h h m m ☐ p.m. ☐ Refused ☐ Don't know	

ADUCPT02.00DU

Subject Label

Assignment ID,
Subject ID, Event Type

- “Safety exclusion”—This code does not apply to this biospecimen collection activity.
 - “Physical limitations”—Mark this box to indicate that the participant has a physical limitation that prevented him or her from providing a urine specimen. Record a brief description of the type of physical limitation in the Comments section in Part C.
 - “Quantity not sufficient”—This code does not apply to this biospecimen collection activity.
 - “Defective collection kit”—Mark this box to indicate that the urine specimen was not collected because of a problem with the Adult Urine Collection Kit. This includes not having the appropriate supplies available in the home or clinic.
 - “Slide broken”—This code does not apply to this biospecimen collection activity.
 - “Language issue, Spanish”—Mark this box to indicate that the urine specimen was not collected because the biospecimen data collector does not speak Spanish well enough to communicate the necessary instructions to the participant.
 - “Language issue, non-Spanish”—Mark this box to indicate that the urine specimen was not collected because the biospecimen data collector is unable to communicate the necessary instructions to the participant.
 - “Cognitive disability”—Mark this box to indicate that the urine specimen was not collected because the participant is cognitively or developmentally impaired and therefore unable to understand the specimen collection instructions.
 - “Parent/caregiver refusal”—Mark this box to indicate that the participant is younger than 18 years old and his or her parent or guardian refused to allow her to provide a urine specimen.
 - “Other—specify”—Mark this box to indicate that the urine specimen was not collected for a reason other than those listed; specify the reason in the space provided.
- *Time collection kit opened*—Record the time the Adult Urine Collection Kit was opened. Be sure to zero fill the spaces when necessary and to mark the box to indicate “a.m.” or “p.m.” For example if data collection kit is opened at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”

	National Children's Study Adult Urine Data Collection Form
T1-1 st , T1-Prior, P1, T3-1 st , T3 Prior, T1 Dad	

(Only for use when FACE is not available)

Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office Time collection kit opened: : ☐ a.m. h h m m ☐ p.m. Place Adult Urine Collection DC Label Here	Collection Status (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for Not Done/Partial (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient ☐ Defective collection kit ☐ Slide broken ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other-specify: _____
Part B: Adult Urine Collection Questions	
1. When did you last urinate? : ☐ a.m. <i>¿A qué hora orinó por última vez?</i> h h m m ☐ p.m. ☐ Refused ☐ Don't know	
2. When was the last time you had anything to eat or drink other than water? : ☐ a.m. <i>¿A que hora comió o bebió algo por última vez, aparte de agua?</i> h h m m ☐ p.m. ☐ Refused ☐ Don't know	

ADUCPT02.00DU

Subject Label

Assignment ID,
Subject ID, Event Type

- **Kit Label**—Before reviewing the Adult Urine Collection Instructions with the participant, open the Adult Urine Collection Kit and place the “DC” label in the appropriate place on the form.

Part B: Adult Urine Collection Questions

1. *When did you last urinate?*

Record the time of the participant’s last urination prior to collecting the specimen. Be sure to zero fill the spaces when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the participant last urinated at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.” If the participant refuses to answer or does not know, mark the corresponding box.

2. *When was the last time you had anything to eat or drink other than water?*

Record the time that the participant reports last eating or drinking anything other than water. Be sure to zero fill the spaces when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the kit is opened at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”

Subject Label

Obtain a subject label from the visit coordinator’s biospecimen folder and affix it to the bottom right corner of the data collection form.

3. The last time that you ate, how much of what you ate was beef, pork, cod, tuna, or salmon? <i>La última vez que comió, ¿qué tanto de lo que comió era carne de res, cerdo, bacalao, atún o salmón?</i> ☐ None / <i>Nada</i> ☐ Less than one quarter of the meal / <i>Menos de un cuarto de la comida</i> ☐ One quarter to one half of the meal / <i>De un cuarto a la mitad de la comida</i> ☐ Less than three quarters of the meal / <i>Menos de tres cuartos de la comida</i> ☐ Three quarters to all of the meal / <i>De tres cuartos a toda la comida</i> ☐ All of the meal / <i>Toda la comida</i> ☐ Refused ☐ Don't know	
4. Do you take creatine supplements? ☐ Yes ☐ No <i>¿Toma suplementos de creatina?</i> ☐ Refused ☐ Don't know	
Part C: Adult Urine Collection	
UR01 or UR02 Urine collection container	Collection Status (Mark one.) ☐ Collected (END) ☐ Not collected Reason not collected (Mark one.) ☐ Quantity not sufficient ☐ Other—specify: _____ ☐ Refused
UR03 Urine collection container For Urine 2 Cup Kit Only	Collection Status (Mark one.) ☐ Collected (END) ☐ N/A ☐ Not collected Reason not collected (Mark one.) ☐ Quantity not sufficient ☐ Other—specify: _____ ☐ Refused
Comments:	

Data collector ID for field QC:

Date entered into FACE: / / 20 m m d d y y y y
ID of data collector who entered the form:

3. *The last time that you ate, how much of what you ate was beef, pork, cod, tuna, or salmon?*

Read each of the responses and mark the box that corresponds to the participant's response. If the participant refuses to answer or does not know, mark the corresponding box.

4. *Do you take creatine supplements?*

Mark the box that corresponds to the participant's response. If the participant refuses to answer or does not know, mark the corresponding box.

Part C: Adult Urine Collection

- *Collection Status* (Mark one)—Mark the box that corresponds to the status of the adult urine collection.
 - “Collected”—Mark this box to indicate that the specimen was collected. When the specimen is collected, no additional information is required and the form is complete.
 - “Not collected”—Mark this box to indicate that the specimen was not collected. When this box is marked, indicate the reason that the urine specimen was not collected.
 - “N/A” (UR03 only)—Mark this box to indicate that the collection status is not applicable. UR03 will only be collected if using the Urine 2 Cup Collection Kit.
- *Reason for Not Collected* (Mark one)—Mark the box that corresponds to the choice that best explains why the specimen was not collected.
 - “Quantity not sufficient”—Choose one of the following:
 1. “UR01 or UR02”—Mark this box to indicate that the urine specimen was not collected because the study participant did not have enough urine to be able to provide a specimen.
 2. “UR03” (If using the Urine 2 Cup Collection Kit only)—Mark this box to indicate that no urine was transferred from the UR02 collection cup into the UR03 collection cup either because UR02 was not collected or because ≤ 20 mL of urine was collected in UR02. A minimum of 20 mL of urine is required in UR02 in order to collect UR03.
 - “Other—specify”—Mark this box to indicate that the adult urine specimen was not collected for a reason other than those listed; specify the reason in the space provided.

3. The last time that you ate, how much of what you ate was beef, pork, cod, tuna, or salmon? <i>La última vez que comió, ¿qué tanto de lo que comió era carne de res, cerdo, bacalao, atún o salmón?</i> ☐ None / <i>Nada</i> ☐ Less than one quarter of the meal / <i>Menos de un cuarto de la comida</i> ☐ One quarter to one half of the meal / <i>De un cuarto a la mitad de la comida</i> ☐ Less than three quarters of the meal / <i>Menos de tres cuartos de la comida</i> ☐ Three quarters to all of the meal / <i>De tres cuartos a toda la comida</i> ☐ All of the meal / <i>Toda la comida</i> ☐ Refused ☐ Don't know	
4. Do you take creatine supplements? ☐ Yes ☐ No <i>¿Toma suplementos de creatina?</i> ☐ Refused ☐ Don't know	
Part C: Adult Urine Collection	
UR01 or UR02 Urine collection container	Collection Status (Mark one.) ☐ Collected (END) ☐ Not collected Reason not collected (Mark one.) ☐ Quantity not sufficient ☐ Other-specify: _____ ☐ Refused
UR03 Urine collection container For Urine 2 Cup Kit Only	Collection Status (Mark one.) ☐ Collected (END) ☐ N/A ☐ Not collected Reason not collected (Mark one.) ☐ Quantity not sufficient ☐ Other-specify: _____ ☐ Refused
Comments:	

Data collector ID for field QC:

Date entered into FACE: / / 20 m m d d y y y y
ID of data collector who entered the form:

- “Refused”—Mark this box to indicate that the participant is unwilling to provide a urine specimen.
- *Comments*—Additional comments may include reasons that the urine specimen was not collected or problems encountered during the collection that may affect analysis. Problems with post-collection processing also should be recorded here.

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Part 2

Appendix 2-C

Adult Urine Collection Instructions

Appendix 2-C. Adult Urine Collection Instructions

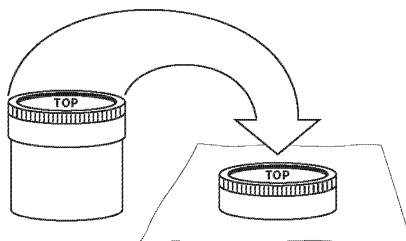
OMB Control Number: 0925-0593
Expiration Date: 09/30/2011

National Children's Study Adult Urine Collection Instructions

As part of the National Children's Study, we ask you to collect a sample of your urine.
This kit includes everything you will need to collect the sample: a prelabeled urine collection cup with lid and 2 paper towels.

Instructions

1. Wash your hands with soap and water.
2. Lay one paper towel on a flat surface. Unscrew the lid from the collection cup and place it on the paper towel. The inside of the lid should be placed face down on the paper towel. Do not touch the inside of the lid or the collection cup. Do not allow the inside of the collection cup or the inside of the lid to come in contact with any part of your body, clothing, or bathroom surfaces.



3. Start urinating into the toilet, then urinate directly into the collection cup. If possible, fill the cup at least half full. Do not fill to overflowing.
4. Screw the lid on the collection cup immediately so that the urine is only briefly exposed to the air.
5. Use the other paper towel to wipe any urine from the outside of the cup.
6. Remember to wash your hands with soap and water after collecting the sample.
7. Give the collection cup back to the study staff.

If you have any questions please ask study staff.

Thank you for providing this sample!

Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

ADUCIN01.00DU

Appendix 2-C. Adult Urine Collection Instructions (continued)

Número de control de OMB: 0925-0593
Fecha de vencimiento: 09/30/2011

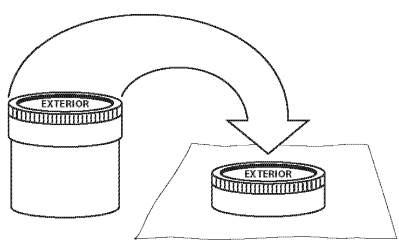
Estudio Nacional de los Niños Instrucciones para tomar la muestra de orina de un adulto

Como parte del Estudio Nacional de los Niños queremos pedirle que tome una muestra de su orina.

Con estos materiales usted tendrá todo lo que necesita para tomar la muestra, incluyendo un envase con tapa para muestras de orina previamente etiquetado y 2 toallas de papel.

Instrucciones

1. Lávese las manos con agua y jabón.
2. Extienda una toalla de papel en una superficie plana. Quite la tapa del envase y póngala sobre la toalla. El interior de la tapa debe quedar boca abajo sobre la toalla. No toque el interior de la tapa ni el interior del envase. Tampoco permita que el interior del envase ni el de la tapa toquen ninguna parte de su cuerpo, ropa o las superficies del baño.



3. Comience a orinar en el inodoro o excusado y continúe orinando directamente dentro del envase para la muestra. Si es posible, llene el envase al menos hasta la mitad. No permita que se derrame.
4. Ajuste la tapa del envase de inmediato para que la orina no esté en contacto con el aire más que por unos breves momentos.
5. Con la otra toalla de papel, limpie el exterior del envase.
6. Recuerde lavarse bien las manos con agua y jabón después de tomar la muestra.
7. Entregue el envase al personal del estudio.

Si tiene alguna pregunta, por favor pregunte al personal del estudio.

¡Gracias por darnos esta muestra!

Se calcula que el promedio de tiempo necesario para esta recolección de información es de 7 minutos por entrevista, incluyendo el tiempo para leer las instrucciones, buscar fuentes de información existentes, reunir y mantener la información necesaria y completar y revisar la recolección de información. **Ninguna agencia puede llevar a cabo ni patrocinar una recolección de información y ninguna persona está obligada a responder a dicha recolección a menos que ésta muestre un número de control vigente de OMB.** Envíe los comentarios acerca de este cálculo de tiempo necesario, incluyendo sugerencias sobre cómo reducirlo, o acerca de cualquier otro aspecto de esta recolección de información a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). No devuelva el formulario contestado a esta dirección.

ADUCIN01.00DU

Part 2

Appendix 2-D

Pregnancy Test and Urine Data Collection Form (English)

Appendix 2-D.
Pregnancy Test and Urine Data Collection Form (English)



6761



National Children's Study

Pregnancy Test and Urine Data Collection Form

P1

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☐ on the wrong answer.
- ➔ Your answers are important. Please print clearly using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study, we are asking you to collect a urine sample the morning after your positive pregnancy test. This should be an early morning sample, collected the first time you urinate after you wake up to start your day. Only collect this urine sample if you had a positive pregnancy test.

You have been provided with:

- A prelabeled urine collection cup with lid
- 2 paper towels
- A sealable plastic bag
- Instructions you will need to collect your urine sample.

Please follow the instructions provided.

1. What was the date of your positive pregnancy test?

/

/

2

0

m m
d d
y y y y

2. What is today's date?

/

/

2

0

m m
d d
y y y y

3. What time did you collect your sample?

:

h h
m m

☐ a.m.

☐ p.m.

4. Was this the first time you urinated after you woke up?

☐ Yes
☐ No
☐ Not sure, explain: _____

5. At what time did you last urinate before this collection?

:

h h
m m

☐ a.m.

☐ p.m.

Please complete the question on the back.



URPREG01.00EN

**For
Office Use
Only**

**Place Subject ID
Label Here**

**Appendix 2-D.
Pregnancy Test and Urine Data Collection Form (English) (continued)**



6. What time did you place your urine sample in the freezer?

: ☐ a.m. ☐ p.m.
 h h m m

Contact the Study Center to let them know you are pregnant and that you have a urine sample ready for pick up.

Please call the Study Center number on your Local Contact Sheet if you have any questions.

Thank you for taking the time to provide this information today.

For Data Collector's Use

Date kit provided to participant:

/ /
 m m d d y y y y

Data collector ID:

Date urine specimen picked up:

/ /
 m m d d y y y y

Was the urine specimen frozen when received from the participant? ☐ Yes ☐ No

Time urine specimen was placed in the cooler:

: ☐ a.m. ☐ p.m.
 h h m m

**Pregnancy Test
Kit ID**

Part 2

Appendix 2-E

Pregnancy Test and Urine Data Collection Form (Spanish)

Appendix 2-E. Pregnancy Test and Urine Data Collection Form (Spanish)



Número de control de OMB: 0925-0593
Fecha de vencimiento: 09/30/2011



THE NATIONAL
CHILDREN'S
STUDY

SALUD · CRECIMIENTO · AMBIENTE

Estudio Nacional de los Niños

Formulario de información de la muestra de orina y la prueba de embarazo

P1

Instrucciones

- ➔ Por favor use una pluma o bolígrafo de tinta negra o azul para completar este formulario. No use marcador ni lápiz.
- ➔ Marque con una ☒ para indicar su respuesta.
- ➔ Si desea cambiar su respuesta, tache la respuesta errónea así: ✕.
- ➔ Sus respuestas son importantes. Por favor escriba en letra clara, en letras de imprenta mayúsculas (por ejemplo, "MIÉRCOLES").

Como parte del Estudio Nacional de los Niños, queremos pedirle que tome una muestra de orina a la mañana siguiente de haber obtenido un resultado positivo en su prueba de embarazo. Esta muestra se debe tomar temprano en la mañana, la primera vez que orine después de despertarse para comenzar el día. Tome esta muestra solamente si obtuvo un resultado positivo en la prueba de embarazo.

Se incluyen los siguientes materiales:

- Un envase con tapa para muestras de orina previamente etiquetado
- 2 toallas de papel
- Una bolsa de plástico sellable
- Las instrucciones que necesitará para tomar su muestra de orina.

Por favor siga las instrucciones que se incluyen.

1. ¿En qué fecha obtuvo un resultado positivo en su prueba de embarazo?

		/			/	2	0				
m	m		d	d		a	a	a	a		

2. ¿Cuál es la fecha de hoy?

		/			/	2	0				
m	m		d	d		a	a	a	a		

3. ¿A qué hora tomó su muestra?

		:				
h	h		m	m	☐ a.m.	☐ p.m.

4. ¿Fue ésta la primera vez que orinó desde que se despertó?

- ☐ Sí
- ☐ No
- ☐ No está segura, explique: _____

Por favor responda las preguntas al otro lado de la página.



URPREG00.03SP

REVIEW

**For
Office Use
Only**

Place Subject ID
Label Here

Appendix 2-E.
Pregnancy Test and Urine Data Collection Form (Spanish) (continued)



Draft

5. ¿A qué hora orinó por última vez antes de tomar esta muestra?

: ☐ a.m. ☐ p.m.
 h h m m

6. ¿A qué hora puso la muestra de orina en el congelador?

: ☐ a.m. ☐ p.m.
 h h m m

Comuníquese con el Centro del Estudio y avíseles que está embarazada y que su muestra de orina está lista para que la pasen a buscar.

Por favor si desea hacer alguna pregunta llame al número del Centro del Estudio que hay en su Hoja de Contactos Locales.

Gracias por tomarse el tiempo hoy para darnos esta información.

For Data Collector's Use

Date kit provided to participant:

/ /
 m m d d y y y y

Data collector ID:

Date urine specimen picked up:

/ /
 m m d d y y y y

Was the urine specimen frozen when received from the participant? ☐ Yes ☐ No

Time urine specimen was placed in the cooler:

: ☐ a.m. ☐ p.m.
 h h m m

**Pregnancy Test
Kit ID**

Part 2

Appendix 2-F

Pregnancy Test Instructions

Appendix 2-F. Pregnancy Test Instructions

OMB Control Number: 0925-0593
Expiration Date: 09/30/2011

National Children's Study Pregnancy Test Instructions

As part of the National Children's Study, we are asking you to take a pregnancy test the first day of your missed period. For example, if you expect your period on the 20th day of the month and have not started your period by the 21st day, please take the test.

The kit includes:

- 5 Pregnancy tests
- 5 Plastic cups
- 1 Urine collection kit to be used the morning after a positive pregnancy test

Pregnancy Test Instructions

For the most accurate results, the pregnancy test should be done the first time you urinate in the morning. Follow the instructions below. You may also refer to the First Response instructions included in the kit.

1. Collect your urine in one of the clean plastic cups included in the pregnancy test kit. The cup should be at least half full.
2. Remove the overcap from the absorbent tip.
3. Immerse the entire absorbent tip in the urine for **5 seconds only**.
4. Remove the absorbent tip from the urine.
5. With the tip still pointing down toward the urine, replace the overcap and lay the test stick on a flat surface with the result window facing up. (The test will still work if you do not replace the overcap.)
6. Read the result after **3 minutes**.
 - o **Positive Test (pregnant)** – You will see **two parallel pink lines** in the result window. One line may be lighter than the other.
 - o **Negative Test (not pregnant)** – You will see **one pink line** in the result window.



Important Notes

- There should be at least one pink line in the result window after 5 minutes to indicate that the test is complete and was done correctly. If one pink line does not appear after 5 minutes, the test is invalid.
- Reasons for an invalid test:
 - o Not enough urine on the absorbent tip.
 - o Not holding the test stick with the absorbent tip pointing downward while replacing the cap.
- If the test is invalid, retest by carefully following the instructions above using a new test stick.
- A positive result will last for 48 hours. A negative result cannot be read after 10 minutes.
- The test results may be affected by medications that contain the pregnancy hormone (hCG). Examples of these types of medications include but are not limited to: A.P.L.[™], Pregnyl[™], Profasi[™], and Pergonal[™].

After conducting the test, follow the directions below:

- If the test is positive:
 - o Collect a urine sample tomorrow morning. This should be an early morning sample that you will collect the first time you urinate after you wake up.
 - o Be sure to record the date of the positive pregnancy test on the Pregnancy Test and Urine Data Collection Form.
- If the test is negative, and you do not begin your period within 2 days, take another test.
- If the tests continue to be negative and you do not begin your period in 7 days, call your doctor or other health care provider.

Please call the Study Center number on your Local Contact Sheet if you have any questions.

Thank you for your important contribution to the National Children's Study.

Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

PGTIN01.00DU

Appendix 2-F. Pregnancy Test Instructions (continued)

Número de control de OMB: 0925-0593
Fecha de vencimiento: 09/30/2011

Estudio Nacional de los Niños Instrucciones para la prueba de embarazo

Como parte del Estudio Nacional de los Niños, queremos pedirle que se haga una prueba de embarazo el primer día que se atrase su menstruación. Por ejemplo, si espera la menstruación el día 20 del mes y no ha empezado a menstruar el día 21, por favor hágase la prueba.

Los materiales incluyen:

- 5 pruebas de embarazo
- 5 envases de plástico
- 1 paquete con los materiales para tomar una muestra de orina que deberá usarse la mañana siguiente después de haber obtenido una prueba de embarazo positiva.

Instrucciones para la prueba de embarazo

Para mayor precisión en los resultados, la prueba de embarazo debe hacerse cuando orine por primera vez en la mañana. Siga las instrucciones a continuación. También puede usar las instrucciones de First Response que se incluyen en los materiales.

1. Orine en uno de los envases de plástico sin usar que se incluyen en el paquete de materiales para la prueba de embarazo. Debe llenar al menos la mitad del envase.
2. Quite la tapa protectora de la punta absorbente.
3. Sumerja completamente la punta absorbente en la orina **solamente durante 5 segundos**.
4. **Saque la punta absorbente de la orina.**
5. Con la punta todavía apuntando hacia abajo, hacia la orina, ponga la tapa protectora y coloque la prueba sobre una superficie plana con la ventana de resultados mirando hacia arriba. (La prueba funcionará correctamente aun sin poner la tapa.)
6. Lea el resultado después de **3 minutos**.
 - **Prueba positiva (embarazada)** – Verá dos líneas paralelas de color rosado en la ventana de resultados. Una línea puede estar más clara que la otra.
 - **Prueba negativa (no está embarazada)** – Verá una línea de color rosado en la ventana de resultados.



Información importante

- Debe haber al menos una línea de color rosado en la ventana de resultados después de 5 minutos para indicar que la prueba se ha completado y que se hizo de manera correcta. Si no aparece una línea de color rosado después de 5 minutos, la prueba no es válida.
- Razones para una prueba inválida:
 - No hubo suficiente orina en la punta absorbente.
 - No sujetó la prueba con la punta absorbente hacia abajo mientras puso la tapa.
- No sujetó la prueba con la punta absorbente hacia abajo mientras puso la tapa. Si la prueba no es válida, vuelva a hacerla, siguiendo las instrucciones anteriores con atención y utilizando una nueva prueba.
- Un resultado positivo se podrá ver por 48 horas. Un resultado negativo no se puede leer después de 10 minutos.
- Los resultados de la prueba pueden verse afectados por medicamentos que contienen la hormona del embarazo (hCG). Ejemplos de este tipo de medicamentos incluyen pero no se limitan a: A.P.L.TM, PregnylTM, ProfasiTM y PergonalTM.

Después de hacer la prueba, siga las instrucciones a continuación:

- Si la prueba es positiva:
 - Tome una muestra de orina mañana en la mañana. Debe tomar esta muestra temprano en la mañana, la primera vez que orine después de despertarse.
 - Asegúrese de anotar la fecha de la prueba de embarazo positiva en el Formulario de información de la muestra de orina y la prueba de embarazo.
- Si la prueba es negativa y no le ha llegado la menstruación en un plazo de 2 días, hágase otra prueba.
- Si la prueba continúa siendo negativa y no le ha llegado la menstruación en 7 días, llame a su médico o a otro proveedor de cuidado de salud.

Por favor llame al número del Centro del Estudio que se encuentra en su Hoja de Contactos Locales si tiene alguna pregunta.

Gracias por su importante contribución al Estudio Nacional de los Niños.

Se calcula que el promedio de tiempo necesario para esta recolección de información es de 7 minutos por entrevista, incluyendo el tiempo para leer las instrucciones, buscar fuentes de información existentes, reunir y mantener la información necesaria y completar y revisar la recolección de información. Ninguna agencia puede llevar a cabo ni patrocinar una recolección de información y ninguna persona está obligada a responder a dicha recolección a menos que ésta muestre un número de control vigente de OMB. Envíe los comentarios acerca de este cálculo de tiempo necesario, incluyendo sugerencias sobre cómo reducirlo, o acerca de cualquier otro aspecto de esta recolección de información a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). No devuelva el formulario contestado a esta dirección.



New
Appendix

Part 2

Appendix 2-G

Infant Urine Data Collection Form

Appendix 2-G. Infant Urine Data Collection Form

 National Children's Study Infant Urine Data Collection Form		6-Mo
(Only for use when the FACE is not available)		
Part A: Administrative		
Date: / / 2 0 m m d d y y y y	Visit location: ☐ Home ☐ Clinic/Office	
Data collector ID:	Place Infant Urine Bag Collection Kit DC Label Here Collection Status: (Mark one.) ☐ Complete ☐ Partial ☐ Not done Reason for Not Done/Partial: (Mark one.) ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitation ☐ Quantity not sufficient ☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/Guardian refusal ☐ Other—specify: _____	
READ ONLY WHEN PARENT REFUSES TO ALLOW URINE COLLECTION. I am sorry that you have chosen not to participate in this collection. Can you tell me why? <i>Lamento que haya decidido no participar en la toma de esta muestra. ¿Podría decirme por qué?</i>		
☐ Concerned about allergic reaction/Skin irritation <i>Le preocupan las reacciones alérgicas/la irritación de la piel</i> ☐ Child has a diaper rash <i>El niño tiene rozadura a causa del pañal</i> ☐ Other—specify: _____ <i>Otro—especifique:</i>		
Part B: Infant Urine Collection Questions		
1. When did you last change (name/your child's) diaper? : ☐ a.m. <i>¿A qué hora fue la última vez que le cambió el pañal a (name/su bebé)?</i> h h m m ☐ p.m.		
☐ Refused ☐ Don't know		

Child Subject Label

 Assignment ID,
Subject ID, Event Type

URDC6M01.00DU

Appendix 2-G.
Infant Urine Data Collection Form (continued)

2. When was the last time he/she had anything to drink? <i>¿A qué hora fue la última vez que él/ella bebió algo?</i>	: h h m m ☐ a.m. ☐ p.m. ☐ Refused ☐ Don't know																				
3. Have you or anyone else used any of the following products on your child's diaper area in the past 24 hours? (Mark all that apply.) <i>En las últimas 24 horas, ¿ha aplicado usted u otra persona alguno de los siguientes productos en la piel de su bebé, en las zonas donde lo toca el pañal? (Marque todo lo que corresponda).</i> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">None (<i>Nada</i>)</td> <td style="width: 30%; text-align: center;">☐</td> </tr> <tr> <td>Infant powder/Talc/Cornstarch (<i>talcos para niños/talcos/maizena</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Diaper cream/Ointment (<i>crema/ungüento para la rozadura de pañal</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Vaseline (<i>vaselina</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Infant wipes (<i>pañitos para bebés</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Infant shampoo (<i>champú para bebés</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Infant lotion (<i>crema para bebés</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Baby oil (<i>aceite para bebés</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Other—please describe: _____</td> <td style="text-align: center;">☐</td> </tr> <tr> <td><i>Otro – por favor describa:</i> _____</td> <td></td> </tr> </table> ☐ Refused ☐ Don't know		None (<i>Nada</i>)	☐	Infant powder/Talc/Cornstarch (<i>talcos para niños/talcos/maizena</i>)	☐	Diaper cream/Ointment (<i>crema/ungüento para la rozadura de pañal</i>)	☐	Vaseline (<i>vaselina</i>)	☐	Infant wipes (<i>pañitos para bebés</i>)	☐	Infant shampoo (<i>champú para bebés</i>)	☐	Infant lotion (<i>crema para bebés</i>)	☐	Baby oil (<i>aceite para bebés</i>)	☐	Other—please describe: _____	☐	<i>Otro – por favor describa:</i> _____	
None (<i>Nada</i>)	☐																				
Infant powder/Talc/Cornstarch (<i>talcos para niños/talcos/maizena</i>)	☐																				
Diaper cream/Ointment (<i>crema/ungüento para la rozadura de pañal</i>)	☐																				
Vaseline (<i>vaselina</i>)	☐																				
Infant wipes (<i>pañitos para bebés</i>)	☐																				
Infant shampoo (<i>champú para bebés</i>)	☐																				
Infant lotion (<i>crema para bebés</i>)	☐																				
Baby oil (<i>aceite para bebés</i>)	☐																				
Other—please describe: _____	☐																				
<i>Otro – por favor describa:</i> _____																					
Part C: Infant Urine Collection																					
BU01 Urine collection container	Collection Status: (Mark one.) ☐ Collected ☐ Not collected Reason for Not Collected: (Mark one.) <table style="width: 100%;"> <tr> <td>☐ Bag leaked</td> <td>☐ Bag spilled</td> </tr> <tr> <td>☐ Bag torn/Pulled off</td> <td>☐ Sample contaminated</td> </tr> <tr> <td>☐ Quantity not sufficient</td> <td>☐ Refused</td> </tr> <tr> <td colspan="2">☐ Other—specify: _____</td> </tr> </table>	☐ Bag leaked	☐ Bag spilled	☐ Bag torn/Pulled off	☐ Sample contaminated	☐ Quantity not sufficient	☐ Refused	☐ Other—specify: _____													
☐ Bag leaked	☐ Bag spilled																				
☐ Bag torn/Pulled off	☐ Sample contaminated																				
☐ Quantity not sufficient	☐ Refused																				
☐ Other—specify: _____																					
Who placed the urine bag on the child?	☐ Data collector ☐ Parent ☐ Other—specify: _____																				
If a second bag was applied, who placed the second bag on the child?	☐ Second bag not required ☐ Data collector ☐ Parent ☐ Other—specify: _____																				
Comments:																					

Data collector ID for field QC:	Date entered into FACE: / /20 ID of data collector who entered the form:



New
Appendix

Part 2

Appendix 2-H

Infant Urine Data Collection Form: Field-By-Field Instructions

Appendix 2-H.
Infant Urine Data Collection Form: Field-by-Field Instructions

**INFANT URINE DATA COLLECTION FORM:
FIELD-BY-FIELD INSTRUCTIONS**

This form is only to be used when the Field-Administration Collection Environment (FACE) is not available and should be completed by the postnatal biospecimen data collector for the 6-Month and 12-Month data collection. Instructions for completing each item on the form are provided in this field-by-field.

After Completing the Form

- Within 2 hours of the visit, the form should be checked to make sure that it is accurate, legible, and complete.
- Make sure that all of the appropriate boxes are completely filled. Comments should be limited to the area provided.
- The data collector who checks the form for completeness should write her data collector ID in the space provided at the bottom of the last page.
- The data collector who enters the data in FACE will record the date of data entry and her data collector ID in the space provided on the last page of the form.

6-Mo

Part A: Administrative

Date: / / m m d d y y y y Data collector ID:	Visit location: ☐ Home ☐ Clinic/Office
Place Infant Urine Bag Collection Kit DC Label Here	Collection Status: (Mark one.) ☐ Complete ☐ Partial ☐ Not done
	Reason for Not Done/Partial: (Mark one.) ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitation ☐ Quantity not sufficient ☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/Guardian refusal ☐ Other—specify: _____

READ ONLY WHEN PARENT REFUSES TO ALLOW URINE COLLECTION.

 I am sorry that you have chosen not to participate in this collection. Can you tell me why?
Lamento que haya decidido no participar en la toma de esta muestra. ¿Podría decirme por qué?

☐ Concerned about allergic reaction/Skin irritation
Le preocupan las reacciones alérgicas/la irritación de la piel
☐ Child has a diaper rash
El niño tiene rozadura a causa del pañal
☐ Other—specify: _____
Otro—especifique:

Part B: Infant Urine Collection Questions

1. When did you last change (name/your child's) diaper? : ☐ a.m.
¿A qué hora fue la última vez que le cambió el pañal a (name/su bebé)? h h m m ☐ p.m.

☐ Refused ☐ Don't know

Assignment ID,
Subject ID, Event Type

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Part A: Administrative Section

- *Date*—Record the date that the infant urine collection was completed or attempted. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002). The date of collection should not be recorded in advance of the participant’s study visit.
- *Data collector ID*—Record the data collector ID of the person who completes the form.
- *Visit location*—Mark the box corresponding to the location of the visit.
- *Collection status* (Mark one)—Mark the box that corresponds to the status of the infant urine collection.
 - “Complete”—Mark this box to indicate that the infant urine was collected.
 - “Partial”—Mark this box to indicate that the infant urine collection was initiated but the specimen was not collected. When this box is marked, indicate the reason the infant urine collection is partially complete.
 - “Not done”—Mark this box to indicate that an infant urine collection was not initiated. When this box is marked indicate the reason the collection was not initiated.
- *Reason for Not Done/Partial* (Mark one)—Mark the box that corresponds to the choice that best explains why the specimen was not collected or the collection was partially complete.
 - “Participant ill/ Emergency”—Mark this box to indicate that the child participant was ill during the visit and was unable to provide an infant urine specimen. This box also is marked if the participant/parent has an emergency that required termination of the visit prior to the collection of the infant urine specimen. Record a brief description of the nature of the emergency or illness in the Comments section in Part C.
 - “No time”—Mark this box to indicate that the infant urine specimen was not collected because the visit was ended ahead of schedule. Record a brief description of the reason the visit was ended in the Comments section on Part C.
 - “Safety exclusion”—This code does not apply to this biospecimen collection activity.
 - “Physical limitation”—Mark this box to indicate that the child participant has a physical limitation that prevents collection of an infant urine specimen. Record a brief description of the type of physical limitation in the Comments section in Part C.
 - “Quantity not sufficient”—Mark this box to indicate that the specimen was not collected because the child did not urinate into the collection bag or there was not enough urine to transfer to the collection container (i.e., a few drops).

6-Mo

Part A: Administrative

Date: / / m m d d y y y y	Visit location: ☐ Home ☐ Clinic/Office
Data collector ID:	Collection Status: (Mark one.) ☐ Complete ☐ Partial ☐ Not done
Place Infant Urine Bag Collection Kit DC Label Here	Reason for Not Done/Partial: (Mark one.) ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitation ☐ Quantity not sufficient ☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/Guardian refusal ☐ Other—specify: _____

READ ONLY WHEN PARENT REFUSES TO ALLOW URINE COLLECTION.

 I am sorry that you have chosen not to participate in this collection. Can you tell me why?
Lamento que haya decidido no participar en la toma de esta muestra. ¿Podría decirme por qué?

☐ Concerned about allergic reaction/Skin irritation
Le preocupan las reacciones alérgicas/la irritación de la piel
☐ Child has a diaper rash
El niño tiene rozadura a causa del pañal
☐ Other—specify: _____
Otro—especifique:

Part B: Infant Urine Collection Questions

1. When did you last change (name/your child's) diaper? : ☐ a.m.
¿A qué hora fue la última vez que le cambió el pañal a (name/su bebé)? h h m m ☐ p.m.

☐ Refused ☐ Don't know

Assignment ID,
Subject ID, Event Type

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- “Defective collection kit”—Mark this box to indicate that the infant urine specimen was not collected due to a problem with the collection kit. This includes not having the appropriate supplies available.
- “Language issue, Spanish”—Mark this box to indicate that the infant urine specimen was not collected because the data collector did not speak Spanish well enough to communicate with the parent regarding the infant urine collection procedures.
- “Language issue, non-Spanish”—Mark this box to indicate that the infant urine specimen was not collected because the data collector was unable to communicate with the parent regarding the infant urine collection procedures.
- “Cognitive disability”—Mark this box to indicate that the infant urine specimen was not collected because the parent is cognitively or developmentally impaired and therefore unable to understand the infant urine collection procedures.
- “Parent/Guardian refusal”—Mark this box to indicate that the child’s parent or guardian refused to allow the infant urine collection. Go to the next section in Part A titled “READ ONLY WHEN PARENT REFUSES TO ALLOW URINE COLLECTION.”
- “Other—specify”—Mark this box to indicate that the infant urine specimen was not collected for a reason other than those listed; specify the reason in the space provided.
- Place Infant Urine Bag Collection Kit DC Label Here—Place the kit DC label in the appropriate place on the form, if the kit was opened and the collection was initiated.
- READ ONLY WHEN PARENT REFUSES TO ALLOW URINE COLLECTION.

I am sorry that you have chosen not to participate in this collection. Can you tell me why?

- “Concerned about allergic reaction/Skin irritation”—Mark this box to indicate that the parent refused to allow the infant urine collection because he or she is concerned that application and/or removal of the urine collection bag may cause an allergic reaction or skin irritation for the child.
- “Child has a diaper rash”—Mark this box to indicate that the child’s parent or guardian refused to allow the infant urine collection because the child has a diaper rash.
- “Other—specify”—Mark this box to indicate that the child’s parent or guardian refused to allow the infant urine collection for a reason other than those listed; specify the reason in the space provided.

Child Subject Label

Affix a subject label for the child assignment to the bottom right corner of the data collection form in the space provided.

2. When was the last time he/she had anything to drink? <i>¿A qué hora fue la última vez que él/ella bebió algo?</i>	: h h m m ☐ a.m. ☐ p.m. ☐ Refused ☐ Don't know																				
3. Have you or anyone else used any of the following products on your child's diaper area in the past 24 hours? (Mark all that apply.) <i>En las últimas 24 horas, ¿ha aplicado usted u otra persona alguno de los siguientes productos en la piel de su bebé, en las zonas donde lo toca el pañal? (Marque todo lo que corresponda).</i> <table style="width: 100%;"> <tr> <td>None (<i>Nada</i>)</td> <td>☐</td> </tr> <tr> <td>Infant powder/Talc/Cornstarch (<i>talcos para niños/talcos/maizena</i>)</td> <td>☐</td> </tr> <tr> <td>Diaper cream/Ointment (<i>crema/ungüento para la rozadura de pañal</i>)</td> <td>☐</td> </tr> <tr> <td>Vaseline (<i>vaselina</i>)</td> <td>☐</td> </tr> <tr> <td>Infant wipes (<i>pañitos para bebés</i>)</td> <td>☐</td> </tr> <tr> <td>Infant shampoo (<i>champú para bebés</i>)</td> <td>☐</td> </tr> <tr> <td>Infant lotion (<i>crema para bebés</i>)</td> <td>☐</td> </tr> <tr> <td>Baby oil (<i>aceite para bebés</i>)</td> <td>☐</td> </tr> <tr> <td>Other—please describe: _____</td> <td>☐</td> </tr> <tr> <td>Otro – por favor describa: _____</td> <td></td> </tr> </table> ☐ Refused ☐ Don't know		None (<i>Nada</i>)	☐	Infant powder/Talc/Cornstarch (<i>talcos para niños/talcos/maizena</i>)	☐	Diaper cream/Ointment (<i>crema/ungüento para la rozadura de pañal</i>)	☐	Vaseline (<i>vaselina</i>)	☐	Infant wipes (<i>pañitos para bebés</i>)	☐	Infant shampoo (<i>champú para bebés</i>)	☐	Infant lotion (<i>crema para bebés</i>)	☐	Baby oil (<i>aceite para bebés</i>)	☐	Other—please describe: _____	☐	Otro – por favor describa: _____	
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Data collector ID for field QC:	Date entered into FACE: / / m m d d y y y y ID of data collector who entered the form:

Part B: Infant Urine Collection Questions

1. *When did you last change (name/your child's) diaper?*
 - *Time*—Record the time the parent states in his or her response. Be sure to complete the fields with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the child's diaper was last changed at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.” If the parent refuses to answer or does not know, mark the corresponding box.
2. *When was the last time he/she had anything to drink?*
 - *Time*—Record the time the parent states in his or her response. Be sure to complete the fields with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the child was last fed breast milk at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.” If the parent refuses to answer or does not know, mark the corresponding box.
3. *Have you or anyone else used any of the following products on your child's diaper area in the past 24 hours? (Mark all that apply.)*
 - Read each of the choices and mark the boxes that correspond to the parent's responses. Mark all choices that apply. For example, if the parent used diaper ointment and infant wipes on the child's diaper area in the past 24 hours, mark both boxes corresponding to these responses.
 - If the parent responds that a product was used on the child's diaper area within the past 24 hours that is not listed, mark “Other” and record the product that was used in the space provided.
 - If the parent refuses to answer or does not know, mark the corresponding box.

Part C: Infant Urine Collection

Complete the following information for the infant urine collection:

- *Collection status* (Mark one)—Mark the box that corresponds to the status of the infant urine collection.
 - “Collected”—Mark this box to indicate that the infant urine specimen was collected and transferred from the urine collection bag to the collection container.
 - “Not Collected”—Mark this box to indicate that the infant urine specimen was not collected. When this box is marked, indicate the reason the infant urine specimen was not collected.
- *Reason for Not Collected* (Mark one)—Mark the box that corresponds to the choice that best explains why the specimen was not collected.
 - “Bag leaked” —Mark this box to indicate that the urine collection bag leaked after the bag was applied to the child's genital area.
 - “Bag torn/Pulled off”—Mark this box to indicate that the urine collection bag was torn or the child pulled the bag off after it was applied to the child's genital area.

2. When was the last time he/she had anything to drink? <i>¿A qué hora fue la última vez que él/ella bebió algo?</i>	: h h m m ☐ a.m. ☐ p.m. ☐ Refused ☐ Don't know																														
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Comments:																															

Data collector ID for field QC:	Date entered into FACE: / /20 m m d d y y y y ID of data collector who entered the form:

- “Quantity not sufficient”—Mark this box to indicate that the specimen was not collected because the child did not urinate into the collection bag or there was not enough urine to transfer to the collection container (i.e., a few drops).
- “Bag spilled”—Mark this box to indicate that the contents of the urine collection bag were spilled after the bag was removed from the child’s genital area.
- “Sample contaminated”—Mark this box to indicate that the infant urine specimen was contaminated because the child had a bowel movement while the collection bag was applied and it was not possible to obtain an uncontaminated sample.
- “Refused”—Mark this box to indicate that the parent is unwilling to allow the infant urine collection.
- “Other—specify:”—Mark this box to indicate that the infant urine specimen was not collected for a reason other than those listed; specify the reason in the space provided.

1. *Who placed the urine bag on the child?*

- Mark the box that corresponds to the appropriate choice.
 - “Data collector”—Mark this box to indicate that the data collector applied the urine collection bag to the child.
 - “Parent”—Mark this box to indicate that the parent applied the urine collection bag to the child.
 - “Other-specify:”—Mark this box to indicate that someone other than the data collector or the parent applied the urine collection bag to the child; specify who in the space provided.

2. *If a second bag was applied, who placed the second bag on the child?*

- Mark the box that corresponds to the appropriate choice.
 - “Second bag not required”—Mark this box to indicate that a second urine collection bag was not applied to the child to collect the specimen.
 - “Data collector”—Mark this box to indicate that the data collector applied the second urine collection bag to the child.
 - “Parent”—Mark this box to indicate that the parent applied the second urine collection bag to the child.
 - “Other-specify:”—Mark this box to indicate that someone other than the data collector or the parent applied the second urine collection bag to the child; specify who in the space provided.

- *Comments*—Additional comments may include reasons why the infant urine specimen was not collected or problems encountered during the collection that may affect analysis. Problems with post collection processing should also be recorded here.

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New
Appendix

Part 2

Appendix 2-I

Infant Urine Bag Collection Instructions

Appendix 2-I Infant Urine Bag Collection Instructions

OMB Control Number: 0925-0593
Expiration Date: 09/30/2011

National Children's Study Infant Urine Bag Collection Instructions

As part of the National Children's Study, we are asking you to allow us to collect a sample of your child's urine. This kit contains the following items:

- 1 diaper
- 1 wipe
- 1 urine specimen collection bag
- 1 adhesive remover wipe
- 1 sterile prelabeled collection container.

Important Instructions before getting started

- **The parent must be present during both the application and the removal of the urine collection bag.**
- **Inform the parent that the adhesive on the bag may cause mild irritation.**

Instructions for Placing Urine Bag on Child

1. Cleanse your hands and put on gloves.
2. Lay the child on his or her back.
3. Remove the child's diaper.
4. Cleanse the child's entire genital area.
5. Ensure that the skin is dry before applying the collection bag.
6. Remove the paper backing from the bottom half of the adhesive patch. *Note:* It is easier to leave the top half of the adhesive covered until the bottom section has been applied to the skin.
7. Open the child's legs to expose the genital area. Begin application of the adhesive on the tiny area of skin between the anus and genitals, smoothing any folds of skin if necessary.
8. For girls, it is best to place the adhesive so that the urethral opening is at the top of the bag opening (see the following figure).



9. For boys, the adhesive can be placed on or below the scrotum. Ensure that the penis is inside the bag opening (see the following figure).



10. Press the adhesive firmly against the skin, avoiding wrinkles. When the bottom section is in place, remove the paper backing from the upper portion of the adhesive patch. Work upward to complete application.
11. Place a diaper on the child over the collection bag.

Instructions for Removing Urine Bag and Transferring Sample

1. Periodically check the collection bag for urine.
2. Remove the urine bag as soon as possible after the child has urinated.
3. Remove the bag, beginning at the top and working downward. Avoid discomfort to the child by pushing the skin away from the adhesive rather than pulling the adhesive from the skin.
4. If necessary use the adhesive remover wipe to aid in removing the bag from the child.
5. Transfer the urine into the sterile urine collection container. Be careful not to touch the inside of the sterile collection container or the lid. Put the lid on the collection cup immediately so that the urine is only briefly exposed to the air.

Public reporting burden for this collection of information is estimated to average **XX** minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

URCIN601.00DU

Appendix 2-I Infant Urine Bag Collection Instructions (continued)

Número de control de OMB: 0925-0593
Fecha de vencimiento: 09/30/2011

Estudio Nacional de los Niños Instrucciones para tomar la muestra de orina del bebé con una bolsa

Como parte del Estudio Nacional de los Niños, quisiéramos pedirle que nos permita tomar una muestra de orina de su hijo. Los materiales incluyen:

- 1 pañal
- 1 pañito
- 1 bolsa para la muestra de orina
- 1 pañito para quitar adhesivos
- 1 recipiente para muestras esterilizado y previamente etiquetado.

Instrucciones importantes para antes de empezar

- El padre o la madre debe estar presente tanto al momento de poner la bolsa para la muestra de orina como al momento de quitarla.
- Avísele al padre o a la madre que el adhesivo de la bolsa puede causar una leve irritación.

Instrucciones para ponerle al niño la bolsa para la muestra de orina

12. Lávese las manos y póngase los guantes.
13. Acueste al niño boca arriba.
14. Quítele el pañal al niño.
15. Limpie toda la zona de los genitales del niño.
16. Asegúrese de que la piel esté seca antes de poner la bolsa para la muestra.
17. Quite el papel que cubre la parte de abajo del parche adhesivo. *Nota:* Es más fácil no quitar la parte de arriba del adhesivo hasta que haya pegado la parte de abajo a la piel.
18. Abra las piernas del niño para que la zona genital quede expuesta. Comience a pegar el adhesivo en la pequeña zona de piel entre el ano y los genitales, estirando la piel con cuidado para que no haya pliegues.
19. Para las niñas, es mejor pegar el adhesivo de manera que la abertura de la uretra (de donde sale la orina) quede en la parte de arriba de la abertura de la bolsa (ver el siguiente dibujo).



20. Para los niños, el adhesivo se puede pegar en o debajo del escroto. Asegúrese de que el pene quede dentro de la abertura de la bolsa (ver el siguiente dibujo).



21. Oprima el adhesivo firmemente contra la piel, tratando de que no se formen arrugas. Cuando haya pegado la parte de abajo, quite el papel de la parte de arriba del parche adhesivo. Vaya pegando la bolsa desde abajo hacia arriba.
22. Póngale un pañal al niño por encima de la bolsa para la muestra.

Instrucciones para quitar la bolsa de orina y transferir la muestra

6. Revise la bolsa periódicamente para ver si se ha recogido orina.
7. Quite la bolsa tan pronto como sea posible después de que el niño haya orinado.
8. Para quitar la bolsa, comience estirándola desde arriba hacia abajo. Para no causarle molestias al niño, es mejor ir despegando la piel del adhesivo, en lugar de tirar directamente del adhesivo.
9. Si es necesario use el pañito para quitar adhesivos para ayudar a quitarle la bolsa al niño.
10. Pase la muestra de orina al recipiente esterilizado para muestras de orina. Asegúrese de no tocar la parte de adentro del recipiente ni de la tapa. Para que la orina esté expuesta al aire sólo por unos segundos, tape el recipiente de inmediato.

Se calcula que el promedio de tiempo necesario para esta recolección de información es de XX minutos por entrevista, incluyendo el tiempo para leer las instrucciones, buscar fuentes de información existentes, reunir y mantener la información necesaria y completar y revisar la recolección de información. Ninguna agencia puede llevar a cabo ni patrocinar una recolección de información y ninguna persona está obligada a responder a dicha recolección a menos que ésta muestre un número de control vigente de OMB. Envíe los comentarios acerca de este cálculo de tiempo necesario, incluyendo sugerencias sobre cómo reducirlo, o acerca de cualquier otro aspecto de esta recolección de información a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). No devuelva el formulario contestado a esta dirección.

URCIN601.00DU

Vaginal Swab Collection and Transport Procedures

Vaginal swab specimens will be collected at the P1 mother, T1 mother, and T3 mother study events. Vaginal specimens will be analyzed to obtain information about markers of infection and inflammation.

At the T3 mother visit only, the data collector will measure and record the pH of one of the vaginal swabs.

It is preferred that the participant self-collects the vaginal specimens at the same time (i.e., during the same bathroom visit) as the urine specimen, when possible.

3.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to collect and transport vaginal swabs:

- Vaginal Swab Collection Kit (kit contents are in the next list)
- pH strips (4.0 to 7.0) (*T3 mother event only*)
- Specimen collection tray
- Disposable laboratory coat
- Gloves
- Hand sanitizer
- Biohazard waste bag
- Biospecimen transport cooler with insulated transport bag
- Dry ice
- Dry ice glove

- Computer tablet with bar code scanner
- Computer keyboard cover

The Vaginal Swab Collection Kit contains the following items:

- Four Dacron swabs (two packages containing two swabs each)
- Two prelabeled 5-mL cryovials containing 900µl of sterile buffered saline solution
- One empty 5-mL cryovial
- One prelabeled glass slide in cardboard slide holder
- One biohazard transport bag with absorbent pad
- Two cleansing towelettes
- Vaginal Swab Self-Collection Instructions
- One adhesive label for Biospecimen Transmittal Form (TM label)
- One adhesive label for hard copy backup Vaginal Swab Data Collection Form (DC label)
- Three additional adhesive labels (EX labels)

The following forms are required to collect and transport vaginal swab specimens:

- Event-specific Biospecimen Transmittal Forms (see Appendices VIII-B through VIII-G for forms and field-by-field instructions).

Vaginal swab collection data will be documented in the Biospecimen instrument in the Field-Administered Collection Environment (FACE). If FACE is not available, then the appropriate hard copy backup Vaginal Swab Data Collection Form must be used to document collection data (see Appendices 3-A and 3-B for form and field-by-field instructions). Once the system becomes available, data must be entered in the system from the backup form.

3.2 Step-by-Step Procedures for Vaginal Swab Collection

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following procedures are to be used for vaginal swab collection. For general guidance on how to use FACE for data collection activities, refer to the FACE User Guide. For detailed question-by-question specifications for administering the Biospecimen instrument, refer to the appropriate section in volume Appendix VIII-A.

1. Put on a disposable laboratory coat.
2. Place the computer keyboard cover on the keyboard if you have not already done so. This will protect the keyboard from contamination when handling specimens during the visit. One keyboard cover will be used for the duration of the biospecimen collection.
3. Launch the Biospecimen Data Collection instrument from FACE on the tablet. If FACE is not available, the hard copy backup Vaginal Swab Data Collection Form should be used.
4. Read the vaginal specimen collection questions to the participant from FACE and enter the responses. If FACE is not available, read the collection questions in Part B of the hard copy backup Vaginal Swab Data Collection Form and record the responses.
5. Locate the Vaginal Swab Collection Kit and event-specific Biospecimen Transmittal Form.
6. Wand the collection kit bar code into FACE and validate the kit type and expiration date.
7. If the kit type is valid and the kit is not expired, open the kit and remove the prelabeled glass slide in the cardboard slide holder, biohazard transport bag with absorbent pad, and extra labels. Insert the vials in the appropriate cut-out spaces in the kit. Do not remove the caps from the vials.
8. Instruct the participant in the self-collection procedures using the Vaginal Swab Self-Collection Instructions (see Appendix 3-C). Open one of the packages containing the swabs so that neither tip is exposed and remove one of the swabs. Demonstrate how to hold the swab when collecting the specimen and how to place the swabs in the vials. After reviewing the instructions, review the remaining contents of the kit with the participant. The participant may refer to the Vaginal Swab Self-Collection Instructions when collecting the specimen.
9. While the participant is in the bathroom collecting the specimens, do the following:
 - a. Place the TM label on the Biospecimen Transmittal Form.

- b. If FACE is not available during the collection procedures, the hard copy backup Vaginal Swab Data Collection Form should be used. Place an extra subject label (from the visit coordinator's supplies) in the appropriate place on the form and place the DC label in the appropriate place on the form.
- c. Put on gloves.

T3 mother only

- d. Prepare to measure the pH by making a pH indicator strip readily accessible. Do not handle pH strips without gloves.
10. Place the specimen collection tray on a flat surface.
11. When the participant returns with the specimens:
- a. Thank the participant for providing the specimens and ask her to place them on the specimen collection tray.
 - b. Snap the handles off the two swabs in the prelabeled vials containing saline solution and cap the vials. Ensure that the vial caps are securely closed.
 - c. Record the collection status of the vaginal swabs in FACE and wand the bar code labels on the two labeled collection containers (VS01 and VS02).
 - d. Place the two vials in the biohazard transport bag with the absorbent pad and seal the bag. Wearing the dry ice glove, immediately place the sealed bag on dry ice in the transport cooler.
 - e. Record the collection status of the third vaginal swab in FACE.
 - f. Prepare the glass slide by using one side of the remaining swab, and place it on the specimen collection tray. Allow the slide to air dry for the remainder of the visit. Do not close the cardboard slide holder until the slide is dry.

T3 mother only

- g. Touch the other side of the third swab to a pH indicator strip (4.0 to 7.0). Be sure an adequate amount of fluid is transferred to the strip.
- h. Compare the pH strip with the color chart provided to determine the pH value to the nearest tenth of a unit (i.e., 4.0).
- i. Discard the swab and vial in the biohazard waste bag.

3.3 Documenting Vaginal Specimen Collection

1. Record the collection status of the vaginal slide in FACE and wand the bar code label on the slide (VL01).
2. Record the pH value of the third swab in FACE or on the hard copy backup form, to the nearest tenth of a unit (i.e., 4.0).
3. Record any comments pertaining to the vaginal specimen collection in FACE (up to a 250-character limit) or on the hard copy backup Vaginal Swab Data Collection Form. If using the backup form, ensure the form is complete.
4. Record the vaginal specimen collection status on the Biospecimen Transmittal Form.
5. If an incident occurs during the vaginal swab collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

3.4 Clean-Up Procedures

1. After completing the vaginal specimen collection procedures, make sure the work area is clean and reusable.
 - a. The work area is reusable if contamination, such as a spill, has *not* occurred.
 - b. If a spill has occurred, clean the tray with a bleach wipe. Discard used items in the biohazard waste bag.
 - c. If the vaginal specimens are the last biospecimens collected at the visit, remove the computer keyboard cover, clean the work area, and pack all collection supplies.
2. After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer. Be sure to pack the biohazard waste bag appropriately for transport so that it is not visible upon leaving the site of data collection. The biohazard waste bag must be disposed of properly at the Specimen Processing and Shipping Center (SPSC).

3.5 Transport Procedures

Vaginal swab specimens will be transported to the SPSC in the dry ice chamber of the biospecimen transport cooler. *Vaginal slide* specimens will be transported to the SPSC in the insulated transport bag. To transport both, follow these procedures:

1. Once dry, place the slide (in its cardboard holder) inside the insulated transport bag.
2. Secure the biohazard transport bag containing the vaginal swab vials in the dry ice.
3. Ensure the appropriate Biospecimen Transmittal Form is complete. If this is the last biospecimen type collected at the visit, place the completed form in the zippered document pouch inside the lid of the transport cooler along with any unused labels.
4. Confirm the cooler is properly closed for transport.

Part 2

Appendix 3-A

Vaginal Swab Data Collection Form

Appendix 3-A. Vaginal Swab Data Collection Form

 National Children's Study Vaginal Swab Data Collection Form	
T1-1 st , T1-Prior, P1, T3-1 st , T3 Prior	
(Only for use when FACE is not available)	
Part A: Administrative	
Date: / / m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office Place Vaginal Swab Collection DC Label Here	Collection status: (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for not done/partial: (Mark one.) ☐ Participant refusal ☐ Participant Ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient ☐ Defective collection kit ☐ Slide broken ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other—specify: _____
Part B: Vaginal Swab Collection Questions	
1) Have you had intercourse within the past 2 days? ☐ Yes ☐ No ¿Ha tenido relaciones sexuales vaginales en los últimos 2 días? ☐ Refused ☐ Don't know	
DATA COLLECTOR: ASK QUESTION 2 AT P1 VISIT ONLY 2) What was the first day of your last menstrual period? Date: / / ¿Cuál fue el primer día de su última menstruación? m m d d y y y y ☐ Refused ☐ Don't know	

Subject Label

Assignment ID,
Subject ID, Event Type

Appendix 3-A. Vaginal Swab Data Collection Form (continued)

Part C: Vaginal Swab Collection	
VS01 Vaginal swab 1	Collection status: (Mark one.) ☐ Collected (END) ☐ Not collected Reason for not collected: (Mark one.) ☐ Refused ☐ Other—specify: _____
VS02 Vaginal swab 2	Collection status: (Mark one.) ☐ Collected (END) ☐ Not collected Reason for not collected: (Mark one.) ☐ Refused ☐ Other—specify: _____
VL01 Vaginal slide	Collection status: (Mark one.) ☐ Collected (END) ☐ Not collected Reason for not collected: (Mark one.) ☐ Broken slide ☐ Refused ☐ Other—specify: _____
pH value Done at T3 Visits ONLY.	☐ . ☐ pH units ☐ Not collected Reason for not collected: (Mark one.) ☐ Quantity not sufficient for pH ☐ No pH strip available ☐ Defective pH strip ☐ Other—specify: _____
Comment: _____ _____ _____	

Data collector ID for field QC

 Date entered into FACE:

m	m	d	d	y	y	y	y

ID of data collector who entered the form:

Part 2

Appendix 3-B

Vaginal Swab Data Collection Form: Field-by-Field Instructions

Appendix 3-B.
Vaginal Swab Data Collection Form: Field-by-Field Instructions

**VAGINAL SWAB DATA COLLECTION FORM:
FIELD-BY-FIELD INSTRUCTIONS**

This form is only to be used when the Field-Administration Collection Environment (FACE) is not available and should be completed by biospecimen data collector at the P1 mother, T1 mother, and T3 mother data collection visits. Instructions for completing each item on the form are provided in this field-by-field.

After Completing the Form

- Within 2 hours of the visit, the form should be checked to make sure that it is accurate, legible, and complete.
- Make sure that all of the appropriate boxes are completely filled. Comments should be limited to the area provided.
- The biospecimen data collector who checks the form for completeness should write her data collector ID in the space provided at the bottom of the last page.
- The data collector who enters the data in FACE will record the date of data entry and her data collector ID in the space provided on the last page of the form.

 National Children's Study Vaginal Swab Data Collection Form T1-1st, T1-Prior, P1, T3-1st, T3 Prior	
(Only for use when FACE is not available)	
Part A: Administrative	
Date: / / m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office Place Vaginal Swab Collection DC Label Here	Collection status: (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for not done/partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient ☐ Defective collection kit ☐ Slide broken ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other—specify: _____
Part B: Vaginal Swab Collection Questions	
1) Have you had intercourse within the past 2 days? <i>¿Ha tenido relaciones sexuales vaginales en los últimos 2 días?</i> ☐ Yes ☐ No ☐ Refused ☐ Don't know	
DATA COLLECTOR: ASK QUESTION 2 AT P1 VISIT ONLY 2) What was the first day of your last menstrual period? <i>¿Cuál fue el primer día de su última menstruación?</i> Date: / / m m d d y y y y ☐ Refused ☐ Don't know	

Subject Label

Assignment ID,
Subject ID, Event Type

Part A: Administrative Section

- *Date*—Record the date that the vaginal swab collection was completed or attempted. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002). The date of collection should not be recorded in advance of the participant’s study visit.
- *Data collector ID*—Record the data collector ID of the person who completes the form.
- *Visit location*—Mark the box corresponding to the location of the visit.
- *Collection status* (Mark one)—Mark the box that corresponds to the status of the vaginal swab collection.
 - “Complete”—Mark this box to indicate that the participant collected all three vaginal swabs.
 - “Partial complete”—Mark this box to indicate that the participant collected fewer than three vaginal swabs. When this box is marked, indicate the reason the vaginal swab specimen collection is partially complete.
 - “Not done”—Mark this box to indicate that the participant did not provide vaginal swab specimens. When this box is marked indicate the reason the vaginal swab specimens were not collected.
- *Reason for not done/partial* (Mark one)—Mark the box that corresponds to the choice that best explains why the specimens were not done or were partially complete. If the reason is determined prior to giving the Vaginal Swab Collection Kit to the participant, complete this section and the items in Part A as described; however, do not open the Vaginal Swab Kit or complete Parts B and C.
 - “Participant refusal”—Mark this box to indicate that the participant was unwilling to provide vaginal swab specimens.
 - “Participant Ill/ Emergency”—Mark this box to indicate that the participant became ill during the visit and was unable to provide vaginal swab specimens. This box also is marked if the participant has an emergency that required termination of the visit prior to the collection of the vaginal swab specimens. Record a brief description of the nature of the emergency or illness in the Comments section in Part C.
 - “No time”—Mark this box to indicate that the vaginal swab specimens were not collected because the visit was ended ahead of schedule. Record a brief description of the reason the visit was ended in the Comments section on Part C.
 - “Safety exclusion”—This code does not apply to this biospecimen collection activity.

 National Children's Study Vaginal Swab Data Collection Form T1-1st, T1-Prior, P1, T3-1st, T3 Prior	
(Only for use when FACE is not available)	
Part A: Administrative	
Date: / / m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office Place Vaginal Swab Collection DC Label Here	Collection status: (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for not done/partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient ☐ Defective collection kit ☐ Slide broken ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other—specify: _____
Part B: Vaginal Swab Collection Questions	
1) Have you had intercourse within the past 2 days? ☐ Yes ☐ No ¿Ha tenido relaciones sexuales vaginales en los últimos 2 días? ☐ Refused ☐ Don't know	
DATA COLLECTOR: ASK QUESTION 2 AT P1 VISIT ONLY 2) What was the first day of your last menstrual period? Date: / / ¿Cuál fue el primer día de su última menstruación? m m d d y y y y ☐ Refused ☐ Don't know	

Subject Label

Assignment ID,
Subject ID, Event Type

- “Physical limitations”—Mark this box to indicate that the participant has a physical limitation that prevents her from providing vaginal swab specimens. Record a brief description of the type of physical limitation in the Comments section in Part C.
 - “Quantity not sufficient”—Mark this box to indicate that the participant collected fewer than three vaginal swabs.
 - “Defective collection kit”—Mark this box to indicate that the vaginal swab specimens were not collected due to a problem with the collection kit. This includes not having the appropriate supplies available.
 - “Slide broken”—Mark this box to indicate that the slide was broken after it was prepared. This box also should be marked when the slide is broken before it is prepared at the visit and there are no extra slides.
 - “Language issue, Spanish”—Mark this box to indicate that the vaginal swab specimens were not collected because the biospecimen data collector did not speak Spanish well enough to communicate the necessary instructions to the participant.
 - “Language issue, Non Spanish”—Mark this box to indicate that the vaginal swab specimens were not collected because the biospecimen data collector was unable to communicate the necessary instructions to the participant.
 - “Cognitive disability”—Mark this box to indicate that the vaginal swab specimens were not collected because the participant is cognitively or developmentally impaired and therefore unable to understand the specimen collection instructions.
 - “Parent/guardian refusal”—Mark this box to indicate that the participant is younger than 18 years old and her parent or guardian refused to allow her to provide a vaginal swab specimen.
 - “Other—specify”—Mark this box to indicate that the vaginal swab specimens were not collected for a reason other than those listed; specify the reason in the space provided.
- *Place Vaginal Swab Collection DC Label Here*—Place the kit DC label in the appropriate place on the form.

 National Children's Study Vaginal Swab Data Collection Form	
T1-1 st , T1-Prior, P1, T3-1 st , T3 Prior	
(Only for use when FACE is not available)	
Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office Place Vaginal Swab Collection DC Label Here	Collection status: (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for not done/partial: (Mark one.) ☐ Participant refusal ☐ Participant Ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient ☐ Defective collection kit ☐ Slide broken ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other—specify: _____
Part B: Vaginal Swab Collection Questions	
1) Have you had intercourse within the past 2 days? <i>¿Ha tenido relaciones sexuales vaginales en los últimos 2 días?</i> ☐ Yes ☐ No ☐ Refused ☐ Don't know	
DATA COLLECTOR: ASK QUESTION 2 AT P1 VISIT ONLY 2) What was the first day of your last menstrual period? <i>¿Cuál fue el primer día de su última menstruación?</i> Date: / / 2 0 m m d d y y y y ☐ Refused ☐ Don't know	

Subject Label

Assignment ID,
Subject ID, Event Type

Part B: Vaginal Swab Collection Questions

1. *Have you had intercourse within the past 2 days?*

- Mark the box that corresponds to the participant's response. If the participant refuses to answer or does not know, mark the corresponding box.

Note: Question 2 should only be asked at the P1 data collection visit.

2. *What was the first day of your last menstrual period?*

- *Date*—Record the date that the study participant states in her response. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002). If the participant refuses to answer or does not know, mark the corresponding box.

Part C: Vaginal Swab Collection	
VS01 Vaginal swab 1	Collection status: (Mark one.) ☐ Collected (END) ☐ Not collected Reason for not collected: (Mark one.) ☐ Refused ☐ Other—specify: _____
VS02 Vaginal swab 2	Collection status: (Mark one.) ☐ Collected (END) ☐ Not collected Reason for not collected: (Mark one.) ☐ Refused ☐ Other—specify: _____
VL01 Vaginal slide	Collection status: (Mark one.) ☐ Collected (END) ☐ Not collected Reason for not collected: (Mark one.) ☐ Broken slide ☐ Refused ☐ Other—specify: _____
pH value Done at T3 Visits ONLY.	☐ . ☐ pH units ☐ Not collected Reason for not collected: (Mark one.) ☐ Quantity not sufficient for pH ☐ No pH strip available ☐ Defective pH strip ☐ Other—specify: _____
Comment: _____ _____ _____	

Data collector ID for field QC

Date entered into FACE: / / 2 0
m m d d y y y y

ID of data collector who entered the form:

Part C: Vaginal Swab Collection

Complete the following information for the swabs contained in the two vials containing saline (VS01, VS02).

- *Collection status* (Mark one)—Mark the box that corresponds to the status of the vaginal swabs collection.
 - “Collected”—Mark this box to indicate that the vial labeled with the corresponding specimen ID contains a vaginal swab collected by the participant.
 - “Not Collected”—Mark this box to indicate that the vial labeled with the corresponding specimen ID does not contain a vaginal swab collected by the participant. When this box is marked, indicate the reason the vaginal swab specimen was not collected.
- *Reason for not collected* (Mark one)—Mark the box that corresponds to the choice that best explains why the specimen was not collected.
 - “Refused”—Mark this box to indicate that the participant is unwilling to provide a vaginal swab specimen.
 - “Other—specify:”—Mark this box to indicate that the vaginal swab specimen was not collected for a reason other than those listed; specify the reason in the space provided.

In addition to the requested information in Part C, indicate the status of the vaginal swab slide (VL01).

- *Collection Status* (Mark one)—Mark the box that corresponds to the status of the vaginal slide (VL01) collection.
 - “Collected”—Mark this box to indicate that the vaginal swab slide was made.
 - “Not collected”—Mark this box to indicate that the vaginal swab slide was not made. When this box is marked, indicate the reason the vaginal swab slide was not made.

Part C: Vaginal Swab Collection	
VS01 Vaginal swab 1	Collection status: (Mark one.) ☐ Collected (END) ☐ Not collected Reason for not collected: (Mark one.) ☐ Refused ☐ Other—specify: _____
VS02 Vaginal swab 2	Collection status: (Mark one.) ☐ Collected (END) ☐ Not collected Reason for not collected: (Mark one.) ☐ Refused ☐ Other—specify: _____
VL01 Vaginal slide	Collection status: (Mark one.) ☐ Collected (END) ☐ Not collected Reason for not collected: (Mark one.) ☐ Broken slide ☐ Refused ☐ Other—specify: _____
pH value Done at T3 Visits ONLY.	☐ . ☐ pH units ☐ Not collected Reason for not collected: (Mark one.) ☐ Quantity not sufficient for pH ☐ No pH strip available ☐ Defective pH strip ☐ Other—specify: _____
Comment: _____ _____ _____	

Data collector ID for field QC

Date entered into FACE: / / 2 0
m m d d y y y y

ID of data collector who entered the form:

Reason for not collected (Mark one)—Mark the box that corresponds to the choice that best explains why the slide was not made.

- “Broken slide”—Mark this box to indicate that the slide was broken and can not be remade. Also mark this box if the kit contained a broken slide or the slide was broken before it was made and a replacement was not available.
 - “Refused”—Mark this box to indicate that the participant is unwilling to provide a vaginal swab specimen.
 - “Other—specify”—Mark this box to indicate that the vaginal swab slide was not made for a reason other than those listed; specify the reason in the space provided.
- *pH value*—During a T3 visit only, measure the pH of the vaginal swab that is used to create the vaginal swab slide. This procedure is done after the slide is created. Use a pH indicator strip from the Biospecimen Auxiliary Bag to measure the pH. Record the value in the space provided on the form. Be sure to zero fill the space to the right of the decimal point if necessary.
 - *Not collected*—Mark this box if the pH measurement was not obtained.
 - *Reason for not collected* (Mark one)—Mark the box that corresponds to the choice that best explains why the pH measurement was not obtained.
 - “Quantity not sufficient for pH”—Mark this box to indicate that the pH measurement was not obtained because there was no third swab collected or there was not enough fluid on the swab to measure the pH.
 - “No pH strip available”—Mark this box to indicate that the pH measurement was not obtained because there were no pH strips available to perform the procedure.
 - “Defective pH strip”—Mark this box to indicate that the pH measurement was not obtained because the pH strips that were available were expired, destroyed, or otherwise compromised in their ability to accurately measure pH.
 - “Other—specify”—Mark this box to indicate that the pH measurement was not obtained for a reason other than those listed, and specify the reason in the space indicated.
 - *Comments*—Additional comments may include reasons why the vaginal swab specimens were not collected or problems encountered during the collection that may affect analysis. Problems with post collection processing should also be recorded here.

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Part 2

Appendix 3-C

Vaginal Swab Self-Collection Instructions

Appendix 3-C. Vaginal Swab Self-Collection Instructions

OMB Control Number: 0925-0593
Expiration Date: 09/30/2011

National Children's Study Vaginal Swab Self Collection Instructions

1. Wash your hands with soap and water.
2. Remove the cap from each of the plastic containers and leave the caps in the bottom of the kit box.
3. Open the towellette and gently clean the outside of your vagina.
4. Remove one swab from the wrapper. Be careful not to touch the soft part of the swab.
5. Using the hand that you write with, hold the handle of the swab between your thumb and two fingers, about 1 inch from the end of the handle (like a tampon) so that the soft part of the swab is pointing toward you.
6. With your other hand, gently open the outside of your vagina and insert the soft end of the swab into the opening. Try not to touch any other part of your genitals.
7. Hold the swab steady and straight. Slowly and gently insert the swab about 2 inches into your vagina (like a tampon) so that it follows the natural path of your vagina.
8. Turn the swab around inside your vagina for 10 to 30 seconds. Try not to let the swab slip out when you are turning it and make sure the swab touches the walls of the vagina so it absorbs moisture.
9. You may feel gentle pressure or a tickling sensation when you turn the swab. If you feel uncomfortable,
 - Do not push the swab inside the vagina quite as hard, or
 - Stop the procedure.
10. Remove the swab from your vagina, again holding the outside of your vagina and making sure not to touch other parts of the genitals.
11. Place the swab directly in the plastic container until the end of the swab touches the bottom of the container. Try not to touch the swab against the rim or the sides of the container.
12. Repeat steps 4–11 for each of the two remaining swabs. When you are done, there should be three swabs. Do not put the caps on the plastic containers.
13. Wash your hands and bring the collection kit to the study staff.



Thank you for providing these samples!

Public reporting burden for this collection of information is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

VGSBIN01.000U

Appendix 3-C. Vaginal Swab Self Collection Instructions (continued)

Número de control de OMB: 0925-0593

Fecha de vencimiento: 09/30/2011

Estudio Nacional de los Niños Instrucciones para tomar la muestra vaginal por sí misma

1. Lávese las manos con agua y jabón.
 2. Destape los tubitos de plástico y ponga las tapas en el fondo de la caja de los materiales.
 3. Abra la toallita y limpie suavemente la parte externa de la vagina.
 4. Saque uno de los aplicadores vaginales del empaque. Tenga cuidado de no tocar la parte blanda del aplicador.
 5. Utilizando la mano con la que escribe, tome el aplicador entre el pulgar y dos dedos, más o menos a 3 centímetros de la punta (como lo haría con un tampón) de manera que la parte blanda del aplicador quede apuntando hacia usted.
 6. Con la otra mano, abra suavemente los labios vaginales e inserte la punta blanda del aplicador en la abertura de la vagina. Trate de no tocar ninguna otra parte de los genitales.
 7. Mantenga el aplicador firme y derecho. Lenta y suavemente insértelo dentro de la vagina unos 5 centímetros (como lo haría con un tampón) de manera que siga la forma natural de la vagina.
 8. Gire el aplicador dentro de la vagina entre 10 y 30 segundos. Trate que el aplicador no se salga cuando lo esté girando y asegúrese de que toque las paredes vaginales para que absorba la humedad.
 9. Puede que sienta una presión suave o un cosquilleo cuando gire el aplicador. Si se siente incómoda:
 - trate de empujar el aplicador dentro de la vagina con menos fuerza o
 - detenga el procedimiento.
 10. Saque el aplicador de la vagina nuevamente manteniendo abiertos los labios vaginales y asegurándose de no tocar otras partes de los genitales.
 11. Ponga el aplicador directamente dentro del tubito de plástico hasta que la punta del aplicador toque el fondo. Trate que el aplicador no toque el borde ni los lados del tubito de plástico.
 12. Repita los pasos 4 a 11 para los otros dos aplicadores vaginales. Cuando haya terminado deberá haber tres. No tape los tubitos de plástico.
 13. Lávese las manos y llévele los materiales para tomar la muestra al personal del estudio.
-



¡ Gracias por darnos estas muestras!

Se calcula que el promedio de tiempo necesario para esta recolección de información es de 12 minutos por entrevista, incluyendo el tiempo para leer las instrucciones, buscar fuentes de información existentes, reunir y mantener la información necesaria y completar y revisar la recolección de información. **Ninguna agencia puede llevar a cabo ni patrocinar una recolección de información y ninguna persona está obligada a responder a dicha recolección a menos que ésta muestre un número de control vigente de OMB.** Envíe los comentarios acerca de este cálculo de tiempo necesario, incluyendo sugerencias sobre cómo reducirlo, o acerca de cualquier otro aspecto de esta recolección de información a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). No devuelva el formulario contestado a esta dirección.

VGSBIN01.00DU

Saliva Collection and Transport Procedures

4.1 Adult 2-Day Saliva

Adult 2-day saliva specimens will be self-collected by the participant at the T1 mother and T3 mother study events. For the 6-Month data collection, adult 2-day saliva will be self-collected by two adults: the mother/primary caregiver, and the father/alternate caregiver. For detailed information regarding assignment of adult roles for the 6-Month data collection, refer to the Site Office training materials on the NCS Collaboration Portal. Depending on the type of study event and location of each data collection visit, self-collection of saliva will occur over the course of 2 days prior to or following the data collection visit.

Saliva specimens will be analyzed to obtain information about various hormones including cortisol, an indicator of stress.

4.1.1 Overview of Study Event-Specific Collections

4.1.1.1 T1 Mother, T3 First, and 6-Month Data Collection

The mother will self-collect saliva specimens during the course of 2 consecutive days¹ within the week *following* a T1 mother or T3 first data collection visit.

The mother/primary caregiver and the father/alternate caregiver will self-collect saliva specimens during the course of 2 consecutive days within the week *following* Day 1 of the 6-Month data collection.

¹ Note: In the event that a study participant collects the saliva specimens on 2 nonconsecutive days, this is acceptable and adequate for the collection and does not need to be reported as a protocol deviation. The participant should be encouraged to record the actual date and time of each sample collection accurately on the Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms, regardless of whether she collected the samples on consecutive or nonconsecutive days. When reviewing the instructions with the participant, the data collector may wish to clarify that the samples should be collected for 2 days in a row, but that it does not have to be the 2 days immediately following or preceding the data collection visit.

The participants will receive an Adult 2-Day Saliva Collection Kit and Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms at the data collection visit. The kit contains instructions for collecting and storing the saliva specimens in the home until they can be picked up by study staff.

For a 1-day data collection visit, the participants will self-collect saliva over the course of 2 consecutive¹ days within the week following the data collection visit. The Site Office will need to make the necessary arrangements for a pick-up visit within 7 days, when the saliva specimens will be picked up from the participant's home by study staff and transported to the Specimen Processing and Shipping Center (SPSC).

For a 2-day data collection visit, the participants will self-collect saliva over the course of 2 consecutive¹ days following the first day's visit. If the second day of data collection is more than 2 days after the first, the biospecimen data collector will pick up the saliva specimens during the second day's visit. If the second day of data collection is within 2 days of the first, the Site Office will need to make the necessary arrangements for a pick-up visit within 7 days, when the saliva specimens will be picked up from the participant's home by study staff and transported to the SPSC.

4.1.1.2 T3 Prior

The mother will self-collect saliva specimens over the course of 2 consecutive¹ days within the week *prior to* a T3 prior data collection visit.

For a T3 prior clinic visit, at least 1 week before the scheduled visit the Site Office will mail the participant an Adult 2-Day Saliva Collection Kit, pre-labeled Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms, a transport bag containing ice packs, and instructions for transporting the saliva specimens to the clinic on the day of the visit. The kit contains instructions for collecting and storing the saliva specimens in the home. Approximately 3 days before the T3 prior data collection visit, the participant will receive a reminder call from the Site Office to remind her of her appointment, to ask her to collect her saliva samples if she has not already done so, and to bring them to the clinic visit using the instructions and materials provided in the mailer.

For a T3 prior home visit, at least 1 week before the scheduled visit, the Site Office will mail the participant an Adult 2-Day Saliva Collection Kit and prelabeled Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms. The kit contains instructions for collecting and storing the saliva specimens in the home. Approximately 3 days before the T3 prior data collection visit, the participant will receive a reminder call from the Site Office to remind her of her appointment and ask her to collect her saliva samples if she has not already done so, using the instructions and materials provided in the mailer. The biospecimen data collector will pick up the saliva specimens at the T3 prior home data collection visit.

If a study participant does not have a home freezer, the data collector should request that the participant store the saliva samples in the refrigerator until they can be picked up by study staff. If a study participant does not have a refrigerator either, the data collector should request that the participant store the saliva samples at room temperature until they can be picked up by study staff. Information about storage temperature in the participant's home should be recorded appropriately in the Field-Administered Collection Environment (FACE) or on the Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms.

4.1.2 Providing Participants with 2-Day Saliva Collection Materials (T1 Mother, T3 First, and 6-Month Data Collection)

4.1.2.1 Equipment, Supplies, and Forms

The following equipment, supplies, and forms are required:

- Adult 2-Day Saliva Collection Kit (kit contents are in the next list);
- Saliva collection straw and container for demonstration;
- Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms. These are self-administered questionnaires (SAQs) to be completed by the participant at the time of collection (see Appendices 4-B through 4-E); and
- Computer tablet with bar code scanner.

The Adult 2-Day Saliva Collection Kit contains the following items:

- Cardboard kit box with cut-outs for holding saliva vials;

- Six collection straws;
- Three prelabeled blue collection vials for Day 1 collection;
- Three prelabeled yellow collection vials for Day 2 collection;
- One biohazard transport bag with absorbent pad. The bag also contains the following adhesive labels:
 - One adhesive label for appropriate Biospecimen Transmittal Form (TM label);
 - One adhesive label for Day 1: Adult 2-Day Saliva Data Collection Form (DC01 label);
 - One adhesive label for Day 2: Adult 2-Day Saliva Data Collection Form (DC02 label); and
 - Three additional adhesive labels (EX labels);
- Adult 2-Day Saliva Collection Instructions (see Appendix 4-A).

4.1.2.2 Procedures for Providing Participants with 2-Day Saliva Collection Materials

For the T1 mother, T3 first, and 6-Month study events, the adult 2-day saliva collection materials are given to the study participants during the data collection visit.

For the T1 mother and T3 first study events, the data collector will launch the Self-Administered Questionnaire (SAQ) instrument from FACE when providing the participant with the adult 2-day saliva collection materials. Detailed instructions for administering the Self-Administered Questionnaire (SAQ) instrument for adult 2-day saliva collection are found in Volume Appendix VIII-A.

For the 6-Month data collection, the data collector will launch the Biospecimen instrument from FACE when providing each of the two adult participants with the adult 2-day saliva collection materials. The Biospecimen instrument must be completed separately for each adult participant (i.e., the data collector will launch the instrument twice; once for each adult assignment). The data collector may provide the kits and instructions to both participants at the same time, or at different times during the visit, depending on the circumstances of the visit and the participants’

availability. Detailed instructions for administering the Biospecimen instrument for adult 2-day saliva collection are found in Volume Appendix VIII-A.

For general guidance on how to use FACE for data collection activities, refer to the FACE User Guide.

1. Locate the Adult 2-Day Saliva Collection Kit and Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms. Launch the SAQ instrument (T1, T3) or the Biospecimen instrument (6-Month) from FACE on the tablet.
2. Instruct the participant in the saliva self-collection procedures using the Adult 2-Day Saliva Collection Instructions and demonstrate the collection procedure with an extra straw and collection container.
3. Verify that the participant agrees to perform the collection and record this in FACE.
4. Wand the collection kit bar code into FACE and validate the kit type and expiration date. If FACE is not available, validate the kit type and expiration date manually.
5. If the kit type is valid and the kit is not expired, open the kit. Open the biohazard transport bag and remove the DC labels from the bag.
6. Review the instructions for completing the data collection forms with the participant.
7. Place the DC labels in the appropriate place on each of the Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms.
8. Review the contents of the kit with the participant and place the Day 1 collection vials in the appropriate cut-outs in the kit box. The participant should refer to the Adult 2-Day Saliva Collection Instructions when collecting the specimens.
9. Place the remaining adhesive labels inside the biohazard transport bag used to store the saliva specimens and ask the participant to keep them in the biohazard transport bag when storing the saliva specimens.
10. If collection kits are being distributed to two participants during the visit, implement the following steps so that the two adults completing the 2-day saliva collection can clearly identify which collection kit and forms have been assigned to each participant. These steps will help ensure that the saliva specimens and forms are correctly associated with each participant.
 - Verify which collection kit (previously wanded into FACE) and data collection forms (labeled with Subject labels) are associated with each participant.
 - Select an identifier for each participant that can be used to label the collection materials (for example, a first initial, a nickname, or a symbol). The identifiers

should be understood by the participants but must not personally identify the individuals (for example, do not use first or last names).

- Being careful to match the identifiers with the correct materials, write the identifier for each participant on each of the following items: 1) on the outside of each collection kit; 2) on the outside of each biohazard transport bag that will be used to store specimens in the participants' freezer; and 3) on each of the Day 1 and Day 2 data collection forms (inside the purple or yellow header at the top of each Teleform).
- 11. Give the Adult 2-Day Saliva Collection Kit and labeled Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms to the participant.
- 12. Record in FACE that the Adult 2-Day Saliva Collection Kit was given to the participant.
- 13. If collection kits were distributed to two participants during the visit, break off the FACE session after the saliva kit is distributed to the second adult. To do so, select "Break Off" and click on the End Exam button () at the top of the screen. Select "Planned Break" at the End of Section screen.

4.1.3 Mailing the Participant Adult 2-Day Saliva Collection Materials (T3 Prior Study Event Only)

4.1.3.1 Supplies and Forms

For the T3 prior study event, the Site Office will mail the adult 2-day saliva collection materials to the study participant at least 1 week before the scheduled T3 prior visit. The following supplies and forms should be mailed to the participant for all T3 prior study events:

- Adult 2-Day Saliva Collection Kit
- Folder containing the following:
 - Prelabeled Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms. These are SAQs to be completed by the participant at the time of collection (see Appendices 4-B through 4-E). The forms must be prelabeled with the Subject label and collection kit labels (DC01 and DC02 labels).
 - Instructions for Transporting Adult 2-Day Saliva Samples (see Appendix 4-F)
- Two -1° C cold packs

- Rubber band
- Insulated transport bag.

4.1.3.2 Procedures for Mailing the Participant Adult 2-Day Saliva Collection Materials

For detailed instructions regarding mailing adult 2-day saliva collection materials to study participants, refer to the Site Office training materials on the NCS Collaboration Portal.

4.1.4 Pick-Up/Receipt and Transport of Adult 2-Day Saliva

For T1 mother, T3 first, T3 prior (home visit), and 6 month study events, adult 2-day saliva specimens will be picked up from the study participant's home by a data collector and transported to the SPSC.

For a T3 prior clinic visit, adult 2-day saliva specimens will be transported to the clinic by the participant using the insulated biohazard transport bag and cold packs provided in the mailer. At the clinic visit, the data collector will receive the specimens from the participant and transport them to the SPSC along with the other biospecimens collected at the visit. When possible, the data collector should request the specimens from the participant at the beginning of the visit and place the specimens on dry ice until receipt of the saliva specimens can be documented in FACE using the Checkout instrument.

4.1.4.1 Equipment, Supplies, and Forms

The following equipment, supplies, and forms are required to pick up 2-day saliva from a participant's home or clinic, and to transport specimens to the SPSC.

- Specimen collection tray
- Disposable laboratory coat
- Gloves
- Hand sanitizer

- Biohazard waste bag
- Biospecimen transport cooler
- Dry ice
- Computer tablet with bar code scanner
- Computer keyboard cover
- Event-specific Biospecimen Transmittal Form (see volume Appendices VIII-B through VIII-J for form and field-by-field instructions).

4.1.4.2 Step-by-Step Procedures for Pick-Up/Receipt of Adult 2-Day Saliva

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

For the T1 mother and T3 first study events, the data collector will launch the Checkout instrument from FACE when picking up the 2-day saliva specimens. Detailed instructions for administering the Checkout instrument for adult 2-day saliva pickup are found in Volume Appendix VIII-A.

For the 6-Month data collection, the data collector will launch the Biospecimen instrument from FACE when picking up the 2-day saliva specimens that were collected by the two adult participants. The Biospecimen instrument must be completed separately for each adult participant (i.e., the data collector will launch the instrument twice; once for each adult assignment). However, only one of the participants needs to be present during the pickup of the specimens. Detailed instructions for administering the Biospecimen instrument for adult 2-day saliva pickup are found in Volume Appendix VIII-A.

For general guidance on how to use FACE for data collection activities, refer to the FACE User Guide.

1. Put on a laboratory coat.
2. Place the computer keyboard cover on the keyboard if you have not already done so. This will prevent the keyboard from contamination when handling specimens during the visit. One keyboard cover will be used for the duration of the biospecimen collection.

3. Locate the event-specific Biospecimen Transmittal Form. Launch the Checkout instrument (T1, T3) or Biospecimen instrument (6-Month) from FACE.

6-Month data collection only

Continue the FACE session by selecting “Collect Specimens.”

4. Request the participant retrieve the saliva specimens from the freezer and the Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms.

T3 prior clinic visit only

If the saliva specimens have not been already received from the study participant and placed on dry ice, obtain the insulated biohazard transport bag containing the saliva specimens from the participant.

5. Put on a clean pair of gloves.
6. Place the specimen collection tray on a flat surface.
7. When the participant returns with the specimens, do the following:
 - Thank the participant for providing the specimens and ask him or her to place the biohazard transport bag containing the specimens on the specimen collection tray.

T3 prior clinic visit only

The study participant may keep the insulated transport bag that was used to transport the saliva specimens to the clinic.

- Remove the TM label from the biohazard bag and place it on the Biospecimen Transmittal Form.
- Check the caps on the saliva vials to make sure they are securely closed.

4.1.5 Documenting Adult 2-Day Saliva Pick-Up/Receipt

1. Record the saliva collection status in FACE and wand the bar code label on each collection vial.
2. Immediately place the vials back into the biohazard transport bag with the absorbent pad. Seal the bag and place the bag securely on dry ice in the transport cooler.
3. Review the Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms for legibility and completeness and verify that the DC labels from the collection kit are

affixed to the forms. . If the DC labels were not affixed to the forms and are no longer available, manually record the collection kit ID with the suffix “DC01” onto the form (for example, “AB1234567-DC01”). The kit ID is the 9-digit sequence before the item ID. Because the form is a Teleform, this information should be written in block letters above the label box.

4. Record the following data on the back of the form in the “For Data Collector’s Use” box:
 - Data collector ID
 - Date of pick-up
 - Sample condition at pick-up
 - Time placed in cooler.
5. Record the 2-day saliva collection status on the Biospecimen Transmittal Form.
6. If an incident occurs during the saliva pick-up procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I (Incident Reporting) for more information regarding documentation of incidents.

4.1.6 Clean-Up Procedures

After completing the saliva pick-up procedures, make sure the work area is clean and reusable.

- The work area is reusable if contamination, such as a spill, has *not* occurred.
- If a spill has occurred, clean the tray with a bleach wipe. Discard in the biohazard waste bag.
- If the 2-day saliva specimens are the last biospecimens collected at the visit, remove the computer keyboard cover, clean the work area, and pack all collection supplies.

After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer. Be sure to pack the biohazard waste bag appropriately for transport so that it is not visible upon leaving the site of data collection. The biohazard waste bag must be disposed of properly at the SPSC.

4.1.7 Transport Procedures

Adult 2-day saliva specimens will be transported to the SPSC in the dry ice chamber of the biospecimen transport cooler.

Day 1 and Day 2 Adult 2-Day Saliva Data Collection Forms will be transported with other SAQs and forms to the Site Office by the visit coordinator.

1. Ensure that the Biospecimen Transmittal Form is complete. If this is the last biospecimen type collected at the visit, place the completed form in the zippered document pouch inside the lid of the transport cooler along with any unused labels.
2. Secure the biohazard transport bag containing the collection vials in the dry ice and confirm the cooler is properly closed for transport.

4.2 Adult BNC (Blood Not Collected) Saliva

Adult BNC saliva specimens *may be collected* at the P1 mother, T1 mother, T1 father, and T3 mother study events. These saliva specimens will only be collected if the participant does not provide a blood specimen and agrees to provide a saliva specimen. The following procedures should be followed if a participant refuses or is unable to provide a blood specimen because he or she meets one of the exclusion criteria after completing the blood prescreening questions. If two unsuccessful phlebotomy attempts were made to draw blood from the participant, BNC saliva should not be collected. The purpose of collecting this saliva specimen is to obtain a source of DNA from the participant.

4.2.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to collect and transport adult BNC saliva:

- Adult BNC Saliva Collection Kit (kit contents are in the next list)
- Specimen collection tray
- Disposable laboratory coat
- Gloves

- Hand sanitizer
- Biohazard waste bag
- Biospecimen transport cooler with insulated transport bag
- Computer tablet with bar code scanner
- Computer keyboard cover.

The Adult BNC Saliva Collection Kit should be in the Biospecimen Auxiliary Bag for all study events and contains the following items:

- One Oragene[®] saliva collection container with instruction insert
- One paper towel
- One biohazard transport bag with absorbent pad
- One adhesive label for the saliva collection container (SB01 label)
- One adhesive label for Biospecimen Transmittal Form (TM label)
- One adhesive label for hard copy backup Adult Blood Data Collection Form (DC label)
- One additional adhesive label (EX label).

The following forms are required to collect and transport adult BNC saliva specimens:

- Event-specific Biospecimen Transmittal Form (see volume Appendices VIII-B through VIII-G for forms and field-by-field instructions).

BNC saliva collection data will be documented in the Biospecimen Blood instrument in FACE. If FACE is not available, then the appropriate hard copy backup Adult Blood Data Collection Form must be used to document collection data (see Appendices 1-B through 1-F in Chapter 1, Part 4 of this volume for forms and field-by-field instructions). Once the system becomes available, data must be entered in the system from the backup form.

4.2.2 Step-by-Step Procedures for Adult BNC Saliva Collection

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following procedures are to be used for adult BNC saliva collection. For general guidance on how to use FACE for data collection activities, refer to the FACE User Guide. For detailed question-by-question specifications for administering the BNC module in the Biospecimen Blood instrument, refer to the appropriate section in volume Appendix VIII-A.

1. Put on a disposable laboratory coat.
2. Place the computer keyboard cover on the keyboard if you have not already done so. This will prevent the keyboard from contamination when handling specimens during the visit. One keyboard cover will be used for the duration of the biospecimen collection.
3. Launch the Biospecimen Blood instrument on the tablet. If the participant refused or was unable to provide a blood specimen in Module 1, the instrument will automatically redirect the user to Module 2 (Saliva BNC) for the collection. If FACE is not available, the hard copy backup Adult Blood Data Collection Form should be used.
4. Read the saliva collection question to the participant from the tablet and enter the response. If FACE is not available read the collection question in Part F of the hard copy backup Adult Blood Data Collection Form and record the response.
5. Put on gloves.
6. Locate the Adult BNC Saliva Collection Kit and event-specific Biospecimen Transmittal Form.
7. Place the specimen collection tray on a flat surface.
8. Wand the collection kit bar code into FACE and validate the kit type and expiration date.
9. If the kit type is valid and the kit is not expired, open the kit and remove the Oragene saliva collection container, paper towel, and labels. Remove the saliva collection container from the plastic bag and place the SB01 label on the bottom of the clear collection container as indicated in Exhibit 4-1.

Exhibit 4-1



10. Place the TM label on the Biospecimen Transmittal Form. If using the hard copy backup Adult Blood Data Collection Form, place the DC label in the appropriate place on the form.
11. Instruct the participant in the saliva self-collection procedures using the prompts in the instrument and the instructions provided in the kit. Show the participant the picture in the Oragene insert to indicate how full the clear container should be.
12. Give the participant the labeled clear container. Do not remove the plastic film from the blue cap.
13. Once the participant has collected the specimen, do the following:
 - Thank the participant for providing the specimen and ask him or her to place the Oragene container on the specimen collection tray.
 - Verify that a sufficient amount of saliva has been collected. The collection container should be filled to the fill line as shown in the Oragene insert. If not, ask the participant to continue collecting the specimen. The spitting must be completed within 30 minutes of when it began.
 - Once a sufficient amount of saliva has been collected, cap the container tightly with the blue lid and invert gently several times.

4.2.3 Documenting Adult BNC Saliva Collection

1. Record the BNC saliva collection status in FACE and wand the bar code label on the saliva collection container into FACE.
2. Place the saliva collection container in the biohazard transport bag with the absorbent pad. Seal the bag and place the bag in the insulated transport bag.
3. Record any comments pertaining to the BNC saliva specimen collection in FACE (up to a 250-character limit) or on the hard copy backup Adult Blood Data Collection Form. If using the form, ensure the form is complete.

4. Record the BNC saliva collection status on the Biospecimen Transmittal Form.
5. If an incident occurs during the saliva collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

4.2.4 Clean-Up Procedures

After completing the saliva collection procedures, make sure the work area is clean and reusable.

- The work area is reusable if contamination, such as a spill, has *not* occurred.
- If a spill has occurred, clean the tray with a bleach wipe. Discard in the biohazard waste bag.
- If the BNC saliva specimen is the last biospecimen collected at the visit, remove the computer keyboard cover, clean the work area and pack all collection supplies.

After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer. Be sure to pack the biohazard waste bag appropriately for transport so that it is not visible upon leaving the site of data collection. The biohazard waste bag must be disposed of properly at the SPSC.

4.2.5 Transport Procedures

Adult BNC saliva specimens will be transported to the SPSC in the insulated transport bag.

- Ensure the Biospecimen Transmittal Form is complete. If this is the last biospecimen type collected at the visit, place the completed form in the zippered document pouch inside the lid of the transport cooler, along with any unused labels.
- Secure the biohazard transport bag containing the saliva collection container in the insulated transport bag for transport.

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Part 2

Appendix 4-A

Adult 2-Day Saliva Collection Instructions

Appendix 4-A.

Adult 2-Day Saliva Collection Instructions

OMB Control Number: 0925-0593
Expiration Date: 09/30/2011

National Children's Study Adult Saliva Collection Instructions

This kit contains everything you will need to provide a sample of your saliva:

- 6 straws
- 6 small containers
- 1 re-sealable plastic bag with absorbent pad

We are asking you to collect saliva samples for two days in a row. You should collect your first saliva sample as soon as you wake up (☼ sample); collect the second sample 30 minutes after the first (+30 sample); and collect the third saliva sample at night before you go to bed, at least 1 hour after eating but before brushing your teeth (🌙 sample).

Day 1 Use the three small containers labeled with a **Blue** label marked with a ☼, +30, and a 🌙.
Use the small container marked with a ☼ to collect the first sample.
Use the small container marked with a +30 to collect the second sample.
Use the small container marked with a 🌙 to collect the third sample.

Day 2 Use the three small containers labeled with a **Yellow** label marked with a ☼ +30, and a 🌙.
Use the small container marked with a ☼ to collect the first sample.
Use the small container marked with a +30 to collect the second sample.
Use the small container marked with a 🌙 to collect the third sample.

IMPORTANT NOTES

- ✓ Please record the time that you collect each sample.
- ✓ **Take the first sample as soon as you wake up! It is okay to either wake up naturally or to an alarm clock, but you should not lie in bed and doze before you begin.**
- ✓ Do not eat, drink, smoke or brush your teeth before collecting both morning samples (☼ and +30)
- ✓ Do not eat, drink, smoke or brush your teeth for 1 hour before collecting the Bedtime sample (🌙). If this cannot be avoided, rinse your mouth thoroughly with water at least 5 minutes before collecting the sample.
- ✓ Do not drink alcohol for 12 hours prior to collecting the samples.
- ✓ If your mouth is dry, do not use salivary stimulants such as chewing gum, lemon drops, sugar, or drink crystals such as Kool-Aid or Crystal Light prior to collecting the samples.
- ✓ Avoid heavy exercise on the days that you are collecting these samples.
- ✓ Do not collect samples within 24 hours after having dental work.

Instructions for collection:

Day 1

1. To collect your first sample use the small container with a **blue** label marked with a ☼. Remove the cap.
2. Remove a single straw from the plastic bag. Place one end of the straw into the small container.
3. Place your mouth on the other end of the straw. Imagine eating your favorite food and allow saliva to pool in your mouth. (It is okay to gently chew on the end of the straw.)
4. Tilt your head forward and drool down the straw to collect your saliva in the small container. Do not spit or blow through the straw as this will cause excess foam. The small container should be half full of liquid not including any foam that may have formed.
5. Tightly screw the cap on the small container, place the small container in the re-sealable plastic bag that contains an absorbent pad, seal the bag, and place the bag in the freezer.
6. Complete the Day 1: Adult 2-Day Saliva Data Collection Form including the time the sample was collected.
7. 30 minutes after you collect the Day 1 ☼ sample, repeat steps 2-6 for the Day 1 +30 sample. Remember not to eat, drink, smoke or brush your teeth before you collect the Day 1 +30 sample. Record the time the sample was collected on the Day 1: Adult 2-Day Saliva Data Collection Form.
8. Before you go to bed, collect the Day 1 🌙 sample as described in steps 2-6. Remember you should collect this sample before you brush your teeth and at least 1 hour after eating. Complete the Day 1: Adult 2-Day Saliva Data Collection Form.

Day 2

Repeat steps above using the small container with the **yellow** labels for the Day 2 ☼, Day 2 +30, and the

Day 2 🌙 samples and complete the Day 2: Adult 2-Day Saliva Data Collection Form.

Please keep the re-sealable plastic bag containing the saliva samples in the freezer until the samples can be picked up by study staff.

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

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Appendix 4-A. Adult 2-Day Saliva Collection Instructions (continued)

Número de control de OMB: 0925-0593
Fecha de vencimiento: 09/30/2011

Estudio Nacional de los Niños Instrucciones para tomar la muestra de saliva de un adulto

Estos materiales contienen todo lo que necesita para tomar su muestra de saliva:

- 6 popotes (pajillas, sorbetes)
- 6 tubitos
- 1 bolsa de plástico con cierre reusable con almohadilla absorbente

Queremos pedirle que tome las muestras de saliva dos días seguidos. Debe tomar la primera muestra de saliva tan pronto se despierte (muestra ☼); tome la segunda muestra 30 minutos después de la primera muestra (muestra +30); y tome la tercera muestra de saliva en la noche antes de acostarse, por lo menos 1 hora después de comer pero antes de cepillarse los dientes (muestra ☾).

Día 1 Use los tres tubitos que tienen una etiqueta **Azul** marcada con un ☼, +30 y una ☾.

Use el tubito marcado con un ☼ para tomar la primera muestra.

Use el tubito marcado con un +30 para tomar la segunda muestra.

Use el tubito marcado con una ☾ para tomar la tercera muestra.

Día 2 Use los tres tubitos que tienen una etiqueta **Amarilla** marcada con un ☼, +30 y una ☾.

Use el tubito marcado con un ☼ para tomar la primera muestra.

Use el tubito marcado con un +30 para tomar la segunda muestra.

Use el tubito marcado con una ☾ para tomar la tercera muestra.

INFORMACIÓN IMPORTANTE

- ✓ **Por favor, anote la hora en que tomó cada muestra.**
- ✓ **¡Tome la primera muestra tan pronto se despierte! Está bien si se despierta por su propia cuenta o con un despertador, sin embargo no debe quedarse en la cama dormitando antes de comenzar a tomar la muestra.**
- ✓ **No coma, beba, fume ni se cepille los dientes antes de tomar las muestras de la mañana (☼ y +30).**
- ✓ **No coma, beba, fume, ni se cepille los dientes por 1 hora antes de tomar la muestra a la hora de acostarse (☾). Si no lo puede evitar, enjuáguese la boca muy bien con agua al menos 5 minutos antes de tomar la muestra.**
- ✓ **No beba alcohol por 12 horas antes de tomar las muestras.**
- ✓ **Si tiene la boca reseca, no use estimulantes para la saliva tales como goma de mascar, caramelos de limón, azúcar granulada o bebidas en polvo como Kool-Aid o Crystal Light antes de tomar las muestras.**
- ✓ **Evite hacer ejercicios intensos los días que tome las muestras.**
- ✓ **No tome las muestras por un periodo de 24 horas después de haber ido al dentista.**

Instrucciones para tomar las muestras:

Día 1

1. Para tomar su primera muestra, use el tubito que tiene una etiqueta **azul** marcada con un ☼. Destape el tubito.
2. Saque un popote de la bolsa de plástico y ponga un extremo del popote dentro del tubito.
3. Ponga la boca en el otro extremo del popote. Imagínese que está comiendo su comida preferida y deje que la saliva se acumule en la boca. (Puede morder suavemente el popote).
4. Incline la cabeza hacia adelante y deje que la saliva escurra por el popote hasta el tubito. No escupa ni sople a través del popote ya que eso causará que se forme demasiada espuma. El tubito deberá estar lleno de líquido hasta la mitad sin incluir ninguna espuma que se haya podido formar.
5. Tape firmemente el tubito y póngalo dentro de la bolsa de plástico con cierre reusable que contiene una almohadilla absorbente, cierre la bolsa y póngala en el congelador.
6. Complete el formulario "Día 1: Formulario de información de la muestra de saliva de 2 días para adultos", incluyendo la hora en que tomó la muestra.
7. Después de 30 minutos de haber tomado la muestra del Día 1 ☼, repita los pasos 2 a 6 para la muestra +30 del Día 1. Recuerde no comer, beber, fumar ni cepillarse los dientes antes de tomar la muestra del Día 1 +30. Anote la hora en que tomó la muestra en el formulario "Día 1: Formulario de información de la muestra de saliva de 2 días para adultos".
8. Antes de irse a dormir, tome la muestra del Día 1 ☾, como se describe en los pasos 2 a 6. Recuerde que debe tomar esta muestra antes de cepillarse los dientes y por lo menos 1 hora después de haber comido. Complete el formulario "Día 1: Formulario de información de la muestra de saliva de 2 días para adultos".

Día 2

Repita los pasos que se explican anteriormente usando los tubitos que tienen la etiqueta **amarilla** para las muestras del Día 2 ☼, Día 2 +30 y Día 2 ☾ y complete el formulario "Día 2: Formulario de información de la muestra de saliva de 2 días para adultos".
Por favor, mantenga la bolsa de plástico con cierre reusable con las muestras de saliva en el congelador hasta que el personal del estudio vaya a buscarlas.

Se calcula que el promedio de tiempo necesario para esta recolección de información es de 10 minutos por entrevista, incluyendo el tiempo para leer las instrucciones, buscar fuentes de información existentes, reunir y mantener la información necesaria y completar y revisar la recolección de información. **Ninguna agencia puede llevar a cabo ni patrocinar una recolección de información y ninguna persona está obligada a responder a dicha recolección a menos que ésta muestre un número de control vigente de OMB.** Envíe los comentarios acerca de este cálculo de tiempo necesario, incluyendo sugerencias sobre cómo reducirlo, o acerca de cualquier otro aspecto de esta recolección de información a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). No devuelva el formulario contestado a esta dirección.

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Part 2

Appendix 4-B

Day 1 Adult 2-Day Saliva Data Collection Form (English)

Appendix 4-B.
Day 1 Adult 2-Day Saliva Data Collection Form (English)



National Children's Study
DAY 1: ADULT 2-DAY SALIVA
DATA COLLECTION FORM

Instructions

- Please use a black or blue pen to complete this form. Do not use a felt tip pen or a pencil.
- Mark ☒ to indicate your answer.
- If you want to change your answer, mark ☒ on the wrong answer.

Please collect your saliva samples on the 2 days following our visit to your home on

/ /

m m d d y y y y

Please write down the exact time that you collected each saliva sample in the spaces below.

Day 1 Saliva Samples

On what date did you collect the Day 1 saliva samples?

/ /

m m d d y y y y

Container	When to Take Sample	Time Collected
	As soon as you wake up	: ☐ a.m. ☐ p.m. Go to Question 1

Please answer the following question after you have collected the ☀ saliva sample:

1. Did you spend any time dozing in bed before you collected the first saliva sample (☀ saliva sample) this morning?

☐ Yes ☐ No

2. If yes, estimate of time spent dozing before collecting the ☀ saliva sample

minutes

Container	When to Take Sample	Time Collected
+30	30 minutes after waking up	: ☐ a.m. ☐ p.m.

Container	When to Take Sample	Time Collected
	At Bedtime before brushing your teeth and at least 1 hour after eating for the last time today	: ☐ a.m. ☐ p.m.

Please complete questions on the back.



SALAD101.00EN

**For
Office Use
Only**

Place Label Here

Appendix 4-B. Day 1 Adult 2-Day Saliva Data Collection Form (English) (continued)



26796

3. During the 2 hours prior to collecting the 2 saliva sample, have you done any of the following:

Consumed a caffeinated beverage (coffee, tea, soda)? ☐ Yes ☐ No

Smoked? ☐ Yes ☐ No

Consumed alcohol? ☐ Yes ☐ No

4. During the 2 hours prior to collecting the 2 saliva sample, what was your level of physical activity?

None ☐

Light (standing, light walking, light house work) ☐

Moderate (yard work, brisk walking) ☐

Intense (jogging, exercise classes) ☐

5. Please write down the name of any prescription or over the counter medications you have taken today. Please be specific. For example, if you took Robitussin DM®, write Robitussin DM®, not Robitussin ®. If you did not take any prescription or over the counter medications today, please mark None.

None ☐

Please call the Study Center number on your Local Contact Sheet if you have any questions.

Thank you for taking the time to provide this information today.

For Data Collector's Use

Date kit provided to participant

/ /
m m d d y y y y

☐ Recollection

Data Collector ID:

Date samples picked up

/ /
m m d d y y y y

Were the saliva samples frozen when received from the participant? ☐ Yes ☐ No

2 Day Adult Saliva
Kit ID

Part 2

Appendix 4-C

Day 1 Adult 2-Day Saliva Data Collection Form
(Spanish)

Appendix 4-C.
Day 1 Adult 2-Day Saliva Data Collection Form (Spanish)



14665



Estudio Nacional de los Niños
DÍA 1: FORMULARIO DE
INFORMACIÓN DE LA MUESTRA DE
SALIVA DE 2 DÍAS PARA ADULTOS

Instrucciones

- ➔ Por favor use una pluma or bolígrafo de tinta negra o azul para completar este formulario.
Por favor no utilice marcador ni lápiz.
- ➔ Marque con una ☒ para indicar su respuesta.
- ➔ Si desea cambiar su respuesta, tache la respuesta errónea con una X.

Por favor, tome sus muestras de saliva durante los 2 días después de nuestra visita a su hogar en

/ /
mes día año

Por favor, anote la hora exacta en que tomó cada muestra de saliva en los espacios a continuación.

Muestras de saliva del Día 1

¿En qué fecha tomó las muestras de saliva del Día 1?

/ /
mes día año

Tubito	Cuando tomar la muestra	Hora en que tomó la muestra
	Tan pronto se despierte	: ☐ a.m. ☐ p.m. (Vaya a la pregunta 1)

Por favor, responda la siguiente pregunta después de tomar la muestra de saliva ☀ :

1. ¿Pasó algún tiempo dormitando en la cama esta mañana antes de tomar la primera muestra de saliva (muestra de saliva ☀)?

☐ Sí ☐ No

2. Si respondió "Sí", calcule el tiempo que pasó dormitando antes de tomar la muestra de saliva ☀

minutos

Tubito	Cuando tomar la muestra	Hora en que tomó la muestra
+ 30	30 minutos después de despertarse	: ☐ a.m. ☐ p.m.

Tubito	Cuando tomar la muestra	Hora en que tomó la muestra
	A la hora de acostarse antes de cepillarse los dientes y por lo menos 1 hora después de comer por última vez hoy	: ☐ a.m. ☐ p.m.

Por favor responda las preguntas en la parte de atrás de la hoja.



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Appendix 4-C. Day 1 Adult 2-Day Saliva Data Collection Form (Spanish) (continued)



14665

3. Durante las 2 horas antes de tomar la muestra de saliva , ¿ha hecho alguna de las siguientes cosas?

¿Tomó alguna bebida con cafeína (café, te, gaseosa o soda)? ☐ Sí ☐ No

¿Fumó? ☐ Sí ☐ No

¿Bebió alcohol? ☐ Sí ☐ No

4. Durante las 2 horas antes de tomar la muestra de saliva , ¿cuál fue su nivel de actividad física?

Ninguno ☐

Leve (permanecer de pie, caminar un poco, hacer quehaceres domésticos livianos) ☐

Moderado (trabajar en el jardín, caminar a paso ligero) ☐

Intenso (correr, participar en una clase de ejercicios) ☐

5. Por favor anote el nombre de cualquier medicamento con o sin receta médica que haya tomado hoy. Por favor sea específica. Por ejemplo, si tomó Robitussin DM®, anote Robitussin DM®, y no Robitussin ®. Si hoy no tomó ningún medicamento con o sin receta médica, marque Ninguno.

Ninguno ☐

Por favor llama al número del Centro del Estudio que hay en su Hoja de Contacto Local si tiene alguna pregunta.

Gracias por tomarse el tiempo para dar esta información hoy.

Para uso del entrevistador

Date kit provided to participant

		/			/	2	0		
m	m		d	d		y	y	y	y

☐ **Recollection**

Data Collector ID:

Date samples picked up

		/			/	2	0		
m	m		d	d		y	y	y	y

Were the saliva samples frozen when received from the participant? ☐ Yes ☐ No

**2 Day Adult Saliva
Kit ID**

Part 2

Appendix 4-D

Day 2 Adult 2-Day Saliva Data Collection Form
(English)

Appendix 4-D.
Day 2 Adult 2-Day Saliva Data Collection Form (English)



9973



National Children's Study
DAY 2: ADULT 2-DAY SALIVA
DATA COLLECTION FORM

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☒ on the wrong answer.

Please collect your saliva samples on the 2 days following our visit to your home on

/ /

m m d d y y y y

Please write down the exact time that you collected each saliva sample in the spaces below.

Day 2 Saliva Samples

On what date did you collect the Day 2 saliva samples?

/ /

m m d d y y y y

Container	When to Take Sample	Time Collected
	As soon as you wake up	: ☐ a.m. ☐ p.m. Go to Question 1

Please answer the following question after you have collected the saliva sample:

1. Did you spend any time dozing in bed before you collected the first saliva sample (saliva sample) this morning? ☐ Yes ☐ No

2. If yes, estimate of time spent dozing before collecting the saliva sample minutes

Container	When to Take Sample	Time Collected
+ 30	30 minutes after waking up	: ☐ a.m. ☐ p.m.

Container	When to Take Sample	Time Collected
	At Bedtime before brushing your teeth and at least 1 hour after eating for the last time today	: ☐ a.m. ☐ p.m.

Please complete questions on the back.



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Place Label Here

Appendix 4-D. Day 2 Adult 2-Day Saliva Data Collection Form (English) (continued)



9973

3. During the 2 hours prior to collecting the  saliva sample, have you done any of the following:

Consumed a caffeinated beverage (coffee, tea, soda)? ☐ Yes ☐ No

Smoked? ☐ Yes ☐ No

Consumed alcohol? ☐ Yes ☐ No

4. During the 2 hours prior to collecting the  saliva sample, what was your level of physical activity?

None ☐

Light (standing, light walking, light house work) ☐

Moderate (yard work, brisk walking) ☐

Intense (jogging, exercise classes) ☐

5. Please write down the name of any prescription or over the counter medications you have taken today. Please be specific. For example, if you took Robitussin DM®, write Robitussin DM®, not Robitussin ®. If you did not take any prescription or over the counter medications today, please mark None.

None ☐

Please call the Study Center number on your Local Contact Sheet if you have any questions.

Thank you for taking the time to provide this information today.

For Data Collector's Use

Date kit provided to participant

/ /
m m d d y y y y

☐ Recollection

Data Collector ID:

Date samples picked up

/ /
m m d d y y y y

Were the saliva samples frozen when received from the participant? ☐ Yes ☐ No

2 Day Adult Saliva
Kit ID

Part 2

Appendix 4-E

Day 2 Adult 2-Day Saliva Data Collection Form
(Spanish)

Appendix 4-E.
Day 2 Adult 2-Day Saliva Data Collection Form (Spanish)



46171



Estudio Nacional de los Niños
DÍA 2: FORMULARIO DE
INFORMACIÓN DE LA MUESTRA DE
SALIVA DE 2 DÍAS PARA ADULTOS

Instrucciones

- ➔ Por favor use una pluma or bolígrafo de tinta negra o azul para completar este formulario.
Por favor no utilice marcador ni lápiz.
- ➔ Marque con una ☒ para indicar su respuesta.
- ➔ Si desea cambiar su respuesta, tache la respuesta errónea con una ☒.

Por favor, tome sus muestras de saliva durante los 2 días después de nuestra visita a su hogar en

/ /
mes día año

Por favor, anote la hora exacta en que tomó cada muestra de saliva en los espacios a continuación.

Muestras de saliva del Día 2

¿En qué fecha tomó las muestras de saliva del Día 2? / /
mes día año

Tubito	Cuando tomar la muestra	Hora en que tomó la muestra
	Tan pronto se despierte	: ☐ a.m. ☐ p.m. (Vaya a la pregunta 1)

Por favor, responda la siguiente pregunta después de tomar la muestra de saliva ☀ :

- ¿Pasó algún tiempo dormitando en la cama esta mañana antes de tomar la primera muestra de saliva (muestra de saliva ☀)? ☐ Sí ☐ No
- Si respondió "Sí", calcule el tiempo que pasó dormitando antes de tomar la muestra de saliva ☀ minutos

Tubito	Cuando tomar la muestra	Hora en que tomó la muestra
+30	30 minutos después de despertarse	: ☐ a.m. ☐ p.m.

Tubito	Cuando tomar la muestra	Hora en que tomó la muestra
	A la hora de acostarse antes de cepillarse los dientes y por lo menos 1 hora después de comer por última vez hoy	: ☐ a.m. ☐ p.m.

Por favor responda las preguntas en la parte de atrás de lo hoja.



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Only**

Place Label Here

Appendix 4-E.
Day 2 Adult 2-Day Saliva Data Collection Form (Spanish) (continued)



46171

3. Durante las 2 horas antes de tomar la muestra de saliva , ¿ha hecho alguna de las siguientes cosas?

- ¿Tomó alguna bebida con cafeína (café, te, gaseosa o soda)? ☐ Sí ☐ No
- ¿Fumó? ☐ Sí ☐ No
- ¿Bebió alcohol? ☐ Sí ☐ No

4. Durante las 2 horas antes de tomar la muestra de saliva , ¿cuál fue su nivel de actividad física?

- Ninguno ☐
- Leve (permanecer de pie, caminar un poco, hacer quehaceres domésticos livianos) ☐
- Moderado (trabajar en el jardín, caminar a paso ligero) ☐
- Intenso (correr, participar en una clase de ejercicios) ☐

5. Por favor anote el nombre de cualquier medicamento con o sin receta médica que haya tomado hoy. Por favor sea específica. Por ejemplo, si tomó Robitussin DM®, anote Robitussin DM®, y no Robitussin ®. Si hoy no tomó ningún medicamento con o sin receta médica, marque Ninguno.

Ninguno ☐

Por favor llama al número del Centro del Estudio que hay en su Hoja de Contacto Local si tiene alguna pregunta.

Gracias por tomarse el tiempo para dar esta información hoy.

Para uso del entrevistador

Date kit provided to participant

		/			/	2	0		
m	m		d	d		y	y	y	y

☐ Recollection

Data Collector ID:

Date samples picked up

		/			/	2	0		
m	m		d	d		y	y	y	y

Were the saliva samples frozen when received from the participant? ☐ Yes ☐ No

**2 Day Adult Saliva
Kit ID**

Part 2

Appendix 4-F

Adult 2-Day Saliva Transport Instructions

Appendix 4-F.

Adult 2-Day Saliva Transport Instructions

National Children's Study Instructions for Transporting Adult 2-Day Saliva Samples

You are being asked to bring the Adult 2-Day Saliva samples that you have collected to your T3 clinic visit.

Here are the instructions that you will need to follow to make sure that your saliva samples remain frozen while traveling from your home to the clinic.

The following materials are included in the package that was mailed to you:

- An Adult 2-Day Saliva Collection Kit
- A folder containing Day 1 and Day 2 Adult 2-Day Saliva Data Collection forms
- An insulated bag
- Two ice packs
- A rubber band

When you receive the Adult 2-Day Saliva materials:

- ✓ Immediately place the ice packs in your freezer lying flat, so that they are ready for use when it is time to transport the samples to the clinic.
- ✓ Keep the labels that came with the kit inside the plastic transport bag provided. You will store the saliva samples in this bag in your freezer.

On the day of your T3 clinic visit:

- ✓ Place the plastic bag containing the saliva samples between the two ice packs, and fasten the rubber band around the ice packs to hold them tightly against the bag.
 - ✓ Place the ice packs and plastic bag into the insulated bag.
 - ✓ Bring the insulated bag to the clinic along with the folder that contains your completed Day 1 and Day 2 Adult 2-Day Saliva Data Collection forms.
-

**Please call the Study Center number on your
Local Contact Sheet if you have any questions.**

Thank you.

SAL2DI01.00DU

Appendix 4-F.
Adult 2-Day Saliva Transport Instructions (continued)

Estudio Nacional de los Niños
Instrucciones para transportar las muestras de saliva de 2 días de un adulto

Queremos pedirle que traiga a su visita T3 a la clínica, las muestras de saliva de 2 días.

Éstas son las instrucciones que debe seguir para asegurarse de que sus muestras de saliva permanezcan congeladas mientras las lleva desde su casa hasta la clínica.

Los siguientes materiales se incluyen en el paquete que le enviaron por correo:

- Materiales para tomar las muestras de saliva de 2 días de un adulto
- Una carpeta con los formularios de información de la muestra de saliva de 2 días para adultos (Día 1 y Día 2)
- Una bolsa aislante
- Dos paquetes de hielo
- Una liga o goma elástica

Cuando reciba los materiales para tomar la muestra de saliva de 2 días de un adulto:

- ✓ De inmediato ponga los paquetes de hielo en su congelador, asegurándose de que queden horizontales para que estén listos para cuando llegue el momento de llevar las muestras a la clínica.
- ✓ Mantenga las etiquetas que venían con los materiales dentro de la bolsa de plástico para transportar las muestras. Ésta es la bolsa que usará para guardar las muestras de saliva en su congelador.

El día de su visita T3 a la clínica:

- ✓ Ponga la bolsa de plástico que contiene las muestras de saliva en medio de los dos paquetes de hielo. Ajuste la liga o goma elástica alrededor de los paquetes de hielo para que sujeten bien la bolsa.
- ✓ Ponga los paquetes de hielo y la bolsa de plástico en la bolsa aislante.
- ✓ Traiga la bolsa aislante a la clínica junto con la carpeta que contiene sus formularios de información de la muestra de saliva de dos días para adultos (día 1 y día 2) respondidos.

Por favor llame al número del Centro del Estudio que se encuentra en su Hoja de Contactos Locales si tiene alguna pregunta.

Gracias.

Hair Collection and Transport Procedures

5.1 Adult Hair

Adult hair specimens will be collected at the P1 mother, T1 father, and T3 mother study events. Adult hair specimens will be analyzed to obtain information about exposure to mercury and other environmental chemicals.

5.1.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to collect and transport adult hair specimens:

- Adult Hair Collection Kit (kit contents are in the next list)
- Specimen collection tray
- Stainless steel scissors
- 6" stainless steel ruler
- Disposable laboratory coat
- Gloves
- Hand sanitizer
- Biohazard waste bag
- Insulated transport bag
- Computer tablet with bar code scanner
- Computer keyboard cover

The Adult Hair Collection Kit contains the following items:

- Plastic comb
- 2 alcohol wipes
- Hair clip
- Prelabeled (HR01 label) prescreened plastic collection bag (2"x3")
- One duplicate adhesive label for taping the hair specimen (HR01 label)
- One adhesive label for the Biospecimen Transmittal Form (TM label)
- One adhesive label for the hard copy back-up Adult Hair Data Collection Form (DC label)
- One additional adhesive label for the plastic collection bag (EX01)

The following form is required to collect and transport adult hair specimens:

- Event-specific Biospecimen Transmittal Form (see volume Appendices VIII-B through VIII-G for forms and field-by-field instructions).

Hair collection data will be documented in the Biospecimen instrument in the Field-Administered Collection Environment (FACE). If FACE is not available, the appropriate hard copy back-up Adult Hair Data Collection Form must be used to document collection data (see Appendices 5-A and 5-B for form and field-by-field instructions). Once the system becomes available, data must be entered in the system from the back-up form.

5.1.2 Step-by-Step Procedures for Adult Hair Collection

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

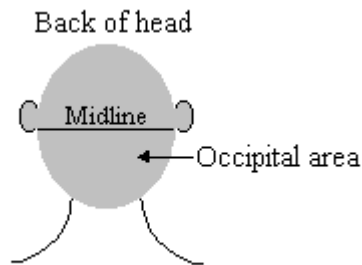
The following procedures are to be used for adult hair collection. For general guidance on how to use FACE for data collection activities, refer to the FACE User Guide. For detailed question-by-question specifications for administering the Biospecimen instrument, refer to the appropriate section in volume Appendix VIII-A.

Hair collection for NCS requires a minimum of 20 strands of the study participant's own head hair that are at least 1 cm in length. If the participant does not have a sufficient amount or length of hair, record the appropriate reason for not collecting the hair specimen in FACE or on the hard copy back-up form. A hair specimen should not be obtained from facial (e.g., mustache, beard) or other body hair.

1. Put on a laboratory coat.
2. Place the computer keyboard cover on the keyboard if you have not already done so. This will protect the keyboard from contamination when handling specimens during the visit. One keyboard cover will be used for the duration of the biospecimen collection.
3. Launch the Biospecimen instrument from FACE on the tablet. If FACE is not available, the hard copy back-up Adult Hair Data Collection Form should be used. If using the form, place an extra Subject label (from the visit coordinator's supplies) in the appropriate place on the form.
4. Explain to the participant that you will cut a small amount of hair close to the scalp on the back of the head, emphasizing that it will not hurt and will not leave a visible bald spot.
5. Read the hair collection questions to the participant from FACE and enter the responses. If FACE is not available, read the collection questions in Part B of the hard copy back-up Adult Hair Data Collection Form and record the responses.
6. Locate the Adult Hair Collection Kit and event-specific Biospecimen Transmittal Form.
7. Wand the collection kit bar code into FACE and validate the kit type and expiration date.
8. If the kit type is valid and the kit is not expired, open the kit and remove the kit contents.
9. Place the specimen collection tray on a flat surface. Lay out the materials needed for the collection.
10. Place the TM label on the Biospecimen Transmittal Form. If using the back-up form, place the DC label in the appropriate place on the form.
11. Follow the prompts in FACE to guide the discussion with the participant. Ask the participant to sit in a place that allows for easy access to the back of the head for cutting the hair.

12. Cleanse your hands and put on gloves.
13. Be sure the adhesive label for taping the hair specimen (HR01 label) is within easy reach when collecting the specimen.
14. Wipe the stainless steel scissor blades and the ruler with an alcohol wipe and allow them to air dry.
15. If the hair is long, use the comb to partition the hair between the ears on the back of the head below the midline. This is the occipital area at the rear base of the head (see Exhibit 5-1).

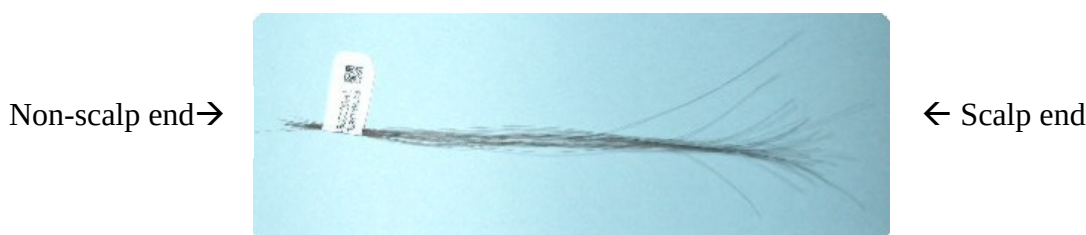
Exhibit 5-1. Location of occipital area



16. If necessary, fasten the hair above the ears out of the way with the hair clip provided in the kit.
17. Use the ruler to measure the length of the hair. If the hair is less than 1 cm in length, do not collect a hair specimen.
18. Grasp a minimum of 20 strands of hair. Pull the hair tight, and label and cut the hair as follows:
 - If the hair is ≤ 3 cm in length, cut the hair as close to the scalp as possible and drop it in the prelabeled collection bag without taping it together.
 - If the hair is 3–12 cm in length:
 1. Wrap the adhesive label around the hair *toward the non-scalp end of the hair* so that all the hairs are taped together, as shown in Exhibit 5-2. Be sure to place the adhesive label as far as possible from the scalp end of the hair. The scalp end of the hair will be used for analysis.
 2. Make one cut as close to the scalp as possible to obtain the specimen.
 - If the hair is > 12 cm in length:
 1. Using the ruler, measure 12 cm from the scalp and make a first cut at 12 cm from the scalp. Discard this hair.

2. Holding the remaining hair, wrap the adhesive label around the hair *toward the non-scalp end of the hair* so that all the hairs are taped together, as shown in Exhibit 5-2. Be sure to place the adhesive label as far as possible from the scalp end of the hair. The scalp end of the hair will be used for analysis.
 3. Make a second cut as close to the scalp as possible to obtain a specimen that is 12 cm in length.
- Cut from an additional location in the occipital area if necessary to collect a sufficient sample. If hair was obtained from more than one site in the occipital area, follow the instructions above to tape the hair from the additional cut, using the EX01 label provided in the kit.

Exhibit 5-2. Hair specimen collection



19. Place the taped hair specimen (or both specimens if two cuts were made) into the prelabeled plastic collection bag provided in the kit and seal the bag.

5.1.3 Documenting Adult Hair Collection

1. Record the hair specimen collection status in FACE and wand the bar code label on the specimen collection bag.
2. Place the collection bag in the insulated transport bag.
3. Record any comments pertaining to the hair specimen collection in FACE (up to a 250-character limit) or on the hard copy back-up Adult Hair Data Collection Form. If using the back-up form, ensure the form is complete.
4. Record the hair specimen collection status on the Biospecimen Transmittal Form.
5. If an incident occurs during the hair collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

5.1.4 Clean-Up Procedures

1. Discard any remaining hair and other used supplies in the biohazard waste bag.
2. Wipe the ruler and scissors with a new alcohol wipe. The participant may keep the comb and hairclip if desired.
3. After completing the hair collection procedures, make sure the work area is clean and reusable.
4. If the hair specimen is the last biospecimen collected at the visit, remove the computer keyboard cover, clean the work area, and pack all collection supplies.
5. After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands. Be sure to pack the biohazard waste bag appropriately for transport so that it is not visible upon leaving the site of data collection. The biohazard waste bag must be disposed of properly at the Specimen Processing and Shipping Center (SPSC).

5.1.5 Transport Procedures

Hair specimens will be transported to the SPSC in the insulated transport bag.

1. Ensure the Biospecimen Transmittal Form is complete. If this is the last biospecimen type collected at the visit, place the completed form in the zippered document pouch inside the lid of the transport cooler along with any unused labels.
2. Secure the plastic collection bag containing the hair specimen in the insulated transport bag for transport.

Part 2

Appendix 5-A

Adult Hair Data Collection Form

Appendix 5-A Adult Hair Data Collection Form

	National Children's Study Adult Hair Data Collection Form	P1, T1-Father, T3 1 st , T3 Prior

(Only for use when FACE is not available)

Part A: Administrative	
Date: / / m m d d y y y y	Place Adult Hair Collection DC Label Here
Data collector ID:	
Visit location: ☐ Home ☐ Clinic/Office	
Part B: Hair Collection Questions	
DATA COLLECTOR: IF THE RESPONSE TO QUESTION 1 IS "NO", DO NOT COLLECT A HAIR SAMPLE	
1) Are you able to provide a sample of your natural hair today? <i>¿Puede dar una muestra de su pelo natural hoy?</i> ☐ Yes ☐ No (Go to Part C) ☐ Refused ☐ Don't know	
2) Has your hair been treated with hair dye or hair color within the last 3 months? <i>¿Ha usado tintes o colorantes en el pelo en los últimos 3 meses?</i> ☐ Refused ☐ Don't know ☐ Refused ☐ Don't know	
3) Has your hair been given a permanent or treated with a hair straightener within the last 3 months? <i>¿Se ha hecho una permanente o un tratamiento con un producto para alisar el pelo en los últimos 3 meses?</i> ☐ Yes ☐ No ☐ Refused ☐ Don't know	
4) Have you used shampoo or conditioner on your hair in the last 24 hours? <i>¿Ha usado champú o acondicionador en el pelo en las últimas 24 horas?</i> ☐ Yes ☐ No (Go to Q6) ☐ Refused (Go to Q6) ☐ Don't know (Go to Q6)	
5) Have you used any of the following dandruff shampoos or conditioners in the last 24 hours? <i>¿Ha usado alguno de los siguientes champúes o acondicionadores contra la caspa en las últimas 24 horas?</i> ☐ Head and Shoulders ☐ Denorex ☐ Dermarest ☐ Selsun Blue ☐ Other—specify / Otro—especifique: _____ ☐ Refused ☐ Don't know	
6) Have you used other hair care products in the last 24 hours? <i>¿Ha usado otros productos para el cuidado del pelo en las últimas 24 horas?</i> ☐ Yes, specify _____ ☐ No ☐ Refused ☐ Don't know	

HAIRDC01.00DU

Subject LabelAssignment ID,
Subject ID, Event Type

Appendix 5-A **Adult Hair Data Collection Form (continued)**

Part C: Hair Collection	
Collection status: (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for not done/partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient	☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other—specify: _____
HR01 Hair Collection Bag	Collection status (Mark one.) ☐ Collected ☐ Not collected Reason for not collected (Mark one.) ☐ Quantity not sufficient ☐ Hair weave/Wig ☐ Other—specify _____ ☐ Refused
Location of hair collection:	☒ Back of neck ☐ Multiple sites
Comments: 	

Data collector ID for field QC

Date entered into FACE: mmddyyyy
ID of Data collector who entered the form:

Part 2

Appendix 5-B

Adult Hair Data Collection Form: Field-by-Field Instructions

Appendix 5-B.
Adult Hair Data Collection Form: Field-by-Field Instructions

ADULT HAIR DATA COLLECTION FORM FIELD-BY-FIELD INSTRUCTIONS

This form is only to be used when the Field-Administration Collection Environment (FACE) is not available and should be completed by the biospecimen data collector at the P1 mother, T1 father and T3 mother data collection visits. Instructions for completing each item on the form are provided.

After Completing the Form

- Within 2 hours of the visit, the form should be checked to make sure that it is accurate, legible, and complete.
- Make sure that all of the appropriate boxes are completely filled. Comments should be limited to the area provided.
- The biospecimen data collector who checks the form for completion should write her data collector identification number (ID) in the space provided at the bottom of the last page.
- The data collector who enters the data in FACE should record the date of data entry and her data collector ID in the spaces provided on the last page of the form.



National Children's Study Adult Hair Data Collection Form

P1, T1-Father, T3 1st, T3 Prior

(Only for use when FACE is not available)

Part A: Administrative	
Date: / / m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office	Place Adult Hair Collection DC Label Here
Part B: Hair Collection Questions	
DATA COLLECTOR: IF THE RESPONSE TO QUESTION 1 IS "NO", DO NOT COLLECT A HAIR SAMPLE	
1) Are you able to provide a sample of your natural hair today? <i>¿Puede dar una muestra de su pelo natural hoy?</i> ☐ Yes ☐ No (Go to Part C) ☐ Refused ☐ Don't know	
2) Has your hair been treated with hair dye or hair color within the last 3 months? <i>¿Ha usado tintes o colorantes en el pelo en los últimos 3 meses?</i> ☐ Refused ☐ Don't know ☐ Refused ☐ Don't know	
3) Has your hair been given a permanent or treated with a hair straightener within the last 3 months? <i>¿Se ha hecho una permanente o un tratamiento con un producto para alisar el pelo en los últimos 3 meses?</i> ☐ Yes ☐ No ☐ Refused ☐ Don't know	
4) Have you used shampoo or conditioner on your hair in the last 24 hours? <i>¿Ha usado champú o acondicionador en el pelo en las últimas 24 horas?</i> ☐ Yes ☐ No (Go to Q6) ☐ Refused (Go to Q6) ☐ Don't know (Go to Q6)	
5) Have you used any of the following dandruff shampoos or conditioners in the last 24 hours? <i>¿Ha usado alguno de los siguientes champúes o acondicionadores contra la caspa en las últimas 24 horas?</i> ☐ Head and Shoulders ☐ Denorex ☐ Dermarest ☐ Selsun Blue ☐ Other—specify / Otro—especifique: _____ ☐ Refused ☐ Don't know	
6) Have you used other hair care products in the last 24 hours? <i>¿Ha usado otros productos para el cuidado del pelo en las últimas 24 horas?</i> ☐ Yes, specify _____ ☐ No ☐ Refused ☐ Don't know	

HAIRDC01.00DU

Subject Label

Assignment ID,
Subject ID, Event Type

Part A: Administrative Section

- *Date*—Record the date that the adult hair collection was completed or attempted. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002). The date of collection should not be recorded in advance of the participant’s study visit.
- *Data Collector ID*—Record the data collector ID of the person who completes the form.
- *Visit location*—Mark the box corresponding to the location of the visit.
- *Kit Label*— Open the Adult Hair Collection Kit and place the DC label in the appropriate place on the form.

Part B: Hair Collection Questions

1. *Are you able to provide a sample of your natural hair today?*

Mark the box that corresponds to the participant’s response. If the participant refuses to answer or does not know, mark the corresponding box. If the participant’s response is “No,” the participant is excluded from giving a hair sample. Go to Part C of the form and mark the box that corresponds to “Not done.” Also mark the box that corresponds to “Quantity not sufficient” as the reason the collection was “not done/partial.”

2. *Has your hair been treated with a hair dye or hair color within the last 3 months?*

Mark the box that corresponds to the participant’s response. If the participant refuses to answer or does not know, mark the corresponding box. This includes semi-permanent dyes and highlights.

3. *Has your hair been given a permanent or treated with a hair straightener within the last 3 months?*

Mark the box that corresponds to the participant’s response. If the participant refuses to answer or does not know, mark the corresponding box.

4. *Have you used shampoo or conditioner on your hair in the last 24 hours?*

Mark the box that corresponds to the participant’s response. If the participant answers “No,” mark the corresponding box and skip to Question 6. If the participant refuses to answer or does not know, mark the corresponding box and skip to Question 6.



National Children's Study Adult Hair Data Collection Form

P1, T1-Father, T3 1st, T3 Prior

(Only for use when FACE is not available)

Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office	Place Adult Hair Collection DC Label Here
Part B: Hair Collection Questions	
DATA COLLECTOR: IF THE RESPONSE TO QUESTION 1 IS "NO", DO NOT COLLECT A HAIR SAMPLE	
1) Are you able to provide a sample of your natural hair today? <i>¿Puede dar una muestra de su pelo natural hoy?</i> ☐ Yes ☐ No (Go to Part C) ☐ Refused ☐ Don't know	
2) Has your hair been treated with hair dye or hair color within the last 3 months? <i>¿Ha usado tintes o colorantes en el pelo en los últimos 3 meses?</i> ☐ Refused ☐ Don't know ☐ Refused ☐ Don't know	
3) Has your hair been given a permanent or treated with a hair straightener within the last 3 months? <i>¿Se ha hecho una permanente o un tratamiento con un producto para alisar el pelo en los últimos 3 meses?</i> ☐ Yes ☐ No ☐ Refused ☐ Don't know	
4) Have you used shampoo or conditioner on your hair in the last 24 hours? <i>¿Ha usado champú o acondicionador en el pelo en las últimas 24 horas?</i> ☐ Yes ☐ No (Go to Q6) ☐ Refused (Go to Q6) ☐ Don't know (Go to Q6)	
5) Have you used any of the following dandruff shampoos or conditioners in the last 24 hours? <i>¿Ha usado alguno de los siguientes champús o acondicionadores contra la caspa en las últimas 24 horas?</i> ☐ Head and Shoulders ☐ Denorex ☐ Dermarest ☐ Selsun Blue ☐ Other—specify / Otro—especifique: _____ ☐ Refused ☐ Don't know	
6) Have you used other hair care products in the last 24 hours? <i>¿Ha usado otros productos para el cuidado del pelo en las últimas 24 horas?</i> ☐ Yes, specify _____ ☐ No ☐ Refused ☐ Don't know	

HAIRDC01.00DU

Subject Label

Assignment ID,
Subject ID, Event Type

5. *Have you used any of the following dandruff shampoos or conditioners in the last 24 hours?*

Read each of the first five choices (Head and Shoulders, Denorex, Demarest, Selsun Blue, Other) to the participant. Mark the box that corresponds to his or her response. If the participant's response is "Other," mark the corresponding box and specify the shampoo or conditioner used in the space provided. If the participant refuses to answer or does not know, mark the corresponding box.

6. *Have you used any other hair care products including styling products in the past 24 hours?*

Mark the box that corresponds to the participant's response. If the participant's response is "Yes," ask him or her to specify the hair product that was used. Record the hair product specified in the space provided. If the participant refuses to answer or does not know, mark the corresponding box. This includes styling products such as mousse, gel, and hair spray.

Subject Label

Obtain a subject label from the visit coordinator's biospecimen folder and affix it to the bottom right corner of the data collection form.

Part C: Hair Collection	
Collection status: (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for not done/partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient	☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other—specify: _____
HR01 Hair Collection Bag	Collection status (Mark one.) ☐ Collected ☐ Not collected Reason for not collected (Mark one.) ☐ Quantity not sufficient ☐ Hair weave/Wig ☐ Other—specify _____ ☐ Refused
Location of hair collection: ☐ Back of neck ☐ Multiple sites	
Comments: _____ _____ _____	

Data collector ID for field QC

Date entered into FACE:

				2	0		
m	m	d	d	y	y	y	y

ID of Data collector who entered the form:

Part C: Adult Hair Collection

- *Collection Status* (Mark one)—Mark the box that corresponds to the status of the adult hair collection.
 - “*Complete*”—Mark this box to indicate that the participant was able to provide at least 20 strands of his/her own hair that is at least 1cm in length.
 - “*Partial complete*”—Mark this box to indicate that the participant was able to provide fewer than 20 strands of his or her own hair that is at least 1cm in length.
 - “*Not done*”—Mark this box to indicate that the participant did not provide a hair specimen.
- *Reason for Not Done/Partial* (Mark one)—Mark the box that corresponds to the choice that best explains why the specimen was not collected or was partially collected.
 - “Participant Refusal”—Mark this box to indicate that the participant was unwilling to provide a hair specimen.
 - “Participant Ill/Emergency”—Mark this box to indicate that the participant became ill during the visit and was unable to provide a hair specimen. This box also is marked if the participant has an emergency that requires termination of the visit prior to the collection of the hair specimen. Record a brief description of the nature of the emergency or illness in the Comments section in Part C.
 - “No Time”—Mark this box to indicate that a hair specimen was not collected because the participant did not have time to complete the visit.
 - “Safety exclusion”—This code does not apply to this biospecimen collection activity.
 - “Physical limitations”—Mark this box to indicate that the participant has a physical limitation that prevents him or her from providing a hair specimen. Record a brief description of the type of physical limitation in the Comments section in Part C.
 - “Quantity not sufficient”—Mark this box to indicate that the participant does not have a sufficient amount of hair to provide a hair specimen or that the quantity was less than 20 strands of hair.
 - “Defective collection kit”—Mark this box to indicate that a hair specimen was not collected because of a problem with the Adult Hair Collection Kit. This includes not having the appropriate supplies available in the home or clinic.

Part C: Hair Collection	
Collection status: (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for not done/partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient	☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other—specify: _____
HR01 Hair Collection Bag	Collection status (Mark one.) ☐ Collected ☐ Not collected Reason for not collected (Mark one.) ☐ Quantity not sufficient ☐ Hair weave/Wig ☐ Other—specify _____ ☐ Refused
Location of hair collection: ☐ Back of neck ☐ Multiple sites	
Comments: _____ _____ _____	

Data collector ID for field QC

Date entered into FACE: //20
m m d d y y y y

ID of Data collector who entered the form:

- “Language issue, Spanish”—Mark this box to indicate that a hair specimen was not collected because the biospecimen data collector does not speak Spanish well enough to communicate the necessary instructions to the participant.
- “Language issue, non-Spanish”—Mark this box to indicate that a hair specimen was not collected because the biospecimen data collector is unable to communicate the necessary instructions to the participant.
- “Cognitive disability”—Mark this box to indicate that a hair specimen was not collected because the participant is cognitively or developmentally impaired and therefore unable to understand the specimen collection instructions.
- “Parent/guardian refusal”—Mark this box to indicate that the participant is younger than 18 years old and his or her parent or guardian refused to allow her to provide a hair specimen.
- “Other—specify”—Mark this box to indicate that a hair specimen was not collected for a reason other than those listed; specify the reason in the space provided.
- *Collection Status* (Mark one)—Mark the box that corresponds to the status of the adult hair collection.

 - “Collected”—Mark this box to indicate that the participant was able to provide at least 20 strands of his or her own hair that is at least 1cm in length.
 - “Not Collected”—Mark this box to indicate that the participant did not provide a hair specimen.
- *Reason for Not Collected* (Mark one)—Mark the box that corresponds to the reason a hair specimen was not collected.

 - “Quantity not sufficient”—Mark this box to indicate that the participant does not have a sufficient amount of hair to provide a hair specimen or that the quantity was less than 20 strands of hair.
 - “Hair weave/wig”—Mark this box to indicate that the participant has a hair weave or wears a wig, and is therefore unable to provide a sample of his/her own hair.
 - “Other—specify”—Mark this box to indicate that a hair specimen was not collected for a reason other than those listed; specify the reason in the space provided.
 - “Refused”—Mark this box to indicate that the participant was unwilling to provide a hair specimen.

Part C: Hair Collection	
Collection status: (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for not done/partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient	☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other—specify: _____
HR01 Hair Collection Bag	Collection status (Mark one.) ☐ Collected ☐ Not collected Reason for not collected (Mark one.) ☐ Quantity not sufficient ☐ Hair weave/Wig ☐ Other—specify _____ ☐ Refused
Location of hair collection: ☐ Back of neck ☐ Multiple sites	
Comments: _____ _____ _____	

Data collector ID for field QC

Date entered into FACE: //20
m m d d y y y y

ID of Data collector who entered the form:

- *Location of hair collection*
 - “Back of neck”—Mark this box to indicate that the hair specimen was obtained from one site in the occipital area of the head.
 - “Multiple sites”—Mark this box to indicate that the hair specimen was obtained from more than one site in the occipital area of the head.
- *Comments*—Additional comments may include reasons that a hair specimen was not collected or problems encountered during the collection that may affect analysis. Problems with post-collection processing also should be recorded here.

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Toenail Collection and Transport Procedures

6.1 Toenails

Toenail specimens will be self-collected by the study participant at the T3 mother and T1 father study events. Toenail specimens will be analyzed to obtain information about exposure to metals.

6.1.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to collect and transport toenail specimens:

- Toenail Collection Kit (kit contents are in the next list)
- Specimen collection tray
- Nail polish remover pads
- Disposable laboratory coat
- Gloves
- Hand sanitizer
- Biohazard waste bag
- Insulated transport bag
- Computer tablet with bar code scanner
- Computer keyboard cover

The Toenail Collection Kit contains the following items:

- Stainless steel toenail clipper
- Alcohol wipe

- 2 paper towels
- Toenail Collection Instructions
- Prelabeled (NL01 label) prescreened plastic specimen collection bag (2"x3")
- One adhesive label for the Biospecimen Transmittal Form (TM label)
- One adhesive label for the hard copy back-up Toenail Data Collection Form (DC label)
- One additional adhesive label for the plastic collection bag (EX01)

The following form is required to collect and transport toenail specimens:

- Event-specific Biospecimen Transmittal Form (see volume Appendices VIII-B through VIII-G for forms and field-by-field instructions).

Toenail collection data will be documented in the Biospecimen instrument in the Field-Administered Collection Environment (FACE). If FACE is not available, the appropriate hard copy back-up Toenail Data Collection Form must be used to document collection data (see Appendices 6-A and 6-B for form and field-by-field instructions). Once the system becomes available, data must be entered in the system from the back-up form.

6.1.2 Step-by-Step Procedures for Toenail Specimen Collection

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following procedures are to be used for toenail collection. For general guidance on how to use FACE for data collection activities, refer to the FACE User Guide. For detailed question-by-question specifications for administering the Biospecimen instrument, refer to the appropriate section in volume Appendix VIII-A.

If the study participant does not have toenails of sufficient length to provide a specimen, record the appropriate reason for not collecting the toenail specimen in FACE or on the hard copy back-up form. A nail specimen should not be obtained from fingernails.

1. Put on a laboratory coat.

2. Place the computer keyboard cover on the keyboard if you have not already done so. This will protect the keyboard from contamination when handling specimens during the visit. One keyboard cover will be used for the duration of the biospecimen collection.
3. Launch the Biospecimen instrument from FACE on the tablet. If FACE is not available, the hard copy back-up Toenail Data Collection Form should be used. If using the form, place an extra Subject label (from the visit coordinator's supplies) in the appropriate place on the form.
4. Read the toenail specimen collection questions to the study participant from FACE and enter the responses. If FACE is not available, read the collection questions in Part B of the hard copy back-up Toenail Data Collection Form and record the responses.
5. Locate the Toenail Collection Kit and event-specific Biospecimen Transmittal Form.
6. Wand the collection kit bar code into FACE and validate the kit type and expiration date.
7. If the kit type is valid and the kit is not expired, open the kit and remove the kit contents.
8. Place the specimen collection tray on a flat surface. Lay out the materials needed for the collection.
9. Place the TM label on the Biospecimen Transmittal Form. If using the back-up form, place the DC label in the appropriate place on the form.
10. Instruct the study participant in the toenail self-collection procedures using the Toenail Collection Instructions (see Appendix 6-C). The participant may refer to the collection instructions when collecting the specimen.
11. Cleanse your hands and put on gloves.
12. Wipe the toenail clippers with an alcohol wipe and allow them to air dry.
13. Give the study participant the toenail clippers, the paper towels, the prelabeled specimen collection bag, and the nail polish remover pads if necessary.
14. It is not required to observe the study participant collecting the specimen. The participant may collect the specimen in private if this is more comfortable.

Please note that if the study participant cannot comfortably collect a toenail specimen because of a physical limitation, the data collector should not attempt to obtain the specimen by clipping the toenails of the participant. The toenail specimen must be self-collected only.

When the study participant has finished collecting the specimen,

1. Thank the participant for providing the specimen and ask him or her to place it on the specimen collection tray, and
2. Check to make sure the specimen collection bag is sealed.

6.1.3 Documenting Toenail Collection

1. Record the toenail specimen collection status in FACE and wand the bar code label on the specimen collection bag.
2. Place the collection bag in the insulated transport bag.
3. Read the toenail specimen post-collection question to the study participant from FACE and enter the response. If FACE is not available, read the post-collection question in Part B of the hard copy back-up Toenail Data Collection Form and record the response.
4. Record any comments pertaining to the toenail specimen collection in FACE (up to a 250-character limit) or on the hard copy back-up Toenail Data Collection Form. If using the back-up form, ensure the form is complete.
5. Record the toenail specimen collection status on the Biospecimen Transmittal Form.
6. If an incident occurs during the toenail collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

6.1.4 Clean-Up Procedures

1. Discard any used supplies. The study participant may keep the nail clippers if desired.
2. After completing the toenail collection procedures, make sure the work area is clean and reusable.
3. If the toenail specimen is the last biospecimen collected at the visit, remove the computer keyboard cover, clean the work area, and pack all collection supplies.
4. After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands. Be sure to pack the biohazard waste

bag appropriately for transport so that it is not visible upon leaving the site of data collection. The biohazard waste bag must be disposed of properly at the Specimen Processing and Shipping Center (SPSC).

6.1.5 Transport Procedures

Toenail specimens will be transported to the SPSC in the insulated transport bag.

1. Ensure the Biospecimen Transmittal Form is complete. If this is the last biospecimen type collected at the visit, place the completed form in the zippered document pouch inside the lid of the transport cooler along with any unused labels.
2. Secure the specimen collection bag containing the toenail specimen in the insulated transport bag for transport.

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Part 2

Appendix 6-A

Toenail Data Collection Form

Appendix 6-A

Toenail Data Collection Form

	National Children's Study Toenail Data Collection Form	T1-Father, T3 1 st , T3 Prior

(Only for use when FACE is not available)

Part A: Administrative	
Date: / / m m d d y y y y	Place Toenail Collection DC Label Here
Data collector ID:	
Visit location: ☐ Home ☐ Clinic/Office	
Part B: Toenail Collection Questions	
1) Do you use toenail polish? ☐ Yes ☐ No (Go to Q3) <i>¿Se pinta las uñas de los pies con esmalte?</i> ☐ Refused (Go to Q3) ☐ Don't know (Go to Q3)	
2) When was the last time you used toenail polish? (Mark one.) <i>¿Cuándo fue la última vez que se pintó las uñas de los pies con esmalte? (Marque una opción.)</i>	
☐ Within the last week/ <i>La semana pasada</i> ☐ Within the last month/ <i>El mes pasado</i> ☐ Within the last 3 months/ <i>En los últimos 3 meses</i> ☐ Within the last 6 months/ <i>En los últimos 6 meses</i>	☐ Within the last year/ <i>El año pasado</i> ☐ More than 1 year ago/ <i>Hace más de un año</i> ☐ Refused ☐ Don't know
3) Have you ever been treated either orally or topically with a medication for toenail fungus? <i>¿Ha usado medicamentos por vía oral o de uso local para tratarse los hongos de las uñas de los pies?</i>	
☐ Yes ☐ No (Go to Part C) ☐ Refused (Go to Part C) ☐ Don't know (Go to Part C)	
4) When was the last time you used any antifungal treatment? (Mark one.) <i>¿Cuándo fue la última vez que usó un tratamiento contra los hongos? (Marque una opción.)</i>	
☐ Within the last week/ <i>La semana pasada</i> ☐ Within the last month/ <i>El mes pasado</i> ☐ Within the last 3 months/ <i>En los últimos 3 meses</i> ☐ Within the last 6 months/ <i>En los últimos 6 meses</i>	☐ Within the last year/ <i>El año pasado</i> ☐ More than 1 year ago/ <i>Hace más de un año</i> ☐ Refused ☐ Don't know

NAILID01.00DU

Subject LabelAssignment ID,
Subject ID, Event Type

Appendix 6-A

Toenail Data Collection Form (continued)

Part C: Toenail Collection	
Collection status: (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for not done/partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient	☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other—specify: _____
NL01 Toenail Collection Bag	Collection status (Mark one.) ☐ Collected ☐ Not collected Reason for not collected (Mark one.) ☐ Quantity not sufficient ☐ Other—specify _____ ☐ Refused
From how many toes did you collect toenail clippings? ¿De cuántos dedos tomó muestras de recortes de uñas? □□	
Comments: _____ _____	

Data collector ID for field QC □□□□□□□□

Date entered into FACE: □□/□□/20□□ mmddyyyy ID of Data collector who entered the form: □□□□□□□□

Part 2

Appendix 6-B

Toenail Data Collection Form: Field-by-Field Instructions

Appendix 6-B.
Toenail Data Collection Form: Field-by-Field Instructions

TOENAIL DATA COLLECTION FORM: FIELD-BY-FIELD INSTRUCTIONS

This form is only to be used when the Field-Administration Collection Environment (FACE) is not available and should be completed by the biospecimen data collector at the T1 father and T3 mother data collection visits. Instructions for completing each item on the form are provided.

After Completing the Form

- Within 2 hours of the visit, the form should be checked to make sure that it is accurate, legible, and complete.
- Make sure that all of the appropriate boxes are completely filled. Comments should be limited to the area provided.
- The biospecimen data collector who checks the form for completion should write her data collector ID in the space provided at the bottom of the last page.
- The data collector who enters the data in FACE should record the date of data entry and her data collector ID in the spaces provided on the last page of the form.



National Children's Study Toenail Data Collection Form

T1-Father, T3 1st, T3 Prior

(Only for use when FACE is not available)

Part A: Administrative									
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office	Place Toenail Collection DC Label Here								
Part B: Toenail Collection Questions									
1) Do you use toenail polish? ☐ Yes ☐ No (Go to Q3) <i>¿Se pinta las uñas de los pies con esmalte?</i> ☐ Refused (Go to Q3) ☐ Don't know (Go to Q3)									
2) When was the last time you used toenail polish? (Mark one.) <i>¿Cuándo fue la última vez que se pintó las uñas de los pies con esmalte? (Marque una opción.)</i> <table style="width: 100%;"> <tr> <td>☐ Within the last week/ <i>La semana pasada</i></td> <td>☐ Within the last year/ <i>El año pasado</i></td> </tr> <tr> <td>☐ Within the last month/ <i>El mes pasado</i></td> <td>☐ More than 1 year ago/ <i>Hace más de un año</i></td> </tr> <tr> <td>☐ Within the last 3 months/ <i>En los últimos 3 meses</i></td> <td>☐ Refused</td> </tr> <tr> <td>☐ Within the last 6 months/ <i>En los últimos 6 meses</i></td> <td>☐ Don't know</td> </tr> </table>		☐ Within the last week/ <i>La semana pasada</i>	☐ Within the last year/ <i>El año pasado</i>	☐ Within the last month/ <i>El mes pasado</i>	☐ More than 1 year ago/ <i>Hace más de un año</i>	☐ Within the last 3 months/ <i>En los últimos 3 meses</i>	☐ Refused	☐ Within the last 6 months/ <i>En los últimos 6 meses</i>	☐ Don't know
☐ Within the last week/ <i>La semana pasada</i>	☐ Within the last year/ <i>El año pasado</i>								
☐ Within the last month/ <i>El mes pasado</i>	☐ More than 1 year ago/ <i>Hace más de un año</i>								
☐ Within the last 3 months/ <i>En los últimos 3 meses</i>	☐ Refused								
☐ Within the last 6 months/ <i>En los últimos 6 meses</i>	☐ Don't know								
3) Have you ever been treated either orally or topically with a medication for toenail fungus? <i>¿Ha usado medicamentos por vía oral o de uso local para tratarse los hongos de las uñas de los pies?</i> <table style="width: 100%;"> <tr> <td>☐ Yes</td> <td>☐ No (Go to Part C)</td> </tr> <tr> <td>☐ Refused (Go to Part C)</td> <td>☐ Don't know (Go to Part C)</td> </tr> </table>		☐ Yes	☐ No (Go to Part C)	☐ Refused (Go to Part C)	☐ Don't know (Go to Part C)				
☐ Yes	☐ No (Go to Part C)								
☐ Refused (Go to Part C)	☐ Don't know (Go to Part C)								
4) When was the last time you used any antifungal treatment? (Mark one.) <i>¿Cuándo fue la última vez que usó un tratamiento contra los hongos? (Marque una opción.)</i> <table style="width: 100%;"> <tr> <td>☐ Within the last week/ <i>La semana pasada</i></td> <td>☐ Within the last year/ <i>El año pasado</i></td> </tr> <tr> <td>☐ Within the last month/ <i>El mes pasado</i></td> <td>☐ More than 1 year ago/ <i>Hace más de un año</i></td> </tr> <tr> <td>☐ Within the last 3 months/ <i>En los últimos 3 meses</i></td> <td>☐ Refused</td> </tr> <tr> <td>☐ Within the last 6 months/ <i>En los últimos 6 meses</i></td> <td>☐ Don't know</td> </tr> </table>		☐ Within the last week/ <i>La semana pasada</i>	☐ Within the last year/ <i>El año pasado</i>	☐ Within the last month/ <i>El mes pasado</i>	☐ More than 1 year ago/ <i>Hace más de un año</i>	☐ Within the last 3 months/ <i>En los últimos 3 meses</i>	☐ Refused	☐ Within the last 6 months/ <i>En los últimos 6 meses</i>	☐ Don't know
☐ Within the last week/ <i>La semana pasada</i>	☐ Within the last year/ <i>El año pasado</i>								
☐ Within the last month/ <i>El mes pasado</i>	☐ More than 1 year ago/ <i>Hace más de un año</i>								
☐ Within the last 3 months/ <i>En los últimos 3 meses</i>	☐ Refused								
☐ Within the last 6 months/ <i>En los últimos 6 meses</i>	☐ Don't know								

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Subject Label

Assignment ID,
Subject ID, Event Type

Part A: Administrative Section

- *Date*—Record the date that the toenail collection was completed or attempted. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002). The date of collection should not be recorded in advance of the participant’s study visit.
- *Data Collector ID*—Record the data collector ID of the person who completes the form.
- *Visit Location*—Mark the box corresponding to the location of the visit.
- *Kit Label*—Open the Toenail Collection Kit and place the “DC” label in the appropriate place on the form.

Part B: Toenail Collection Questions

1. *Do you use toenail polish?*

Mark the box that corresponds to the study participant’s response. If the participant refuses to answer, does not know, or responds “No,” mark the corresponding box and go to question 3. If the participant’s response is “Yes,” continue to question 2.

2. *When was the last time you used toenail polish?*

Read each of the first six choices to the study participant. Mark the box that corresponds to the participant’s response. If the participant refuses to answer or does not know, mark the corresponding box.

3. *Have you ever been treated either orally or topically with a medication for toenail fungus?*

Mark the box that corresponds to the study participant’s response. If the participant refuses to answer, does not know, or responds “No,” mark the corresponding box and go to Part C. If the participant’s response is “Yes,” continue to question 4.

4. *When was the last time you used any antifungal treatment? (select one)*

Read each of the first six choices to the study participant. Mark the box that corresponds to the participant’s response. If the participant refuses to answer or does not know, mark the corresponding box.

Subject Label

Obtain a subject label from the visit coordinator’s biospecimen folder and affix it to the bottom right corner of the data collection form.

Part C: Toenail Collection	
Collection status: (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for not done/partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient	☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other—specify: _____
NL01 Toenail Collection Bag	Collection status (Mark one.) ☐ Collected ☐ Not collected Reason for not collected (Mark one.) ☐ Quantity not sufficient ☐ Other—specify _____ ☐ Refused
From how many toes did you collect toenail clippings? <i>¿De cuántos dedos tomó muestras de recortes de uñas?</i>	
Comments: _____ _____ _____	

Data collector ID for field QC

Date entered into FACE: / /

m m d d y y y y

ID of Data collector who entered the form:

Part C: Toenail Collection

- *Collection Status* (Mark one)—Mark the box that corresponds to the status of the toenail collection.
 - “Complete”—Mark this box to indicate that the participant was able to provide toenail clippings.
 - “Partial Complete”—Mark this box to indicate that the participant answered the collection questions but did not provide any toenail clippings.
 - “Not done”—Mark this box to indicate that the participant did not answer the collection questions or provide any toenail clippings.
- *Reason for Not Done/Partial* (Mark one)—Mark the box that corresponds to the choice that best explains why the specimen was not collected or was partially collected.
 - “Participant Refusal”—Mark this box to indicate that the participant was unwilling to provide a toenail specimen.
 - “Participant Ill/Emergency”—Mark this box to indicate that the participant became ill during the visit and was unable to provide a toenail specimen. This box also is marked if the participant has an emergency that required termination of the visit prior to the collection of the toenail specimen. Record a brief description of the nature of the emergency or illness in the Comments section in Part C.
 - “No Time”—Mark this box to indicate that a toenail specimen was not collected because the participant did not have time to complete the visit.
 - “Safety exclusion”—This code does not apply to this biospecimen collection activity.
 - “Physical limitations”—Mark this box to indicate that the participant has a physical limitation that prevented him or her from providing a toenail specimen. Record a brief description of the type of physical limitation in the Comments section in Part C.
 - “Quantity not sufficient”—Mark this box to indicate that the participant does not have toenails of sufficient length to provide a toenail specimen.
 - “Defective collection kit”—Mark this box to indicate that a toenail specimen was not collected because of a problem with the Toenail Collection Kit. This includes not having the appropriate supplies available in the home or clinic.

Part C: Toenail Collection	
Collection status: (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for not done/partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient	☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other—specify: _____
NL01 Toenail Collection Bag	Collection status (Mark one.) ☐ Collected ☐ Not collected Reason for not collected (Mark one.) ☐ Quantity not sufficient ☐ Other—specify _____ ☐ Refused
From how many toes did you collect toenail clippings? <i>¿De cuántos dedos tomó muestras de recortes de uñas?</i>	
Comments: _____ _____ _____	

Data collector ID for field QC

Date entered into FACE: / / 2 0

m m d d y y y y

ID of Data collector who entered the form:

- “Language issue, Spanish”—Mark this box to indicate that a toenail specimen was not collected because the biospecimen data collector does not speak Spanish well enough to communicate the necessary instructions to the participant.
- “Language issue, non-Spanish”—Mark this box to indicate that a toenail specimen was not collected because the biospecimen data collector is unable to communicate the necessary instructions to the participant.
- “Cognitive disability”—Mark this box to indicate that a toenail specimen was not collected because the participant is cognitively or developmentally impaired and therefore unable to understand the specimen collection instructions.
- “Parent/guardian refusal”—Mark this box to indicate that the participant is younger than 18 years old and his or her parent or guardian refused to allow her to provide a toenail specimen.
- “Other—specify”—Mark this box to indicate that a toenail specimen was not collected for a reason other than those listed; specify the reason in the space provided.
- *Collection Status (Mark one)*—Mark the box that corresponds to the status of the toenail collection.
 - “Collected”—Mark this box to indicate that the participant was able to provide a toenail specimen.
 - “Not Collected”—Mark this box to indicate that the participant did not provide a toenail specimen.
- *Reason for Not Collected (Mark one)*—Mark the box that corresponds to the reason a toenail specimen was not collected.
 - “Quantity not sufficient”—Mark this box to indicate that the participant does not have toenails of sufficient length to provide a toenail specimen.
 - “Other—specify”—Mark this box to indicate that a toenail specimen was not collected for a reason other than those listed; specify the reason in the space provided.
 - “Refused”—Mark this box to indicate that the participant was unwilling to provide a toenail specimen.

Part C: Toenail Collection	
Collection status: (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for not done/partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient	☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other—specify: _____
NL01 Toenail Collection Bag	Collection status (Mark one.) ☐ Collected ☐ Not collected Reason for not collected (Mark one.) ☐ Quantity not sufficient ☐ Other—specify _____ ☐ Refused
From how many toes did you collect toenail clippings? <i>¿De cuántos dedos tomó muestras de recortes de uñas?</i>	
Comments: _____ _____ _____	

Data collector ID for field QC

Date entered into FACE: / / 2 0

m m d d y y y y

ID of Data collector who entered the form:

After the collection

- *From how many toes did you collect toenail clippings?*

Ask the study participant this question after he or she has provided the specimen. Enter the number of toes from which the participant collected toenail clippings in the box provided.

- *Comments*—Additional comments may include reasons that a toenail specimen was not collected or problems encountered during the collection that may affect analysis. Problems with post-collection processing also should be recorded here.

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Part 2

Appendix 6-C

Toenail Collection Instructions

Appendix 6-C. Toenail Collection Instructions

OMB Control Number: 0925-0593
Expiration Date: 09/30/2011

National Children's Study Toenail Collection Instructions

To collect your toenail clippings, please follow the instructions below:

1. If necessary, remove all toenail polish using the nail polish remover pads provided by the data collector.
2. Unfold the paper towels and place them under each foot to catch the toenail clippings.
3. Clip the nails from all toes on both feet. Please do your best to catch the clippings on the paper towels.
4. Clip each toenail to a length that is comfortable to you (such as you would normally do).
5. Place all clippings in the bag provided by the data collector.
6. Give the bag to the data collector.

Thank you for providing your sample!

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

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Appendix 6-C.
Toenail Collection Instructions (continued)

Número de control de OMB: 0925-0593
Fecha de vencimiento: 9/30/2011

Estudio Nacional de los Niños
Instrucciones para tomar los recortes de uñas de los pies

Para tomar sus recortes de uñas, por favor siga las siguientes instrucciones:

1. Si es necesario, quítese el esmalte de las uñas de los pies usando las almohadillas de quitaesmalte que le ha dado el entrevistador.
2. Desdoble las toallas de papel y póngalas debajo de cada pie para que los recortes de uñas caigan sobre éstas.
3. Recorte las uñas de todos los dedos en ambos pies. Por favor trate de que los recortes caigan en las toallas de papel.
4. Recorte cada uña a un largo que no le incomode (como normalmente lo hace).
5. Ponga todos los recortes en la bolsa que le ha dado el entrevistador.
6. Entréguele la bolsa al entrevistador.

¡Gracias por darnos su muestra!

Se calcula que el promedio de tiempo necesario para esta recolección de información es de 4 minutos por entrevista, incluyendo el tiempo para leer las instrucciones, buscar fuentes de información existentes, reunir y mantener la información necesaria y completar y revisar la recolección de información. **Ninguna agencia puede llevar a cabo ni patrocinar una recolección de información y ninguna persona está obligada a responder a dicha recolección a menos que ésta muestre un número de control vigente de OMB.** Envíe los comentarios acerca de este cálculo de tiempo necesario, incluyendo sugerencias sobre cómo reducirlo, o acerca de cualquier otro aspecto de esta recolección de información a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). No devuelva el formulario contestado a esta dirección.

Birth Biospecimen Collection and Transport Procedures

7.1 Overview

Data collection activities for the National Children’s Study (NCS) birth study event will occur during three distinct time periods and will be performed by NCS data collectors, hospital and birthing center staff, and/or home delivery staff. For comprehensive information regarding all NCS activities for the Birth study event, see Part 9 of Volume V. The biospecimen collection components of the Birth study event will occur during two of these time periods—the first is at the time of delivery (B1) and the second is prior to discharge (B2).

At the time of delivery (i.e., B1), the biospecimen collection activities include the following:

- Collection of venous blood from the mother (prior to delivery when possible)
- Collection of cord blood
- Collection of the placenta and umbilical cord.

The total time for completing the B1 biospecimen collection activities is approximately 1 half-hour; however, these collection activities will not occur over a continuous time period. The venous blood collection from the mother preferably will take place prior to delivery (i.e., before labor if a scheduled delivery or during labor if an unscheduled delivery), while the birth specimens (i.e., cord blood, placenta with umbilical cord) will be collected immediately after the birth. The timing of these specimen collection activities will differ depending on the unique circumstances of each birth.

After birth, the following biospecimens will be collected from the infant:

- Two infant blood spot cards
- Meconium.

These biospecimens will be picked up by the NCS data collector at the data collection visit prior to discharge (i.e., B2), which will normally take place within 1–2 days of the B1 visit.

Table 7-1 shows the types of biospecimens collected during the Birth study event by time period.

Table 7-1. Birth biospecimens collected for the NCS

Biospecimen Type	B1 (Predelivery)	B1 (Delivery)	B2
Mother's venous blood	✓		
Cord blood		✓	
Placenta and umbilical cord		✓	
Infant blood spot cards			✓
Meconium			✓

This chapter provides general information about biospecimen collection activities for the Birth study event and procedures for the collection and transport of each type of birth biospecimen. Specimen collection instruction sheets and data collection forms are located in the appendices at the end of the chapter. Procedures in this chapter are presented in the preferred order of collection activities; however, the unique circumstances of each birth may influence the timing of each collection procedure in the field. Study Centers will need to plan carefully for the implementation of these important activities of the NCS. These procedures will be effective only if Study Center staff and clinical personnel understand and adhere to the specified requirements on the participants' presentation for delivery and if the specified supplies are available.

7.1.1 Staffing for Birth Biospecimen Collection

Collection of birth biospecimens will be performed by a combination of hospital and birthing center staff, home delivery staff, and NCS data collectors. The mother's venous blood will be collected by hospital, birthing center, or home delivery staff, or, if needed, by an NCS data collector trained in phlebotomy. It is anticipated that in most situations, the cord blood, placenta and umbilical cord, infant blood spot cards, and meconium will be collected by hospital, birthing center, or home delivery staff for the majority of births that occur (with the exception of infant blood spot cards not being collected for home births). In most cases, the NCS data collector will act in more of a coordination role, instructing and assisting the hospital, birthing center, or home delivery staff with the biospecimen collection activities and picking up the specimens. The NCS data collector is responsible for ensuring that birth specimen data collection forms and

biospecimen transmittal forms are properly labeled and completed and that biospecimens are properly packed for transport to the Specimen Processing and Shipping Center (SPSC).

Hospital and birthing center staff will not be centrally trained or certified by NCS to perform biospecimen collection activities. It is the responsibility of the Study Center to ensure that hospital and birthing center staff are knowledgeable of and instructed in NCS biospecimen collection procedures. Specimen collection instructions are included inside the biospecimen collection kits provided by NCS. Data collectors will receive training to ensure they have a comprehensive understanding of NCS procedures, enabling them to instruct and assist hospital, birthing center, or home delivery staff in the collection procedures.

For minimum staff requirements for the Birth visit biospecimen collection role and the Birth visit biospecimen coordination role, refer to Chapter 4 of Part 1 in this volume.

7.1.2 Consent

Prior to the Birth study event, the study participant will have signed the general consent form indicating her choice to be a part of the National Children's Study, and the Biological and Environmental Sample Collection consent indicating she agrees to biospecimen collection. The Visit Information Sheet (VIS) for the Birth visit, which provides details about the NCS procedures and biospecimen collections for the birth, will have been reviewed with the participant during the T3 event. If the study participant does not agree to specific biospecimen collections, this information should be documented by the Study Center. The Study Center is responsible for establishing procedures with each hospital or birthing center to communicate the necessary information and to ensure that an Authorization to Obtain Bodily Fluids and Tissues form is completed prior to collecting birth biospecimens.

In addition, an Authorization to Obtain Information from Medical Records form must be on file for NCS staff to access information from the participant's medical record. This includes obtaining a copy of the placenta pathology report (if applicable) if the pathology examination is performed at the hospital pathology laboratory. Study Centers should be aware of the possibility that an additional authorization form may be needed in order to obtain pathology records for a placenta that is sent to an outside pathology laboratory (i.e., not affiliated with the hospital).

More detailed information regarding procurement of placenta pathology reports is located in Section 7.4.

See Volume I for detailed information regarding all consent procedures for the Birth event.

7.1.3 Biospecimen Collection Kits

As for all other biospecimens, the NCS provides premade biospecimen collection kits for the standardized collection of birth specimens. There are five types of birth biospecimen collection kits: (1) the Adult Blood Collection Kit- Birth Mother, (2) the Placenta and Umbilical Cord Collection Kit, (3) the Cord Blood Collection Kit, (4) the Infant Blood Spot Collection Kit, and (5) the Meconium Collection Kit. Similar to other types of kits, birth collection kits contain some collection supplies that have been prescreened for contaminants prior to assembly of kits by the manufacturer (e.g., 3mL lavender blood tubes, cord blood collection bags). Therefore, only NCS collection kits must be used when performing collection of birth specimens and supplies may not be substituted (with the exception of the needle used for the mother's venous blood collection, as further described in Section 7.2). As mentioned previously, specimen collection instructions are included inside each kit for collection. Hospital, birthing center, and home delivery staff should use the provided instructions when performing collection activities.

NCS collection kits for birth biospecimens must be available at the birthing site (e.g., hospital, birthing center, or home, if a home birth) at the time of delivery. Study Centers may choose to assemble the birth collection kits as a delivery visit collection bag for each mother by using the tote bags provided by the NCS. Study Centers should work with local hospitals and birthing centers to procure space for storage of the birth kits or assembled delivery visit collection bags. In addition, a plan should be developed to monitor birth kits at each participating facility to ensure that an adequate supply is available and that kits are not expired. If the Study Center cannot make arrangements for a hospital or birthing center to provide storage space, the Study Center should consider other mechanisms to ensure the kits are available for collection, including providing study participants with the kits prior to birth. If the Study Center chooses to provide kits to mothers, a delivery visit collection bag may be provided at the last study-related pregnancy visit before birth (i.e., T3). In this scenario, the mother is asked to bring the bag with her at the time of delivery and to provide it to study staff or attending hospital delivery staff. Study Centers should have procedures in place to provide delivery visit collection bags to mothers who arrive at the birthing site without one. Collection kits also may be checked out to an

on-call data collector prior to the B1 visit. However, this is the least desirable option because the data collector may arrive at the birthing site after delivery in some cases.

7.1.4 Biospecimen Birth Forms

Hard copy biospecimen data collection forms are to be used to document *all* biospecimen collection data for the Birth study event. This is different from other study event types, where the Field-Administered Collection Environment (FACE) is the primary method for documenting collection data and hard copy forms are used for only backup purposes if the system is unavailable. All birth biospecimen data collection forms are Teleforms that should be returned to the Site Office to be scanned for electronic data capture. There are five types of data collection forms specific for birth specimens: (1) the Adult Blood Data Collection Form, (2) the Placenta and Umbilical Cord Data Collection Form, (3) the Cord Blood Data Collection Form (4) the Infant Blood Spot Data Collection Form, and (5) the Meconium Data Collection Form (see Appendices 7-A through 7-N for forms, field-by-field specifications, and instructions). The individual who performs the specimen collection (or the data collector if assisting in the collection) should complete the appropriate form for each specimen type, including placing the appropriate kit label on each form. In the interest of collecting important, quality data while recognizing the busy nature of work in labor and delivery, Study Centers should emphasize to hospital and birthing center staff the importance of completing the following essential data fields on each data collection form:

- Patient name
- Date and time of specimen collection
- Kit label
- Collection status and reason if not collected.

The data collector may complete remaining data fields at the time of specimen pick-up, if needed, and is responsible for ensuring the forms are legible and complete with the appropriate subject labels.

In addition to birth biospecimen collection kits, biospecimen data collection forms must be available at the birthing site for use at the time of specimen collection. As with collection kits, a supply of biospecimen forms should be kept at hospitals and birthing centers whenever possible.



The Study Center should work with each participating facility to implement this procedure in a manner that is most conducive to the facility's storage capabilities and workflow. One option is to keep birth data collection forms inside each delivery visit collection bag for easy access to kits and forms. It is recommended that the data collector always have extra birth data collection forms when arriving to pick up birth specimens in the case that forms are not available.

A Birth Biospecimen Transmittal Form is required for the transport of birth specimens from the birthing site to the SPSC. This form is used to document the collection status of each birth specimen and should be completed by the data collector that picks up the specimens. As with other study events, the form accompanies the birth specimens to the SPSC.

For multiple births, each specimen collected should have a separate data collection form, and specimens from each infant should be accompanied by a separate transmittal form.

7.1.5 Storage of Specimens

After all birth specimens are collected, they should be stored at refrigerated temperature (2–8 °C) within 2 hours of collection. The exceptions to this requirement are infant blood spot cards and placenta tissue specimens that have been fixed by a pathology laboratory. Infant blood spot cards are air dried after collection for 3–4 hours at ambient temperature and are stored ambient at the hospital. After fixation, placental tissue specimens do not require refrigeration and may be stored and transported at ambient temperature. Study Centers should make arrangements with hospitals and birthing centers to store specimens on site at 2–8 °C until they can be picked up by the data collector. The NCS does not provide coolers or refrigerators for this purpose. If it is not possible to store specimens at 2–8 °C within 2 hours of collection using hospital or birthing center equipment, Study Centers should ensure that specimens can be picked up and placed at 2–8 °C in the biospecimen transport cooler within 2 hours of collection.

7.1.6 Multiple Births

In the case of multiple births, additional measures must be taken when implementing biospecimen collection activities for the Birth study event to ensure that birth specimens are collected and labeled properly. Study Centers should anticipate that the following additional specimens may be collected for multiple births: cord blood (one specimen for each infant's



umbilical cord); placenta and umbilical cord (if there are multiple placentas); and two infant blood spot cards and a meconium specimen for each infant. Each specimen will be collected using a separate biospecimen collection kit. As mentioned previously, every specimen collected must have a separate data collection form, and specimens from each infant should be accompanied by a separate transmittal form to the SPSC.

To ensure that all birth data collection forms, biospecimens, and physical measures collected from each NCS child at the birth visits are consistently identified and labeled, it is extremely important that all Study Center birth data collectors use the method outlined below when completing birth visit data collection activities.

- The Site Office will generate the following items prior to each birth study visit (i.e., B1, B2, 1-month pick-up visit):
 - An Appointment Information Sheet (AIS), and
 - Subject labels for each child.

The AIS displays the NCS subject ID (also referred to as the NCS PID on forms or NCS participant ID) that has previously been assigned to each fetus in the NCS Study Management System (SMS).

- For example, ultrasound data for Fetus A is associated with a specific NCS PID; ultrasound data for Fetus B is associated with a specific NCS PID, etc.
- The biospecimen, physical measures, and medical records abstraction data collectors will refer to the AIS and will use the NCS Participant ID listed on the AIS to identify and label the forms, specimens, and data consistently for each child.
- Each data collector will continue to use the same letter identification assigned prior to birth (e.g., A, B) to identify the children after birth, using the assumption that Fetus A becomes birth order Baby A; Fetus B becomes birth order Baby B; and so on. *This assumption allows all birth data collection to be performed consistently so that all birth data collection forms, biospecimens, physical measures, and medical record data for each NCS child are identified and labeled with the same NCS participant ID.* The concept of birth order (the first baby delivered is Baby A, the second baby delivered is Baby B) is commonly used by hospitals and birthing centers to identify multiples after birth.
- In situations in which a child is missed on the T2 and T3 ultrasounds (i.e., a “surprise” child; this may occur in higher order gestations), the Birth data collector must contact the Site Office to activate and assign a participant ID to this child. The



“surprise” child may be identified during the Delivery Ultrasound or at the time of the actual delivery. The new participant ID as well as the delivery information (date and time of delivery, gender, and birth weight) must be recorded on the Additional PID Needed Form (refer to the Site Office training materials for procedures on the NCS Collaboration Portal for use of the Additional PID Needed Form). Normally, the Birth biospecimen data collector will complete this form because biospecimens are collected at the B1 visit and physical measures are not completed until the B2 visit. However, in situations where the B1 visit does not occur, a physical measures data collector may be the first to collect data for the Birth event and would therefore need to complete the Additional PID Needed Form. A copy of this completed form must be provided to all Birth data collection staff to ensure consistent identification and labeling of data, forms, and specimens.

Because the NCS collects fetal ultrasound data that must later be associated with each NCS child, identification and labeling for multiple births poses a challenge. However, certain ultrasound data that are collected during the T2, T3, and delivery ultrasounds (if applicable) can facilitate this process. The data collected for the T2 and T3 ultrasounds (e.g., fetal presentation, estimated fetal weight) are used to generate a Multiple Gestation Tracking/Linkage Report. The medical records abstraction data collector abstracts the delivery ultrasound data from the medical records into the appropriate fields on the Multiple Gestation Tracking/Linkage Report. This report then is used to match the fetal ultrasound data for each child to the postnatal NCS physical measures and biospecimen data.

The matching process will occur after the medical records abstraction visit and post-visit processing of the visit forms has been completed. The fetus identification from the ultrasound data (i.e., Fetus A) will not necessarily match the birth order. For example, the ultrasound data for Fetus A may be matched with the postnatal data for birth order Baby B. If necessary, the fetal ultrasound data will be reassigned to the correct NCS participant ID in the SMS after the matching process is complete. *Biospecimens and biospecimen data collection forms completed as part of the Birth event will not be reassigned or relabeled with a new NCS participant ID.* For detailed information regarding the use of the Multiple Gestation Tracking/Linkage Report and the matching process, refer to the Site Office training materials for the Birth event and Volume VII (Procedures for Physical Measures).

7.2 Maternal Blood Collection and Transport Procedures

This section provides procedures for the collection and transport of maternal blood specimens for the NCS. Blood specimens will be analyzed to obtain information about physiological conditions

and environmental exposures. After checking into the hospital or birthing center and preferably prior to delivery, venous blood will be collected from the mother using the Adult Blood Collection Kit. Collection of NCS blood tubes preferably will be obtained as part of the routine clinical phlebotomy collection by hospital or birthing center staff. However, if a particular birthing site does not routinely collect blood or if the NCS blood specimens were not collected as part of the routine phlebotomy, the hospital or birthing center staff or NCS phlebotomist may collect the mother's blood when possible. It is preferred to collect the blood specimens prior to delivery, but if this is not possible, blood may be collected prior to discharge. The circumstances of each birth should be taken into account when considering the timing of the blood collection. For example, it may be easier to collect blood specimens in the case of a scheduled delivery (e.g., induction, Cesarean section) than in the case of an unscheduled delivery (e.g., during the later stages of labor). If the mother's blood cannot be collected at all, the delivery staff or the data collector should document this on the Adult Blood Data Collection Form.

The individual who performs the venous blood collection from the mother (or the data collector if assisting in the collection) should complete the Adult Blood Data Collection Form. The prescreening questions on the form should be asked prior to the blood draw. If the mother is not eligible or refuses the blood collection, she should not be asked to provide a blood not collected (BNC) saliva specimen, as is done for the pre-birth data collection visits. Blood collection consists of four blood tubes: one prescreened 3-mL lavender top tube and three 10-mL red top tubes. The collection kit includes a blood tube reference card to guide the phlebotomist in the correct draw order. Blood should be drawn using the prescreened needle provided in the collection kit whenever possible. If this is not possible, the needle used for the routine phlebotomy is acceptable for the collection. The type of needle used for the collection should be documented on the Adult Blood Data Collection Form.

Within 2 hours of collection, the blood tubes should be placed inside the clamshell and stored at 2–8 °C. Within 24 hours of collection, blood tubes must be transported to the SPSC and centrifugation of the red top tubes must be complete. The 2-hour centrifugation time requirement does not apply to the Birth study event because of differences in analytical requirements; therefore, centrifugation does not need to be performed at the birthing site or other field location. The study-provided centrifuge always must be used to process blood specimens for consistency. For detailed receipt, centrifugation, and storage procedures, refer to Chapter 2 of Part 4 in this volume.

7.2.1 Equipment, Supplies, and Forms

The following equipment, supplies, and forms are required to collect and transport the mother's venous blood:

- Adult Blood Collection Kit—Birth Mother (kit contents are in the next list)
- Disposable laboratory coat
- Powder-free gloves
- One lower threshold (0 °C) temperature monitor
- Biospecimen transport cooler
- Four -1 °C cold packs
- One upper threshold (20 °C) temperature monitor, kept on cold packs.

Depending on the location of the birth (e.g., hospital or home birth) and who performs the collection (e.g., hospital staff or data collector), the following items also may be needed:

- Specimen collection tray
- Hand sanitizer
- Phlebotomy ball
- Chux pads
- Biohazard waste bag
- Sharps container.

The Adult Blood Collection Kit—Birth Mother contains the following items:

- One prescreened 3-mL lavender top blood tube
- Three 10-mL red top blood tubes
- One plastic clamshell
- Two alcohol wipes
- One large band aid

- One sterile gauze (2" x 2")
- One 21-gauge butterfly needle assembly unit with 12-inch tubing
- One tourniquet (single use)
- One needle holder (single use)
- Blood Tube Reference Card
- One amber transport bag with absorbent pad
- One adhesive label for Biospecimen Transmittal Form (TM label)
- One adhesive label for hard copy, backup Adult Blood Data Collection Form (DC label)
- Four additional adhesive labels (EX labels).

The following forms and labels are required to collect and transport the blood specimens:

- Adult Blood Data Collection Form—Birth Mother
- Birth Biospecimen Transmittal Form
- Mother's subject labels.

Blood collection data will be documented on the Adult Blood Data Collection Form (see Appendices 7-A and 7-B for form and field-by-field instructions). The transmittal form will accompany specimens from the birthing site to the SPSC (see Appendices VIII-F and VIII-H for form and field-by-field instructions). The mother's subject label must be on the data collection form.

7.2.2 Maternal Blood Collection Procedures

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

If the data collector/phlebotomist collects the venous blood from the mother, the data collector should follow the procedures provided in Chapter 1 of Part 4 in this volume. Blood tubes should

be placed in the clamshell and stored at 2–8 °C within 2 hours of collection. Procedures for preparing the blood tubes for transport are found in Section 7.2.4.

7.2.3 Documenting Maternal Blood Collection

As stated previously, the individual who performs the venous blood collection from the mother (or the data collector if assisting in the collection) should complete the Adult Blood Data Collection Form. After the collection kit is opened, the DC label from the kit must be affixed to the form. *This is very important because it links the specimen ID to the participant.* The data collector is responsible for ensuring the form is legible and complete with the mother's subject label.

The following procedures should be followed by the data collector before transporting the blood specimens to the SPSC:

1. Review the Adult Blood Data Collection Form for legibility and completeness and verify the DC label from the collection kit is affixed to the form. Confirm that the kit ID on the DC label matches the kit ID on the blood tubes. If the DC label was not affixed to the form and is no longer available, record the kit ID from one of the blood tube ID labels on the form. The kit ID is the 9-digit sequence before the item ID. Because the form is a Teleform, this information should be written in block letters above the ID label box.
2. If the blood tubes were labeled with the mother's name, remove any information that can personally identify the study participant from the tubes. The tubes are prelabeled and should not identify the participant by name.
3. Place the mother's subject label on the data collection form in the space indicated. Confirm that the subject ID is matched with the correct participant (i.e., mother's name) on the form. Once the subject ID has been matched to the name, remove the mother's name from the form.
4. Enter your NCS data collector ID on the back of the data collection form.
5. Verify that the correct mother's subject label is affixed to the Birth Biospecimen Transmittal Form.
6. Retrieve the extra adhesive labels from the collection kit and affix the TM label to the Birth Biospecimen Transmittal Form. If the TM labels are no longer available, hand write the kit ID on the form.

7. Record the blood collection status and storage temperature on the Birth Biospecimen Transmittal Form.
8. If an incident occurs during the blood collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

7.2.4 Maternal Blood Transport Procedures

Blood specimens will be transported to the SPSC in the refrigerated chamber of the biospecimen transport cooler. To transport the blood tubes, follow these procedures:

1. If not already in the clamshell, place the blood tubes inside the clamshell.
2. Locate the lower (0 °C) threshold temperature monitor and place it inside the clamshell. This monitor will be used to determine if the temperature of the clamshell falls below 0 °C during transport.
3. Locate the upper (20 °C) threshold temperature monitor in the refrigerated chamber. The monitor must remain cold until just before it is affixed to the clamshell and activated. Remove the adhesive and affix it to the outside of the clamshell (see Exhibit 7-1 for proper placement). Activate the monitor by pulling the tab.

Exhibit 7-1. Placement of threshold temperature monitors in the refrigerated clamshell



4. Place the clamshell inside a plastic transport bag with the absorbent pad and seal the bag. Though these tubes are not light sensitive, an amber bag may be used if available.
5. Position the transport bag securely and upright within the refrigerated chamber of the transport cooler, as shown in Exhibit 7-2.

Exhibit 7-2. Proper packing of the refrigerated chamber



6. Complete the Birth Biospecimen Transmittal Form and place it in the zippered document pouch inside the lid of the transport cooler.
7. Confirm the cooler is properly closed for transport.
8. Transport any remaining kit labels to the SPSC.

The Adult Blood Data Collection Form should be returned to the Site Office along with the other birth specimen data collection forms.

7.3 Cord Blood Collection and Transport Procedures

This section provides procedures for the collection and transport of cord blood specimens for the NCS. Cord blood specimens will be analyzed to obtain information about physiological conditions and environmental exposures in utero. If cord blood is not needed for banking or clinical purposes, it will be collected from the umbilical cord after delivery using the sterile collection bag provided in the NCS Cord Blood Collection Kit. It is preferred that the cord blood be collected prior to delivery of the placenta if possible. If this is not possible, the collection should occur after placental delivery. If a mother wishes to bank her cord blood, this information will be normally communicated to NCS staff prior to the birth. However, if the decision was made after the last study-related visit, the mother or delivery staff should inform Study Center staff at the time of delivery. Information regarding cord blood banking will be normally documented in a consent form in the patient's medical record. Study Centers should work with local hospitals and birthing centers to develop procedures for accessing this information. If the cord blood is not collected, the delivery staff or the data collector should document this on the Cord Blood Data Collection Form.

The cord blood collection bag should be placed at 2–8 °C within 2 hours of collection. The NCS data collector will transport the cord blood to the SPSC at 2–8 °C in the biospecimen transport cooler within 24 hours of collection.

For multiple births, a separate NCS Cord Blood Collection Kit and Cord Blood Data Collection Form are needed for each infant's umbilical cord. It is especially important that the forms are completed properly and labeled with the appropriate collection kit label to ensure that each specimen is associated with the correct infant and to avoid potential mix-ups.

7.3.1 Equipment, Supplies, and Forms

The following equipment, supplies, and forms are required to collect and transport cord blood:

- NCS Cord Blood Collection Kit (kit contents are in the next list)
- Disposable laboratory coat
- Powder-free gloves
- Biospecimen transport cooler
- One Saf-T-Temp HardPak (STP-319), frozen
- Two Saf-T-Temp SoftPaks (STP-319), ambient.

The NCS Cord Blood Collection Kit contains the following items:

- NCS Cord Blood Collection Instructions with manufacturer instructions
- One sterile CPD (i.e., Anticoagulant Citrate Phosphate Dextrose Solution) cord blood collection bag
- Two Betadine swabs
- One biohazard transport bag, 6" x 9", prelabeled
- One absorbent pad (250 mL)
- One cord blood bag crimping device
- One adhesive label for the Cord Blood Data Collection Form (DC label)

- One adhesive label for the transmittal form (TM label)
- One extra adhesive label for the biohazard transport bag (EX label).

The following forms and labels are required to collect and transport cord blood specimens:

- Cord Blood Data Collection Form
- Birth Biospecimen Transmittal Form
- Subject labels (mother's and child's). Note that for multiple births, each infant will have a separate subject label.

Cord blood collection data will be documented on the Cord Blood Data Collection Form (see Appendices 7-C and 7-D for form and field-by-field instructions). The transmittal form will accompany specimens from the birthing site to the SPSC (see Appendices VIII-F and VIII-H for form and field-by-field instructions). The child's subject label must be on the data collection form.

7.3.2 Cord Blood Collection Procedures

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

When collecting the cord blood, the instructions provided in the NCS Cord Blood Collection Kit should be followed (see Appendix 7-E). Cord blood should be stored at 2–8 °C within 2 hours of collection until it can be transported to the SPSC.

7.3.3 Documenting Cord Blood Collection

The individual who performs the cord blood collection (or the data collector if assisting in the collection) should complete the Cord Blood Data Collection Form. After the collection kit is opened, the DC label from the kit must be affixed to the form. *This is very important because it links the specimen ID to the participant.* The data collector is responsible for ensuring the form is legible and complete with the child's subject label.

The following procedures should be followed by the data collector before transporting the cord blood specimen to the SPSC:

1. Review the Cord Blood Data Collection Form for legibility and completeness and verify the DC label from the collection kit is affixed to the form. Confirm that the kit ID on the DC label matches the kit ID on the cord blood bag. If the DC label was not affixed to the form and is no longer available, record the kit ID from the bag ID label onto the form. The kit ID is the 9-digit sequence before the item ID. Because the form is a Teleform, this information should be written in block letters above the ID label box.
2. If the cord blood bag is labeled with the mother's or child's name, remove any information that can personally identify the study participant from the cord blood bag. The transport bag is pre-labeled and neither the cord blood bag nor the transport bag should identify the participant by name.
3. Place the child's subject label on the data collection form in the space indicated. Confirm that the subject ID is matched with the correct participant (i.e., child's name) on the form. Once the subject ID has been matched to the name, remove the mother's and child's names from the form.
4. Enter your NCS data collector ID on the back of the data collection form.
5. Verify that the correct mother's and child's subject labels are affixed to the Birth Biospecimen Transmittal Form.
6. Retrieve the extra adhesive labels from the collection kit and affix the TM label to the Birth Biospecimen Transmittal Form. If the TM labels are no longer available, hand write the kit ID on the form.
7. Record the cord blood collection status and storage temperature on the Birth Biospecimen Transmittal Form.
8. If an incident occurs during the cord blood collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

7.3.4 Cord Blood Transport Procedures

Cord blood specimens will be transported to the SPSC at 2–8 °C in the large chamber of the biospecimen transport cooler. To transport cord blood, follow these procedures:

1. Precondition the refrigerated chamber of the transport cooler for a minimum of 1 hour before placing the cord blood specimen inside. To do so, place a frozen Saf-T-Temp HardPak centered on the bottom of the large chamber and place two Saf-T-Temp SoftPaks on top of the HardPak, so that the SoftPaks form a flat surface. Close the cooler and allow the system to equilibrate for a minimum of 1 hour.
2. Place the cord blood specimen inside the transport cooler on top of the SoftPaks. If you are transporting a fresh placenta specimen at the same time, it is preferred that the cord blood specimen is placed next to the placenta; however, if space is limited, the cord blood specimen may be placed on top of the placenta specimen.
3. Ensure the Birth Biospecimen Transmittal Form is complete and place the completed form in the zippered document pouch inside the lid of the transport cooler.
4. Confirm the cooler is properly closed for transport.
5. Transport any remaining kit labels to the SPSC.

The Cord Blood Data Collection Form should be returned to the Site Office along with the other birth specimen data collection forms.

7.4 Placenta and Umbilical Cord Collection and Transport Procedures

This section provides procedures for the collection and transport of placenta and umbilical cord specimens for the NCS. Placenta and umbilical cord specimens will be analyzed to obtain information about physiological conditions and environmental exposures in utero. The preferred specimen for analysis is a fresh (i.e., unfixed) whole placenta with attached umbilical cord and extraplacental membranes. Throughout this section, the term *placenta* is used to refer to the placenta, the placental membrane, and attached umbilical cord. The term *placental tissue* is used to refer to a partial sample of the placenta.

Placenta specimens will be collected from study participants after delivery and after the collection of cord blood if applicable. If the placenta and umbilical cord do not require a local

pathology examination and can be released immediately after birth, the fresh placenta will be collected directly from the hospital labor and delivery unit or birthing center. The placenta specimen will be double bagged and placed at 2–8 °C within 2 hours of collection. The data collector will transport the placenta to the SPSC at 2–8 °C within 24 hours of collection. At the SPSC, the placenta will be prepared for overnight shipping to a central NCS-designated histology laboratory.

Study Centers are required to work with local hospitals, birthing centers, and pathology departments to implement NCS protocols for placenta collection. As noted previously, the preferred specimen for NCS is a fresh (i.e., unfixed) whole placenta with attached umbilical cord and extraplacental membranes. If a fresh placenta cannot be obtained, a fixed specimen should be obtained; if a whole placenta cannot be obtained, a partial tissue specimen should be obtained; if a pathology examination was performed, a copy of the pathology report should be obtained if no tissue or only partial tissue is obtained after the examination. NCS recognizes that there will be instances in which a fresh, whole placenta cannot be collected. In anticipation of this issue, this section outlines three special situations that are predicted to occur most often. These situations are: (1) a pathology examination is clinically indicated, (2) a placenta is not released within 5 days of delivery, and (3) a partial sample of placental tissue is released. Figure 7-1 presents a flow chart describing the various issues surrounding placenta collection. If a situation arises that is not addressed by the following procedures, Study Centers should use their best judgment or contact the Coordinating Center for additional information with the goal of obtaining placenta specimens whenever possible. If the placenta will not be collected, the delivery staff or the data collector should document this on the Placenta and Umbilical Cord Data Collection Form.

For multiple births with multiple placentas, a separate NCS Placenta and Umbilical Cord Collection Kit and Placenta and Umbilical Cord Data Collection Form are needed for each placenta. It is especially important in such cases that the forms are completed properly and labeled with the appropriate collection kit label to ensure that each specimen is associated with the correct infant and to avoid potential mix-ups. In cases of multiple births with a shared placenta, only one Placenta and Umbilical Cord Data Collection Form is needed.

7.4.1 Placenta Not Released Within 5 Days of Delivery

In some cases, a hospital or birthing center may not release placenta specimens within 5 days of delivery. The hospital or birthing center may have a standard policy about the release of placenta specimens (e.g., a set number of days until all placentas can be released) or there may be specific cases in which a placenta specimen is not released immediately because of circumstances of the birth.

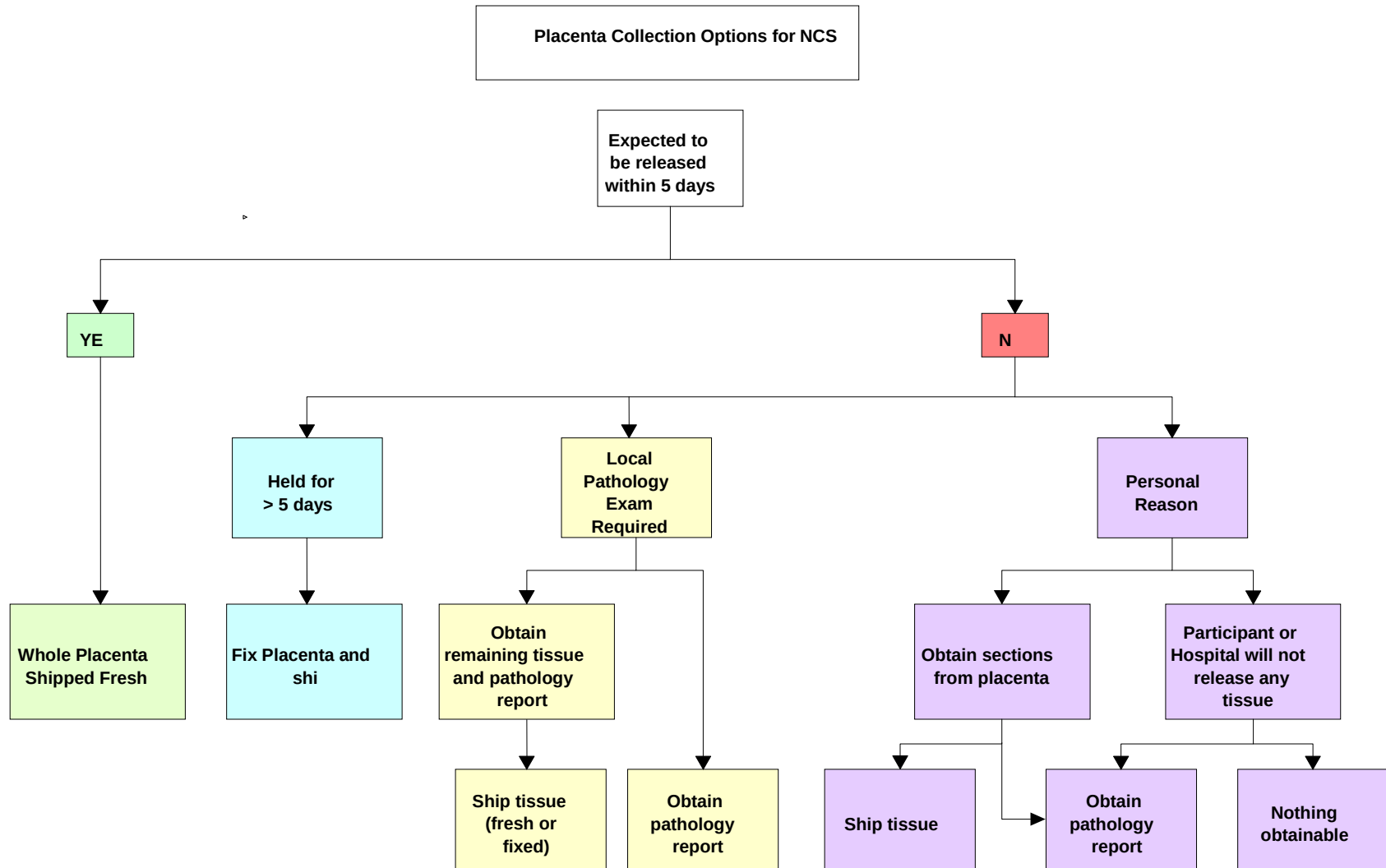
For appropriate analysis, *fresh* placenta specimens must be shipped from Study Centers to arrive at the central NCS histology laboratory *within 7 days of delivery*. If it is anticipated that a hospital will not release a placenta within 5 days of delivery (either routinely or for a specific study participant), it will not be possible for the specimen to arrive at the histology laboratory within 7 days. In these situations, the Study Center should request that the hospital fix the placenta in an appropriate volume of formalin within the first 24–48 hours. For specimens that are fixed, the appropriate items on the Placenta and Umbilical Cord Data Collection Form should be completed to document the date and time of fixation and the reason the tissue was fixed. Procedures for the collection and transport of fixed placenta specimens are found in Section 7.4.5.

7.4.2 Clinically Indicated Pathology Examination

In some cases, a pathology examination of the placenta will be clinically indicated. The Study Center should establish a notification system to ensure that study staff are informed in such cases. For placentas that require a local pathology examination, the Study Center should communicate with the pathology laboratory to obtain remaining placental tissue and a pathology report upon completion of the pathology procedures. If it is not possible to obtain any remaining tissue (fresh or fixed), the Study Center should attempt to obtain the pathology report from the local examination whenever possible. Study Centers are responsible for obtaining the appropriate authorization or release to obtain the pathology records.

The Study Center should work with each hospital and birthing center to devise a plan for obtaining tissue after dissection. This plan should address how remaining fresh or fixed placental tissue will be stored (e.g., refrigerated), in what type of vessel it will be stored (e.g., bag, container), and how it will be identified and labeled by the pathology laboratory until the specimen can be retrieved by the data collector.

Figure 7-1. Placenta collection for NCS



If fresh (i.e., unfixed) remaining tissue is obtainable within 5 days of delivery, the Study Center should obtain the tissue from the pathology department. Procedures for the collection and transport of fresh placenta specimens are found in Section 7.4.4.

If fixed remaining tissue is obtainable, the Study Center should request that the pathology department store the placental tissue in an appropriate volume of formalin until it can be released. For specimens that are fixed, the appropriate items on the Placenta and Umbilical Cord Data Collection Form should be completed to document the date and time of fixation and the reason the tissue was fixed. Procedures for the collection and transport of fixed placenta specimens are found in Section 7.4.5.

If fixed tissue is not obtainable in formalin, Study Centers are encouraged to obtain tissue blocks or pathology slides when possible.

7.4.3 Release of Partial Placental Tissue

In some cases, a study participant may not wish to release the whole placenta (defined as placenta, placental membrane, and attached umbilical cord) to the Study Center. This may happen for cultural, religious, or other personal reasons. In this situation, the Study Center should attempt to make arrangements with the participant and the local pathology department to obtain a partial sample of placental tissue. Partial placental tissue also may be obtained in cases where a hospital is willing to release only a sample or section of the placenta but not the whole placenta.

If a sample of the placenta, membrane, and umbilical cord can be released, the Study Center should request that the local pathology laboratory provide the following specimens:

- A 2½ cm square piece of full thickness placenta, cut from the center of the placenta
- Two cross sections of the umbilical cord (one within 5 cm of insertion and one within 5 cm of the edge, making sure that neither piece is from a location near the cord clamps)
- A small section of trimmed membrane, if possible.

The data collector should complete or request that the pathology department complete the relevant items on the Placenta and Umbilical Cord Data Collection Form to document the location where samples were taken and other anatomical information. If a pathology examination

was performed and partial placental tissue was obtained, the Study Center should attempt to obtain a copy of the pathology report whenever possible.

7.4.4 Fresh Placenta Collection and Transport

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

Fresh placenta specimens are those that are collected at the delivery site and are not fixed. Fresh placenta specimens must be shipped from Study Centers to arrive at the central NCS histology laboratory within 7 days of delivery. When collecting a fresh (i.e., unfixed) placenta specimen, the instructions provided in the NCS Placenta and Umbilical Cord Collection Kit should be followed (see Appendix 7-F). The placenta specimen should be stored at 2–8 °C within 2 hours of collection until it can be transported to the SPSC.

For multiple births, if there are multiple placentas, each specimen collected should have a separate data collection form, and specimens from each infant should be accompanied by a separate transmittal form.

The following equipment and supplies are required to collect and transport fresh (i.e., unfixed) placenta specimens:

- NCS Placenta and Umbilical Cord Collection Kit (kit contents are in the next list)
- Disposable laboratory coat
- Powder-free gloves
- Packing tape
- Biospecimen transport cooler
- One Saf-T-Temp HardPak (STP-319), frozen
- Two Saf-T-Temp SoftPaks (STP-319), ambient.

The NCS Placenta and Umbilical Cord Collection Kit contains the following items:

- NCS Placenta and Umbilical Cord Collection Instructions

- One unlabeled 12" x 12" resealable formalin resistant polyethylene bag (primary bag)
- One prelabeled 12" x 12" resealable formalin resistant polyethylene bag (secondary bag)
- One absorbent pad (500 mL)
- Two preprinted 4" x 4" adhesive labels with the text "Fresh (Unfixed) Specimen"
- One adhesive label for the Placenta and Umbilical Cord Data Collection Form (DC label)
- One adhesive label for the transmittal form (TM label)
- One extra adhesive label for the 12" x 12" secondary collection bag (EX label).

Fresh (i.e., unfixed) placenta specimens will be transported to the SPSC at 2–8 °C in the large chamber of the biospecimen transport cooler. To transport fresh placenta specimens, follow these procedures:

1. Precondition the refrigerated chamber of the transport cooler for a minimum of 1 hour before placing the fresh placenta specimen inside. To do so, place a frozen Saf-T-Temp HardPak centered on the bottom of the large chamber and place two Saf-T-Temp SoftPaks on top of the HardPak, so that the SoftPaks form a flat surface. Close the cooler and allow the system to equilibrate for a minimum of 1 hour.
2. Place one preprinted adhesive label with the text "Fresh (Unfixed) Specimen" on each of the primary and secondary polyethylene bags, so that each label completely covers the preprinted text "10% Formalin." This should be done to avoid inappropriate labeling of the specimen during transport and shipping.
3. Place the placenta specimen inside the transport cooler on top of the SoftPaks, ensuring that it lies as flat as possible.
4. Ensure the Birth Biospecimen Transmittal Form is complete and place the completed form in the zippered document pouch inside the lid of the transport cooler.
5. Confirm the cooler is properly closed for transport.
6. Transport any remaining kit labels to the SPSC. Extra labels should not be placed inside the primary or secondary polyethylene bags with the specimen to avoid ruining the labels in case of leaks or spills.

The Placenta and Umbilical Cord Data Collection Form should be returned to the Site Office along with the other birth specimen data collection forms.

7.4.5 Fixed Placenta Collection and Transport

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

As mentioned previously, the Study Center should work with each hospital and birthing center to obtain fixed placenta or placental tissue from the local pathology laboratory. The Study Center should be aware of how fixed placenta specimens are stored, in what type of vessel they are stored (e.g., bag, container), and how they are identified and labeled by the pathology laboratory until the specimens can be retrieved by the data collector. At the time of specimen pick-up, the data collector should have an NCS Placenta and Umbilical Cord Collection Kit and data collection form. In the case of multiple births with multiple placentas, each placenta specimen requires a separate kit and form, and specimens from each infant should be accompanied by a separate transmittal form.

Fixed placenta specimens must be stored and transported in a 10 percent buffered formalin solution. Formalin is not provided by the NCS to Study Centers and will not be available at the SPSC. Therefore, the Study Center should request that the pathology laboratory prepare the fixed placenta specimen in an appropriate volume of formalin before or at the time of pick-up. The fixed specimen must be transferred to the resealable formalin resistant polyethylene bags provided in the collection kit, along with an adequate volume of formalin to cover the placental tissue.

When collecting a fixed placenta specimen, the specimen should be packaged (i.e., double bagged, taped) using the following materials and procedures. After the data collector picks up the specimen, it will be transported at ambient temperature to the SPSC.

- NCS Placenta and Umbilical Cord Collection Kit (kit contents are in the next list)
- Disposable laboratory coat
- Powder-free gloves
- Packing tape
- Biospecimen transport cooler (*no cold packs required*).

The NCS Placenta and Umbilical Cord Collection Kit contains the following items:

- One unlabeled 12" x 12" resealable formalin resistant polyethylene bag (primary bag)
- One prelabeled 12" x 12" resealable formalin resistant polyethylene bag (secondary bag)
- One absorbent pad (500 mL)
- Two preprinted 4" x 4" adhesive labels with the text "Fresh (Unfixed) Specimen"
- One adhesive label for the Placenta and Umbilical Cord Data Collection Form (DC label)
- One adhesive label for the transmittal form (TM label)
- One extra adhesive label for the 12" x 12" secondary collection bag (EX label).

To collect and transport fixed placenta specimens, follow these procedures:

1. Use powder-free gloves when handling the placenta.
2. Place the fixed placenta specimen inside the unlabeled 12" x 12" resealable polyethylene bag, keeping the specimen as flat as possible, along with an adequate volume of formalin to cover the placental tissue.
3. Seal the bag completely. Fold the top of the bag over. Using packing tape, tape the top that has been folded over to the rest of the bag. Make sure that the tape goes all the way around the bag.
4. Place the 12" x 12" bag containing the specimen inside the prelabeled 12" x 12" resealable polyethylene bag.
5. Place the absorbent pad inside the secondary 12" x 12" bag and seal the bag securely.
6. Place the double-bagged placenta specimen inside the large chamber of the transport cooler, ensuring that it lies as flat as possible.
7. Ensure the Birth Biospecimen Transmittal Form is complete and place the completed form in the zippered document pouch inside the lid of the transport cooler.
8. Confirm the cooler is properly closed for transport.

9. Transport any remaining kit labels to the SPSC. Extra labels should not be placed inside the primary or secondary polyethylene bags with the specimen to avoid ruining the labels in case of leaks or spills.

7.4.6 Documenting Placenta Collection and Transport

The following forms and labels are required to document the collection and transport of NCS placenta specimens:

- Placenta and Umbilical Cord Data Collection Form
- Birth Biospecimen Transmittal Form
- Subject labels (mother's and child's). Note that for multiple births, each infant will have a separate subject label.

Collection data will be documented on the Placenta and Umbilical Cord Data Collection Form (see Appendices 7-G and 7-H for form and field-by-field instructions). The transmittal form will accompany specimens from the birthing site to the SPSC (see Appendices VIII-F and VIII-H for form and field-by-field instructions). The mother's subject label must be on the data collection form.

The individual who performs the placenta collection (or the data collector if assisting in the collection) should complete the Placenta and Umbilical Cord Data Collection Form. After the collection kit is opened, the DC label from the kit must be affixed to the form. *This is very important because it links the specimen ID to the study participant.* The data collector is responsible for ensuring the form is legible and complete with the mother's subject label.

For specimens that are fixed, the relevant items on the Placenta and Umbilical Cord Data Collection Form should be completed, including documenting the date and time of fixation and the reason the tissue was fixed. At the time of specimen pick-up, the data collector should ensure that the relevant information has been obtained from the pathology laboratory and that the form is complete.

The following procedures should be followed by the data collector before transporting placenta specimens to the SPSC:

1. Review the Placenta and Umbilical Cord Data Collection Form for legibility and completeness and verify the DC label from the collection kit is affixed to the form. Confirm that the kit ID on the DC label matches the kit ID on the secondary bag. If the DC label was not affixed to the form and is no longer available, record the kit ID from the bag ID label onto the form. The kit ID is the 9-digit sequence before the item ID. Because the form is a Teleform, this information should be written in block letters above the ID label box.
2. If the specimen was labeled with the study participant's name, remove any information that can personally identify the participant. The outer transport bag is pre-labeled and should not identify the participant by name.
3. Place the mother's subject label on the data collection form in the space indicated. Confirm that the subject ID matches the correct name (i.e., mother's name) on the form. Once the subject ID has been matched to the name, remove the mother's and child's names from the form.
4. Enter your data collector ID on the back of the data collection form.
5. Verify that the correct mother's and child's subject labels are affixed to the Birth Biospecimen Transmittal Form.
6. Retrieve the extra adhesive labels from the collection kit and affix the TM label to the Birth Biospecimen Transmittal Form. If the TM labels are no longer available, hand write the kit ID on the form.
7. Record the placenta collection status and storage temperature on the Birth Biospecimen Transmittal Form.
8. If an incident occurs during the placenta collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

The Placenta and Umbilical Cord Data Collection Form should be returned to the Site Office along with the other birth specimen data collection forms.

7.5 Infant Blood Spot Collection and Transport Procedures

This section provides procedures for the collection and transport of infant blood spot cards for the NCS. Infant blood spot specimens will be analyzed to obtain information about physiological conditions and environmental exposures. Capillary blood from the infant will be obtained in conjunction with the routine heel stick at the hospital or birthing center following birth by using the blood spot cards provided in the NCS Infant Blood Spot Collection Kit. Two blood spot cards will be collected: (1) a Flinders Technology Associates (FTA[®]) Mini card and (2) a Protein Saver card. If blood spot cards are not collected, the delivery staff or the data collector should document this on the Infant Blood Spot Data Collection Form.

Blood spot cards should be air-dried for at least 3–4 hours at ambient temperature. Drying racks for blood spot cards may be provided by NCS if requested by the Study Center. After the blood spot cards are completely dry, the data collector will transport the cards to the SPSC at ambient temperature in the insulated transport bag. Alternatively, Study Centers may choose to request that hospital or birthing center staff mail the dried blood spot cards to the SPSC using envelopes provided by the Study Center.

7.5.1 Equipment, Supplies, and Forms

The following equipment, supplies, and forms are required to collect and transport infant blood spot cards:

- NCS Infant Blood Spot Collection Kit (kit contents are in the next list)
- Disposable laboratory coat
- Powder-free gloves
- Insulated transport bag.

The NCS Infant Blood Spot Collection Kit contains the following items:

- NCS Infant Blood Spot Collection Instructions
- One Whatman 903[®] Protein saver card, prelabeled

- One FTA Mini card, prelabeled
- One adhesive label for the Infant Blood Spot Data Collection form (DC label)
- One adhesive label for the transmittal form (TM label).

Please note that the Infant Blood Spot Collection Kit does not contain a lancet to perform the heel stick. Blood spot cards may be collected only in conjunction with the routine heel stick that is performed at the hospital or birthing center after birth. *An additional heel stick should not be performed to collect the NCS blood spots.*

The following forms and labels are required to collect and transport infant blood spot cards:

- Infant Blood Spot Data Collection Form
- Birth Biospecimen Transmittal Form
- Subject labels (mother's and child's). Note that for multiple births, each infant will have a separate subject label.

Infant blood spot collection data will be documented on the Infant Blood Spot Data Collection Form (see Appendices 7-I and 7-J for form and field-by-field instructions). The Transmittal Form will accompany specimens from the birthing site to the SPSC (see Appendices VIII-F and VIII-H for form and field-by-field instructions). The child's subject label must be on the data collection form.

7.5.2 Infant Blood Spot Collection Procedures

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

When collecting the infant blood spot cards, the instructions provided in the NCS Infant Blood Spot Collection Kit should be followed (see Appendix 7-K). Infant blood spot cards should be dried completely and stored at ambient temperature before transport to the SPSC.

Please note that during the collection, the individual performing the collection should alternate between the Whatman 903 card and the FTA Mini card (beginning with the Whatman 903 card)

to ensure a minimum of one spot is collected on each card. It is not anticipated that all blood spots on both cards will be completely filled on a routine basis.

7.5.3 Documenting Infant Blood Spot Collection

The individual who performs the infant blood spot collection (or the data collector if assisting in the collection) should complete the Infant Blood Spot Data Collection Form. After the collection kit is opened, the DC label from the kit must be affixed to the form. *This is very important because it links the specimen ID to the study participant.* The data collector is responsible for ensuring the form is completed properly and for placing the child's subject label on the form.

The following procedures should be followed by the data collector before transporting the infant blood spot cards to the SPSC:

1. Review the Infant Blood Spot Data Collection Form for legibility and completeness and verify that the DC label from the collection kit is affixed to the form. Confirm that the kit ID on the DC label matches the kit ID on the blood spot cards. If the DC label was not affixed to the form and is no longer available, record the kit ID from one of the blood spot card ID labels onto the form. The kit ID is the 9-digit sequence before the item ID. Because the form is a Teleform, this information should be written in block letters above the ID label box.
2. Place the child's subject label on the data collection form in the space indicated. Confirm that the subject ID matches the correct name (i.e., child's name) on the form. Once the subject ID has been matched to the name, remove the mother's and child's names from the form.
3. Enter your NCS data collector ID on the back of the data collection form.
4. If the blood spot cards were labeled with the study participant's name, remove any information that can personally identify the participant. The infant blood spot cards are prelabeled and should not identify the participant by name.
5. Verify that the correct mother's and child's subject labels are affixed to the Birth Biospecimen Transmittal Form.
6. Retrieve the extra adhesive labels from the collection kit and affix the TM label to the Birth Biospecimen Transmittal Form. If the TM labels are no longer available, hand write the kit ID on the form.
7. Record the infant blood spot collection status on the Birth Biospecimen Transmittal Form.

8. If the blood spot cards are not dry, wait to transport the cards until they are completely dry. Alternatively, provide the hospital or birthing center staff with an addressed, stamped envelope with the child's subject label for mailing the cards to the SPSC. Please note that all applicable USPS and IATA regulations must be followed if the hospital mails blood spot cards to the Study Center, including appropriate packing and labeling procedures.
9. If an incident occurs during the infant blood spot collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

7.5.4 Infant Blood Spot Transport Procedures

Infant blood spot cards will be transported to the SPSC at ambient temperature inside the insulated transport bag. To transport infant blood spot cards, follow these procedures:

1. Ensure that the blood spot cards are completely dry. Do not transport the cards before they are dry.
2. If not already folded, fold the card cover over each card.
3. Place the infant blood spot cards inside the insulated transport bag.
4. Ensure the Birth Biospecimen Transmittal Form is complete and place the completed form in the zippered document pouch inside the lid of the transport cooler or inside the transport bag if the cooler is not being used.
5. Confirm the transport bag is properly closed for transport.
6. Transport any remaining kit labels to the SPSC.

The Infant Blood Spot Data Collection Form should be returned to the Site Office along with the other birth specimen data collection forms.

7.6 Meconium Collection and Transport Procedures

This section provides procedures for the collection and transport of meconium specimens for the NCS. The term *meconium* refers to the first stool of a newborn infant, which is composed of materials ingested during the time the infant is in utero (e.g., cells, mucous, and amniotic fluid).

Meconium specimens will be analyzed to obtain information about physiological conditions and environmental exposures in utero.

Because the infant can pass meconium at any time, either the hospital staff or the data collector may collect the specimen using the NCS Meconium Collection Kit. It is preferred that the first meconium be collected, but if it is not possible to obtain the first meconium, the *first available* diaper containing meconium should be collected. Up to five diapers containing meconium may be collected. Study Centers may choose to request that hospital staff transfer the meconium from diapers into the collection vial provided in the kit.

The meconium diapers or meconium collection vial should be placed at 2-8 °C within 2 hours of collection. At the time of specimen pickup, the NCS data collector may choose to transfer the meconium from the diapers into collection vial or may transport the meconium diapers to the SPSC. The NCS data collector will transport the meconium specimen to the SPSC at 2–8 °C in the biospecimen transport cooler within 24 hours of collection. If meconium was not collected, the delivery staff or the data collector should document this on the Meconium Data Collection Form.

7.6.1 Equipment, Supplies, and Forms

The following equipment, supplies, and forms are required to collect and transport meconium:

- NCS Meconium Collection Kit (kit contents are in the next list)
- Disposable laboratory coat
- Powder-free gloves
- Biospecimen transport cooler
- -1 °C cold packs.

The NCS Meconium Collection Kit contains the following items:

- NCS Meconium Collection Instructions
- One 30-mL Para-pak collection vial with scoop lid, prelabeled
- Five wood tongue depressors

- Five plastic biohazard collection bags, prelabeled (for diapers)
- One plastic biohazard transport bag (for Para-pak vial)
- One adhesive label for the data collection form (DC label)
- One adhesive label for the transmittal form (TM label)
- One extra adhesive label for collection vial (EX label).

The following forms and labels are required to collect and transport meconium specimens:

- Meconium Data Collection Form
- Birth Biospecimen Transmittal Form
- Subject labels (mother's and child's). Note that for multiple births, each infant will have a separate subject label.

Meconium collection data will be documented on the Meconium Data Collection Form (see Appendices 7-L and 7-M for form and field-by-field instructions). The transmittal form will accompany specimens from the birthing site to the SPSC (see Appendices VIII-F and VIII-H for form and field-by-field instructions). The child's subject label must be on the data collection form.

7.6.2 Meconium Collection Procedures

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

When collecting the meconium, the instructions provided in the NCS Meconium Collection Kit should be followed (see Appendix 7-N). Meconium specimens should be stored at 2–8 °C within 2 hours of collection until they can be transported to the SPSC.

7.6.3 Documenting Meconium Collection

The individual who performs the meconium collection (or the data collector if assisting in the collection) should complete the Meconium Data Collection Form. After the collection kit is

opened, the DC label from the kit must be affixed to the form. *This is very important because it links the specimen ID to the study participant.* The data collector is responsible for ensuring the form is legible and complete with the child's subject label.

The following procedures should be followed by the data collector before transporting the meconium specimen to the SPSC:

1. Review the Meconium Data Collection Form for legibility and completeness and verify the DC label from the collection kit is affixed to the form. Confirm that the kit ID on the DC label matches the kit ID on the meconium vial or diapers. If the DC label was not affixed to the form and is no longer available, record the kit ID from the meconium vial ID label onto the form. The kit ID is the 9-digit sequence before the item ID. Because the form is a Teleform, this information should be written in block letters above the ID label box.
2. If the meconium vial is labeled with the study participant's name, remove any information that can personally identify the participant. The vial is pre-labeled with a kit label and the specimen should not be identified by name. If diapers are labeled with the participant's name, remove the name from the diaper label.
3. Place the child's subject label on the data collection form in the space indicated. Confirm that the subject ID matches the correct name (i.e., child's name) on the form. Once the subject ID has been matched to the name, remove the mother's and child's names from the form.
4. Enter your NCS data collector ID on the back of the data collection form.
5. Verify that the correct mother's and child's subject labels are affixed to the Birth Biospecimen Transmittal Form.
6. Retrieve the extra adhesive labels from the collection kit and affix the TM label to the Birth Biospecimen Transmittal Form. If the TM labels are no longer available, hand write the kit ID on the form.
7. Record the meconium collection status and storage temperature on the Birth Biospecimen Transmittal Form.
8. If an incident occurs during the meconium collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

7.6.4 Meconium Transport Procedures

Meconium specimens will be transported to the SPSC at 2–8 °C in the biospecimen transport cooler. To transport meconium, follow these procedures:

1. If the meconium specimen has been transferred to the collection vial, place the meconium specimen inside the small chamber of the transport cooler with the cold packs. If meconium diapers are picked up, the diapers may be transported in either chamber of the transport cooler, given that the large chamber has available space and the Saf-T-Temp system has been preconditioned for a minimum of 1 hour.
2. Ensure the Birth Biospecimen Transmittal Form is complete and place the completed form in the zippered document pouch inside the lid of the transport cooler.
3. Confirm the cooler is properly closed for transport.
4. Transport any remaining kit labels to the SPSC. If meconium diapers are picked up, be sure to transport the empty prelabeled collection vial to the SPSC.

The Meconium Data Collection Form should be returned to the Site Office along with the other birth specimen data collection forms.

Part 2

Appendix 7-A

Adult Blood Data Collection Form—Birth Mother

Appendix 7-A.
Adult Blood Data Collection Form—Birth Mother



58010



National Children's Study
Adult Blood Data Collection Form
Birth Mother

Birth

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☒ on the wrong answer.
- ➔ It is important to print clearly, using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study (NCS), we are asking you to obtain a sample of the mother's venous blood prior to delivery and after checking in at the delivery center. All of the supplies needed for this collection are contained in the NCS Adult Blood Collection-Birth Mother Kit.

1. Mother's name: _____

2. Mother's date of birth:

m	m	d	d	y	y	y	y

3. What is today's date?

				2	0		
m	m	d	d	y	y	y	y

4. Do you have hemophilia or any bleeding disorder?
 ¿Tiene hemofilia o algún problema de coagulación?

- ☐ Yes (END)
☐ No
☐ Don't know (END)
☐ Refused (END)

5. Do you take any blood thinning medications such as Coumadin or warfarin?
 ¿Toma algún medicamento anticoagulante, como Coumadin o warfarina?

- ☐ Yes (END)
☐ No
☐ Don't know (END)
☐ Refused (END)

Please see back of page.



BDFBTM01.00DU

**Place Mother's
 Subject ID Label
 Here**

**Appendix 7-A.
Adult Blood Data Collection Form—Birth Mother (continued)**



58010

6. Was this blood collected using the NCS Adult Blood Collection-Birth Mother Kit?

☐ Yes ☐ No

7. Did you use the NCS needle that was provided in the kit?

☐ Yes ☐ No

8. Date blood was collected:

		/			/	2	0		
m	m		d	d		y	y	y	y

9. Time that the blood was collected:

		:			☐ a.m.
h	h		m	m	☐ p.m.

10. Were all four blood tubes collected?

☐ Yes (END) ☐ No

Please do not write in this box.

11. If no, indicate which tubes were NOT collected. (Mark all that apply.)

- ☐ 3-mL lavender prescreened
- ☐ Red top tube #1
- ☐ Red top tube #2
- ☐ Red top tube #3

12. Please choose the one reason that best describes why the blood was not collected. (Mark one.)

☐ Participant refusal	☐ Hematoma
☐ Parent/guardian refusal	☐ No suitable vein
☐ Defective kit	☐ Bruising
☐ Equipment failure	☐ Vein collapsed during procedure
☐ Light-headedness	☐ Other-specify: _____

NCS Data collector ID:

**Place Adult Blood
Birth Mother
Collection DC Label
Here**

Part 2

Appendix 7-B

Adult Blood Data Collection Form—Birth Mother Field-by-Field Instructions

Appendix 7-B.
Adult Blood Data Collection Form—Birth Mother:
Field-by-Field Instructions

Adult Blood Data Collection Form—Birth Mother:
Field-by-Field Instructions

This form is to be completed with the collection of blood from the birth mother. Ideally the collection will occur prior to delivery and when blood is being collected from the study participant by hospital or birthing center staff. This form is to be completed by the staff performing the phlebotomy (i.e., blood collection). Instructions for completing each item on the form are provided in these field-by-field instructions.



58010



National Children's Study Adult Blood Data Collection Form Birth Mother

Birth

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☐ on the wrong answer.
- ➔ It is important to print clearly, using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study (NCS), we are asking you to obtain a sample of the mother's venous blood prior to delivery and after checking in at the delivery center. All of the supplies needed for this collection are contained in the NCS Adult Blood Collection-Birth Mother Kit.

1. Mother's name: _____

2. Mother's date of birth:

m	m	d	d	y	y	y	y

3. What is today's date?

				2	0		
m	m	d	d	y	y	y	y

4. Do you have hemophilia or any bleeding disorder?
¿Tiene hemofilia o algún problema de coagulación?

- ☐ Yes (END)
☐ No
☐ Don't know (END)
☐ Refused (END)

5. Do you take any blood thinning medications
such as Coumadin or warfarin?
¿Toma algún medicamento anticoagulante,
como Coumadin o warfarina?

- ☐ Yes (END)
☐ No
☐ Don't know (END)
☐ Refused (END)

Please see back of page.



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Place Mother's
Subject ID Label
Here

1. *Mother's name*—This field will be used only if hospital staff are completing the form. The mother's name should be written clearly in the space provided.
2. *Mother's date of birth*—Record the birth mother's date of birth. The month, day, and the year should be recorded (e.g., 02/07/1968).
3. *What is today's date?*—Record the date that the questions are asked. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002). The date of collection should not be recorded in advance of the visit to the hospital, birthing center, or participant's home.

Note: Questions 4 and 5 are asked of the study participant prior to the NCS blood draw.

4. *Do you have hemophilia or any bleeding disorder?*
 - Mark the box that corresponds to the participant's response.
 - If the participant answers "Yes" or "Don't know" or she refuses to answer, mark the corresponding box. No blood should be collected for NCS. The data collection form should be returned to the Site Office.
5. *Do you take any blood thinning medications, such as Coumadin or warfarin?*
 - Mark the box that corresponds to the participant's response.
 - If the participant answers "Yes" or "Don't know," or she refuses to answer, mark the corresponding box "No blood should be collected for NCS." The data collection form should be returned to the Site Office.



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6. Was this blood collected using the NCS Adult Blood Collection-Birth Mother Kit?

☐ Yes ☐ No

7. Did you use the NCS needle that was provided in the kit?

☐ Yes ☐ No

8. Date blood was collected:

		/			/	2	0		
m	m		d	d		y	y	y	y

9. Time that the blood was collected:

		:		
h	h		m	m

☐ a.m. ☐ p.m.

10. Were all four blood tubes collected?

☐ Yes (END) ☐ No

Please do not write in this box.

11. If no, indicate which tubes were NOT collected. (Mark all that apply.)

- ☐ 3-mL lavender prescreened
☐ Red top tube #1
☐ Red top tube #2
☐ Red top tube #3

12. Please choose the one reason that best describes why the blood was not collected. (Mark one.)

☐ Participant refusal	☐ Hematoma
☐ Parent/guardian refusal	☐ No suitable vein
☐ Defective kit	☐ Bruising
☐ Equipment failure	☐ Vein collapsed during procedure
☐ Light-headedness	☐ Other-specify: _____

NCS Data collector ID:

**Place Adult Blood
Birth Mother
Collection DC Label
Here**

6. *Was this blood collected using the NCS Adult Blood Collection-Birth Mother Kit?*
- If the blood was collected using the National Children’s Study (NCS) Adult Blood Collection-Birth Mother Kit, mark the box that corresponds to “Yes.”
 - If the blood was *not* collected using the NCS Adult Blood Collection-Birth Mother Kit, mark the box that corresponds to “No.”
7. *Did you use the NCS needle that was provided in the kit?*
- If the blood was collected using the NCS needle, mark the box that corresponds to “Yes.”
 - If the blood was *not* collected using the NCS needle, mark the box that corresponds to “No.”
8. *Date blood was collected*—Record the date that the blood draw was completed. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002). The date of collection should not be recorded in advance of the collection.
9. *Time that the blood was collected*—Record the time the blood draw was completed. Be sure to fill the space with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the blood draw was completed at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
10. *Were all four blood tubes collected?*
- If all four blood tubes were collected, mark the box that corresponds to “Yes.” This does not include partially collected tubes.
 - If all four tubes were *not* collected, mark the box that corresponds to “No” and complete Question 11 indicating which tubes were not collected.
11. *If no, indicate which tubes were NOT collected. (Mark all that apply.)*—If fewer than four tubes were collected, mark the boxes that correspond to the tubes not collected.



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6. Was this blood collected using the NCS Adult Blood Collection-Birth Mother Kit? ☐ Yes ☐ No

7. Did you use the NCS needle that was provided in the kit? ☐ Yes ☐ No

8. Date blood was collected:

m	m

 /

d	d

 /

2	0		
y	y	y	y

9. Time that the blood was collected:

h	h

 :

m	m

☐ a.m. ☐ p.m.

10. Were all four blood tubes collected? ☐ Yes (END) ☐ No

Please do not write in this box.

11. If no, indicate which tubes were NOT collected. (Mark all that apply.) ☐ 3-mL lavender prescreened

☐ Red top tube #1

☐ Red top tube #2

☐ Red top tube #3

12. Please choose the one reason that best describes why the blood was not collected. (Mark one.)

☐ Participant refusal

☐ Hematoma

☐ Parent/guardian refusal

☐ No suitable vein

☐ Defective kit

☐ Bruising

☐ Equipment failure

☐ Vein collapsed during procedure

☐ Light-headedness

☐ Other-specify: _____

NCS Data collector ID:

**Place Adult Blood
Birth Mother
Collection DC Label
Here**

12. *Please choose the one reason that best describes why the blood was not collected. (Mark one.)*—Mark the box that best describes why the blood was not collected.
- “Participant refusal”—Mark this box to indicate that the birth mother is unwilling to provide a blood specimen.
 - “Parent/guardian refusal”—Mark this box to indicate that the birth mother is younger than 18 years old and her parent or guardian refused to allow her to provide a blood specimen.
 - “Equipment failure”—Mark this box to indicate that the corresponding blood tube was not collected or filled completely because of a problem with the butterfly needle or tubes.
 - “Light-headedness”—Mark this box to indicate that the study participant reported a temporary feeling of lightheadedness, feeling faint, or dizzy. This does not require the completion of an Incident Report Form.
 - “Hematoma”—Mark this box to indicate that the participant experienced a localized mass of blood, usually clotted, in the venipuncture space or surrounding tissue. An Incident Report Form also must be completed.
 - “No suitable vein”—Mark this box to indicate that the study participant does not have a suitable vein to draw the blood specimen.
 - “Bruising”—Mark this box if the study participant experiences a localized collection of blood under the skin in the venipuncture space or the surrounding tissue. Bruising does not require the completion of an Incident Report Form.
 - “Vein collapsed during the procedure”—Mark this box if the vein collapses during the blood draw.
 - “Other—specify”—Mark this box to indicate that the blood was not collected for a reason other than those listed and specify the reason in the space provided. Capital block letters are the best to use.

NCS Data Collector ID

- Record the data collector ID of the phlebotomist who completes the form. If collection was completed by hospital staff, record the data collector ID of the NCS staff member reviewing the form for completeness.



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6. Was this blood collected using the NCS Adult Blood Collection-Birth Mother Kit?

☐ Yes ☐ No

7. Did you use the NCS needle that was provided in the kit?

☐ Yes ☐ No

8. Date blood was collected:

/ /
m m d d y y y y

9. Time that the blood was collected:

: ☐ a.m. ☐ p.m.
h h m m

10. Were all four blood tubes collected?

☐ Yes (END) ☐ No

Please do not write in this box.

11. If no, indicate which tubes were NOT collected. (Mark all that apply.)

- ☐ 3-mL lavender prescreened
☐ Red top tube #1
☐ Red top tube #2
☐ Red top tube #3

12. Please choose the one reason that best describes why the blood was not collected. (Mark one.)

☐ Participant refusal	☐ Hematoma
☐ Parent/guardian refusal	☐ No suitable vein
☐ Defective kit	☐ Bruising
☐ Equipment failure	☐ Vein collapsed during procedure
☐ Light-headedness	☐ Other-specify: _____

NCS Data collector ID:

**Place Adult Blood
Birth Mother
Collection DC Label
Here**

Subject Label

- If a subject label was not affixed prior to completion, obtain one from the visit coordinator's Biospecimen Folder and affix it to the bottom right corner of the data collection form. Immediately following the placement of the subject label on the form, both the mother's and the child's name must be removed completely from the front page of the form using a black permanent marker.

Kit Label (placed on the lower left-hand corner of the back side of the form)

- Open the Adult Blood Collection Kit and place the DC label in the appropriate place on the data collection form.

This page deliberately blank.

Part 2

Appendix 7-C

Cord Blood Data Collection Form

Appendix 7-C. Cord Blood Data Collection Form



National Children's Study Cord Blood Data Collection Form

Birth

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☒ on the wrong answer.
- ➔ It is important to print clearly, using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study (NCS), we are asking you to obtain a sample of the cord blood at delivery unless the cord blood is needed for clinical or private banking purposes. All the materials needed for this collection are included in the NCS Cord Blood Collection Kit. Please follow the instructions in the kit and complete all relevant items on this form.

1. Mother's name: _____

2. Child's name: _____

3. Mother's date of birth:

		/			/				
m	m		d	d		y	y	y	y

4. Child's date of birth:

		/			/	2	0		
m	m		d	d		y	y	y	y

5. Time of child's birth:

		:			☐ a.m.	☐ p.m.
h	h		m	m		

6. Child's gender:

☐ Male ☐ Female

7. Was the cord blood collected for the NCS? ☐ Yes (Go to Q9)

☐ No

Please see back of page.



BDCORD01.00EN

Place Child's
Subject ID Label
Here

Appendix 7-C Cord Blood Data Collection Form (continued)



8. Please choose one reason that best describes why the cord blood was not collected. (Mark one.)

- ☐ Parents chose to bank (END)
- ☐ Need for clinical purposes (END)
- ☐ Other banking program (END)
- ☐ Participant refusal (END)
- ☐ Parent/guardian refusal (END)
- ☐ Quantity not sufficient (END)
- ☐ Defective kit (END)
- ☐ Other-specify: _____ (END)

Please do not write in this box.

9. Date the cord blood was collected:

m	m	d	d	y	y	y	y

10. Time the cord blood was collected:

		:			
h	h		m	m	

☐ a.m.
☐ p.m.

11. Where was the sample collected?

- ☐ In utero
- ☐ Ex utero

12. What type of delivery was performed?

- ☐ Vaginal
- ☐ Cesarean

NCS Data collector ID:

Place Cord Blood
Collection
DC Label Here

Part 2

Appendix 7-D

Cord Blood Data Collection Form: Field-by-Field Instructions

Appendix 7-D.
Cord Blood Data Collection Form:
Field-by-Field Instructions

Cord Blood Data Collection Form:
Field-by-Field Instructions

This form is to be completed with the collection of cord blood from the birth mother. This form is to be completed by the hospital collection staff and/or the birth visit biospecimen coordinator. Instructions for completing each item on the form are provided in this field-by-field instruction.



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National Children's Study Cord Blood Data Collection Form

Birth

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☐ on the wrong answer.
- ➔ It is important to print clearly, using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study (NCS), we are asking you to obtain a sample of the cord blood at delivery unless the cord blood is needed for clinical or private banking purposes. All the materials needed for this collection are included in the NCS Cord Blood Collection Kit. Please follow the instructions in the kit and complete all relevant items on this form.

1. Mother's name: _____

2. Child's name: _____

3. Mother's date of birth:

m	m	d	d	y	y	y	y

4. Child's date of birth:

				2	0		
m	m	d	d	y	y	y	y

5. Time of child's birth:

		:			☐ a.m.	☐ p.m.
h	h		m	m		

6. Child's gender:

☐ Male ☐ Female

7. Was the cord blood collected for the NCS? ☐ Yes (Go to Q9)

☐ No

Please see back of page.



BDCORD01.00EN

Place Child's
Subject ID Label
Here

1. *Mother's name*—This field will be used only if hospital staff are completing the form. The mother's name should be written clearly in the space provided.
2. *Child's name*— This field will be used only if hospital staff are completing the form. The child's name should be written clearly in the space provided.
3. *Mother's date of birth*—Record the mother's date of birth. The month, day, and the year should be recorded (e.g., 02/07/1968).
4. *Child's date of birth*—Record the child's date of birth. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
5. *Time of child's birth*—Record the time of the child's birth. Be sure to fill the space with a zero when necessary and to mark the box to indicate "a.m." or "p.m." For example, if the child was born at 2:05 p.m., record "02:05" and mark the box corresponding to "p.m."
6. *Child's gender*:
 - If the child is male, mark that box that corresponds to "Male."
 - If the child is female, mark the box that corresponds to "Female."
7. *Was the cord blood collected for the NCS?*
 - If the cord blood was collected for NCS, mark the box that corresponds to "Yes" and continue with Question 9.
 - If the cord blood was *not* collected for NCS, mark the box that corresponds to "No."



8. Please choose one reason that best describes why the cord blood was not collected. (Mark one.)

- ☐ Parents chose to bank (END)
- ☐ Need for clinical purposes (END)
- ☐ Other banking program (END)
- ☐ Participant refusal (END)
- ☐ Parent/guardian refusal (END)
- ☐ Quantity not sufficient (END)
- ☐ Defective kit (END)
- ☐ Other-specify: _____ (END)

Please do not write in this box.

9. Date the cord blood was collected:

		/			/	2	0		
m	m		d	d		y	y	y	y

10. Time the cord blood was collected:

		:			☐ a.m.
h	h		m	m	☐ p.m.

11. Where was the sample collected?

- ☐ In utero
- ☐ Ex utero

12. What type of delivery was performed?

- ☐ Vaginal
- ☐ Cesarean

NCS Data collector ID:

**Place Cord Blood
Collection
DC Label Here**

8. *Please choose one reason that best describes why the cord blood was not collected (Mark one.)*—Mark the box that best describes why the cord blood was not collected.
- “Parents chose to bank”—Mark this box to indicate that the parents have chosen to participate in a private cord blood banking program.
 - “Need for clinical purposes”—Mark this box to indicate that cord blood was not collected because the blood was needed for clinical purposes other than cord blood banking.
 - “Other banking program”—Mark this box to indicate that the parents have chosen to participate in a public cord blood banking program.
 - “Participant refusal”—Mark this box to indicate that the birth mother is unwilling to provide a cord blood specimen.
 - “Parent/guardian refusal”—Mark this box to indicate that the birth mother is younger than 18 years old and her parent or guardian refused to allow her to provide a cord blood specimen.
 - “Quantity not sufficient”—Mark this box to indicate that the cord blood collection was attempted but the quantity of blood was insufficient to allow any blood to be collected in the cord blood bag.
 - “Defective kit”—Mark this box to indicate that the specimen was not collected because of a problem with the Cord Blood Collection Kit. This includes not having the appropriate supplies available at the collection site.
 - “Other—specify”—Mark this box to indicate that the cord blood was not collected for a reason other than those listed and specify the reason in the space provided. Capital block letters are the best to use.
9. *Date the cord blood was collected*—Record the date that the cord blood collection was completed. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
10. *Time the cord blood was collected*—Record the time the cord blood collection was completed. Be sure to fill the space with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the collection was completed at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”



8. Please choose one reason that best describes why the cord blood was not collected. (Mark one.)

- ☐ Parents chose to bank (END)
- ☐ Need for clinical purposes (END)
- ☐ Other banking program (END)
- ☐ Participant refusal (END)
- ☐ Parent/guardian refusal (END)
- ☐ Quantity not sufficient (END)
- ☐ Defective kit (END)
- ☐ Other-specify: _____ (END)

Please do not write in this box.

9. Date the cord blood was collected:

		/			/	2	0		
m	m		d	d		y	y	y	y

10. Time the cord blood was collected:

		:			☐ a.m.
h	h		m	m	☐ p.m.

11. Where was the sample collected?

- ☐ In utero
- ☐ Ex utero

12. What type of delivery was performed?

- ☐ Vaginal
- ☐ Cesarean

NCS Data collector ID:

Place Cord Blood
Collection
DC Label Here

11. *Where was the sample collected?*
- If the cord blood was collected prior to delivery of the placenta, mark the box that corresponds to “In utero.”
 - If the cord blood was collected after delivery of the placenta, mark the box that corresponds to “Ex utero.”
12. *What type of delivery was performed?*
- If the delivery was a vaginal delivery, mark the box that corresponds to “Vaginal.”
 - If the delivery was a Cesarean (C-section), mark the box that corresponds to “Cesarean.”

NCS Data Collector ID

- Record the data collector ID of the NCS staff who completes the form. If collection form completion was done by hospital staff, record the data collector ID of the NCS staff member reviewing the form for completeness.

Subject Label

- If a subject label was not affixed prior to completion, obtain one from the visit coordinator’s Biospecimen Folder and affix it to the bottom right corner of the data collection form. Immediately following the placement of the subject label on the form, both the mother’s and the child’s name must be removed completely from the front page of the form by using a black permanent marker.

Kit Label (placed on the lower left-hand corner of the back side of the form)

- Open the Cord Blood Collection Kit and place the DC label in the appropriate place on the data collection form.

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Part 2

Appendix 7-E

Cord Blood Collection Instructions

Appendix 7-E.
Cord Blood Collection Instructions

National Children's Study
Cord Blood Collection Instructions

The Cord Blood Collection Kit contains the following materials:

- 1 Pall sterile cord blood collection bag
 - 2 Betadine swabs
 - 1 Biohazard transport bag 6X9, prelabeled
 - 1 Absorbent pad (250 ml)
 - 1 Cord blood bag crimping device
 - 1 Adhesive label for the Cord Blood Data Collection Form (DC label)
 - 1 Adhesive label for the Transmittal Form (TM label)
 - 1 Extra adhesive label for the biohazard transport bag (EX label)
-

To collect the cord blood, please follow these instructions:

1. Use powder-free gloves when collecting the sample.
2. Collect the cord blood prior to delivery of the placenta if possible. If this is not possible, collect the cord blood after the placenta has been delivered.
3. Collect the cord blood according to the manufacturer instructions (steps 1–4) on the back of this page. Refer to the cord blood collection bag diagram as needed.
4. Make a knot in the tubing or otherwise seal the tubing directly below the Spike Entry Port, close to the Sample Port.
5. Use the cord blood bag crimping device provided in the kit to crimp the tubing just above the knot.
6. Cut the tubing directly above the crimping device to remove excess tubing.
7. Detach and discard the needle and excess tubing according to standard procedures.
8. Invert the bag back and forth to thoroughly mix the cord blood with the anticoagulant.
9. Place the sterile cord blood collection bag containing the sample in the prelabeled biohazard transport bag along with the absorbent pad. If the biohazard transport bag is not prelabeled, affix the EX label contained in the kit onto the biohazard transport bag.
10. Seal the biohazard transport bag and place the bag at 2–8 °C within 2 hours of collection.
11. Complete the Cord Blood Data Collection Form. Place the DC label contained in the kit on the data collection form in the space indicated.
12. Keep the unused collection kit items with the completed form until the National Children's Study data collector picks up the sample.

Thank you for collecting the sample!

CORDIN01.00EN

Appendix 7-E. Cord Blood Collection Instructions (continued)



Medical

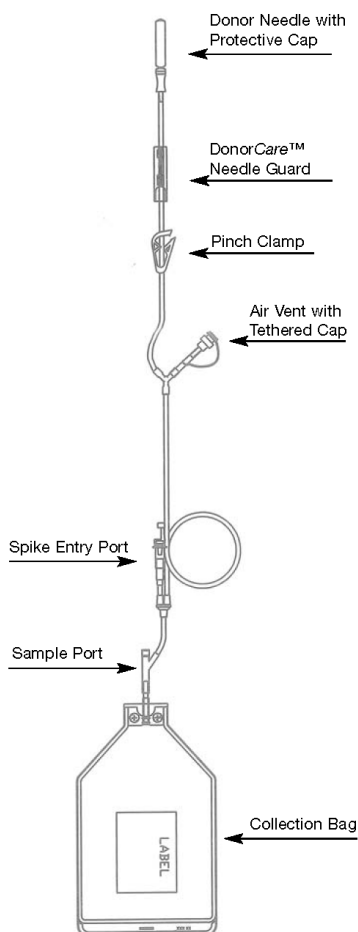
Pall Corporation
East Hills, NY 11548, USA
www.pall.com/medical

Code 791-08

Sterile Cord Blood Collection Unit **Anticoagulant Citrate Phosphate Dextrose** **Solution (CPD)**

For collection of up to 210 ml of umbilical cord blood. Use aseptic technique. Contents inside overwrap pouch, within the foil envelope, are sterile and acceptable for use in a sterile field if pouch is unopened and undamaged; visual inspection to confirm the integrity of overwrap pouch should be performed. Do not use if the package is damaged or seal is incomplete. Precaution: Use only if solution is clear. Sterile, nonpyrogenic fluid path. Sterilized by steam. Rx only. This product is free of natural rubber latex.

Instructions for Use



1. Ensure DonorCare™ Needle Guard (DCNG) is positioned on the tubing between the needle hub and Pinch Clamp. Engage Pinch Clamp. Ensure tethered cap is placed securely on the air vent.
2. Using aseptic technique, insert needle into umbilical vein, disengage Pinch Clamp to collect cord blood, mixing frequently, according to standard procedures. **Note:** Making multiple punctures of the umbilical cord to increase collection volume may increase the risk of contamination.
3. Upon completion of collection, engage Pinch Clamp then withdraw needle from umbilical vein. Slide the DCNG midway over the needle hub. While holding the sides of DCNG near front, grasp tubing and pull smoothly, pulling needle into the DCNG until it locks into place. Confirm that needle is locked by listening for the second click as the needle is drawn into the DCNG. Ensure that tubing cannot be pulled through DCNG.
4. Place the bag on a work surface. While holding the tubing above the bag, open the tethered cap on the air vent. Allow the blood to drain from the tubing into the bag.
5. When the tubing has been drained, hold tubing vertical and seal tubing directly below the Y-piece with air vent.*
6. Detach and discard needle, DCNG, Pinch Clamp, Air Vent and tubing according to standard procedures.*
7. Determine amount of anticoagulated blood collected. If required, add sedimenting agent to CPD anticoagulated blood through Sample Port using a syringe according to standard procedures.
8. Mix well. Take care to strip and mix any blood in tubing.
9. Load bag into centrifuge cup. It is suggested that a means of support is used to prevent bag from collapsing and to reduce wrinkles.
10. Centrifuge according to standard procedures to obtain mononuclear cell-rich plasma.

Note: Do not irradiate collected cord blood or components.

* During processing, always observe the following precautions:

1. Sealing should be done in a manner that avoids fluid splatter.
2. Always dispose of blood-contaminated products in a manner consistent with established BIOHAZARD safety procedures.

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Produced under license from ThermoGenesis Corp.

Better Blood, Better Care.™

147791081, issued Dec. 2007

Part 2

Appendix 7-F

Placenta and Umbilical Cord Collection Instructions

Appendix 7-F.
Placenta and Umbilical Cord Collection Instructions

National Children's Study
Placenta and Umbilical Cord Collection Instructions

These instructions are for the collection of fresh (unfixed) placenta only. For the purpose of this document, the term "placenta" refers to the placenta, the placental membrane, and attached umbilical cord. Fresh placenta must be collected within 2 hours of delivery, preferably after the cord blood is collected.

The Placenta and Umbilical Cord Collection Kit contains the following materials:

- 1 - 12 X 12 resealable formalin resistant polyethylene bag, *unlabeled*
 - 1 - 12 X 12 resealable formalin resistant polyethylene bag, *prelabeled*
 - 1 Absorbent pad (500 mL)
 - 1 Adhesive label for the Placenta and Umbilical Cord Data Collection Form (DC label)
 - 1 Adhesive label for the Transmittal form (TM label)
 - 1 Extra adhesive label for the outer collection bag (EX label)
-

To collect the fresh (unfixed) placenta, please follow these instructions.

1. Use powder-free gloves when handling the placenta.
2. Place the placenta in the unlabeled 12 X 12 resealable polyethylene bag, keeping the specimen as flat as possible.
3. Seal the bag completely. Fold the top of the bag over. Using packing tape or chemically resistant tape, tape the top that has been folded over to the rest of the bag. Make sure that the tape goes all the way around the bag.
4. Place the unlabeled 12 X 12 bag inside the prelabeled 12 X 12 resealable polyethylene bag and seal it securely.
5. Place the double-bagged specimen at 2-8 °C within 2 hours of collection.
6. Complete the Placenta and Umbilical Cord Data Collection Form. Place the DC label contained in the kit on the data collection form in the space indicated.
7. Keep the unused collection kit items with the completed form until the National Children's Study data collector picks up the sample.

If the placenta is fixed, an NCS data collector will pick up the specimen from the pathology or histology laboratory. Please do not use the above instructions for the collection of fixed placenta specimens.

Thank you for collecting the sample!

PLUMIN01.00EN

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Part 2

Appendix 7-G

Placenta and Umbilical Cord Data Collection Form

Appendix 7-G. Placenta and Umbilical Cord Data Collection Form


 56376



**National Children's Study
Placenta and Umbilical Cord
Data Collection Form**

Birth

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☐ on the wrong answer.
- ➔ It is important to print clearly, using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study (NCS), we are asking you to collect the placenta and attached umbilical cord. All the materials needed for this collection are included in the NCS Placenta and Umbilical Cord Collection Kit. Please follow the instructions in the kit and complete all relevant items on this form.

1. Mother's name: _____

2. Child A's name: _____

3. Child B's name: _____

4. Mother's date of birth:

/

/

m m
d d
y y y y

5. Child A's date of birth:

/

/

2

0

m m
d d
y y y y

6. Time of Child A's birth:

:

h h
m m

☐ a.m.

☐ p.m.

7. Participant ID for Child A:

-

8. Child B's date of birth:

/

/

2

0

m m
d d
y y y y

9. Time of Child B's birth:

:

h h
m m

☐ a.m.

☐ p.m.

10. Participant ID for Child B:

-


 PLACDF01.00EN

**Place Mother's
Subject ID Label
Here**

Appendix 7-G. Placenta and Umbilical Cord Data Collection Form (continued)



11. Was the placenta collected?

☐ Yes (Go to 13) ☐ No

12. If not, choose one reason that best describes why the placenta was not collected. (Mark one)

☐ Participant refusal (END)

☐ Defective kit (END)

☐ Parent/guardian refusal (END)

☐ Other-specify: _____ (END)

13. Time of collection of placenta and cord:

:
h h m m

☐ a.m. ☐ p.m.

Please do not write in this box.

14. Date the placenta and cord were placed at 2-8 °C:

/ /
m m d d y y y y

15. Time the placenta and cord were placed at 2-8 °C:

:
h h m m

☐ a.m. ☐ p.m.

16. Is the placenta specimen fresh or fixed?

☐ Fresh (Go to 20)

☐ Fixed

17. Which reason best describes why the specimen was fixed?

☐ Placenta was not released within 5 days of delivery

☐ Tissue fixed as part of pathology lab evaluation

Appendix 7-G. Placenta and Umbilical Cord Data Collection Form (continued)



56376

18. Date the specimen was fixed:

m	m	d	d	y	y	y	y

19. Time the specimen was fixed:

		:		
h	h		m	m

☐ a.m. ☐ p.m.

20. What kind of specimen was collected?

- ☐ Whole placenta (END)
☐ Partial placental tissue

21. If partial placental tissue was collected, using the space below please indicate

- Location where samples were taken using "star"
- Point of cord insertion using a "circle"
- The location of any accessory lobes (if applicable)
- Any irregularities of the disk outline (if applicable)



NCS Data collector ID:

Place Placenta &
Umbilical Cord
Collection DC Label
Here

3

Place Mother's
Subject ID Label
Here

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Part 2

Appendix 7-H

Placenta and Umbilical Cord Data Collection Form: Field-by-Field Instructions

Appendix 7-H.
Placenta and Umbilical Cord Data Collection Form:
Field-by-Field Instructions

Placenta and Umbilical Cord Data Collection Form:
Field-by-Field Instructions

This form is to be completed with the collection of placenta and umbilical cord from the birth mother. For multiple births, a separate form should be completed for each placenta. This form is to be completed by the hospital collection staff, pathology laboratory staff, and/or the birth visit biospecimen coordinator. Instructions for completing each item on the form are provided in this field-by-field instruction.



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National Children's Study Placenta and Umbilical Cord Data Collection Form

Birth

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☒ on the wrong answer.
- ➔ It is important to print clearly, using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study (NCS), we are asking you to collect the placenta and attached umbilical cord. All the materials needed for this collection are included in the NCS Placenta and Umbilical Cord Collection Kit. Please follow the instructions in the kit and complete all relevant items on this form.

1. Mother's name: _____

2. Child A's name: _____

3. Child B's name: _____

4. Mother's date of birth:

		/			/				
m	m		d	d		y	y	y	y

5. Child A's date of birth:

		/			/	2	0		
m	m		d	d		y	y	y	y

6. Time of Child A's birth:

		:			☐ a.m.	☐ p.m.
h	h		m	m		

7. Participant ID for Child A:

						-	

8. Child B's date of birth:

		/			/	2	0		
m	m		d	d		y	y	y	y

9. Time of Child B's birth:

		:			☐ a.m.	☐ p.m.
h	h		m	m		

10. Participant ID for Child B:

						-	



PLACDF01.00EN

Place Mother's
Subject ID Label
Here

1. *Mother's name*—This field will be used only if hospital staff are completing the form. The mother's name should be written clearly in the space provided.
2. *Child A's name*—This field will be used only if hospital staff are completing the form. The child's name should be written clearly in the space provided.
3. *Child B's name*—This field will be used only if hospital staff are completing the form. The child's name should be written clearly in the space provided.
4. *Mother's date of birth*—Record the mother's date of birth. The month, day, and the year should be recorded (e.g., 02/07/1968).
5. *Child A's date of birth*—Record the child's date of birth. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
6. *Time of Child A's birth*—Record the child's time of birth. Be sure to fill the space with a zero when necessary and to mark the box to indicate "a.m." or "p.m." For example, if the child was born at 2:05 p.m., record "02:05" and mark the box corresponding to "p.m."
7. *Participant ID for Child A*—Record the participant identification number (ID) for Child A.
8. *Child B's date of birth*—Record the child's date of birth. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
9. *Time of Child B's birth*—Record the child's time of birth. Be sure to fill the space with a zero when necessary and to mark the box to indicate "a.m." or "p.m." For example, if the child was born at 2:05 p.m., record "02:05" and mark the box corresponding to "p.m."
10. *Participant ID for Child B*—Record the participant ID for Child B.



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11. Was the placenta collected?

☐ Yes (Go to 13) ☐ No

12. If not, choose one reason that best describes why the placenta was not collected. (Mark one)

☐ Participant refusal (END)

☐ Defective kit (END)

☐ Parent/guardian refusal (END)

☐ Other-specify: _____ (END)

13. Time of collection of placenta and cord:

:
h h m m

☐ a.m. ☐ p.m.

Please do not write in this box.

14. Date the placenta and cord were placed at 2-8 °C:

/ /
m m d d y y y y

15. Time the placenta and cord were placed at 2-8 °C:

:
h h m m

☐ a.m. ☐ p.m.

16. Is the placenta specimen fresh or fixed?

☐ Fresh (Go to 20)

☐ Fixed

17. Which reason best describes why the specimen was fixed?

☐ Placenta was not released within 5 days of delivery

☐ Tissue fixed as part of pathology lab evaluation

11. *Was the placenta collected?*
 - If the placenta was collected, mark the box that corresponds to “Yes” and continue with Question 13.
 - If the placenta was *not* collected, mark the box that corresponds to “No.”
12. *If not, choose one reason that best describes why the placenta was not collected. (Mark one)*—Mark the box that corresponds to the reason the placenta was not collected.
 - “Participant refusal”—Mark this box to indicate that the birth mother is unwilling to allow her placenta to be collected.
 - “Parent/guardian refusal”—Mark this box to indicate that the birth mother is younger than 18 years old and her parent or guardian refused to allow her placenta to be collected.
 - “Defective kit”—Mark this box to indicate that the specimen was not collected because of a problem with the Placenta and Umbilical Collection Kit. This includes not having the appropriate supplies available at the collection site.
 - “Other—specify”—Mark this box to indicate that the placenta was not collected for a reason other than those listed and specify the reason in the space provided. Capital block letters are the best to use.
13. *Time of collection of placenta and cord*—Record the time the placenta and cord were collected. Be sure to fill the space with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the placenta was collected at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
14. *Date the placenta and cord were placed at 2–8 °C*—Record the date that the placenta and umbilical cord were placed at 2–8 °C. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
15. *Time the placenta and cord were placed at 2–8 °C*—Record the time that the placenta and umbilical cord were placed at 2–8 °C. Be sure to fill the space with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the placenta and cord were placed at 2–8°C at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
16. *Is the placenta specimen fresh or fixed?*
 - If fresh placenta is collected, mark the box that corresponds to “Fresh” and continue with Question 20.
 - If fixed placenta is collected, mark the box that corresponds to “Fixed.”



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11. Was the placenta collected?

☐ Yes (Go to 13) ☐ No

12. If not, choose one reason that best describes why the placenta was not collected. (Mark one)

☐ Participant refusal (END)

☐ Defective kit (END)

☐ Parent/guardian refusal (END)

☐ Other-specify: _____ (END)

13. Time of collection of placenta and cord:

:
h h m m

☐ a.m. ☐ p.m.

Please do not write in this box.

14. Date the placenta and cord were placed at 2-8 °C:

/ /
m m d d y y y y

15. Time the placenta and cord were placed at 2-8 °C:

:
h h m m

☐ a.m. ☐ p.m.

16. Is the placenta specimen fresh or fixed?

☐ Fresh (Go to 20)

☐ Fixed

17. Which reason best describes why the specimen was fixed?

☐ Placenta was not released within 5 days of delivery

☐ Tissue fixed as part of pathology lab evaluation

17. *Which reason best describes why the specimen was fixed?*
- “Placenta was not released within 5 days of delivery”—Mark this box if NCS staff requested fixing of placenta because hospital, medical staff, or the participant would not release the placenta before 5 days post delivery.
 - “Tissue fixed as part of pathology lab evaluation”—Mark this box if the placenta was sent to pathology after delivery by hospital or medical staff because of clinical indications.



56376

18. Date the specimen was fixed:

		/			/	2	0		
m	m		d	d		y	y	y	y

19. Time the specimen was fixed:

		:			
h	h		m	m	

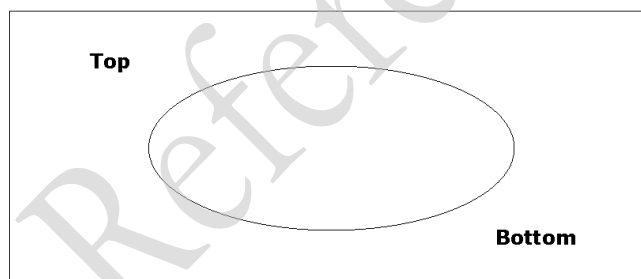
☐ a.m. ☐ p.m.

20. What kind of specimen was collected?

- ☐ Whole placenta (END)
- ☐ Partial placental tissue

21. If partial placental tissue was collected, using the space below please indicate

- Location where samples were taken using "star"
- Point of cord insertion using a "circle"
- The location of any accessory lobes (if applicable)
- Any irregularities of the disk outline (if applicable)



NCS Data collector ID:

Place Placenta &
Umbilical Cord
Collection DC Label
Here

3

Place Mother's
Subject ID Label
Here

18. *Date the specimen was fixed*—Record the date that the placenta was fixed. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
19. *Time the specimen was fixed*—Record the time that the specimen was fixed. Be sure to fill the space with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the sample is fixed at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
20. *What kind of specimen was collected?*
 - If the entire placenta and the umbilical cord were collected, mark the box that corresponds to “Whole placenta.”
 - If the collection is limited to pieces of the placenta and/or umbilical cord, mark the box that corresponds to “Partial placental tissue.” This does not include tissue blocks.
21. *If partial placental tissue was collected, using the space below please indicate:*
 - Location where samples were taken using “star”
 - Point of cord insertion using a “circle”
 - The location of any accessory lobes (if applicable)
 - Any irregularities of the disk outline (if applicable)

This portion of the form should be completed by the pathology lab technician or histologist or the data collector with assistance from the pathology lab technician or histologist. The data collector is responsible for making sure that all of the applicable features are noted on the drawing.

NCS Data Collector ID

- Record the data collector ID of the NCS staff member who completes the form. If the form was completed by hospital staff, record the data collector ID of the NCS staff member reviewing the form for completeness.

Subject Label

- If a subject label was not affixed prior to completion, obtain one from the visit coordinator’s Biospecimen Folder and affix it to the bottom right corner of the data collection form. Immediately following the placement of the subject label on the form, both the mother’s and the child’s name must be removed completely from the front page of the form by using a black permanent marker.

Kit Label (placed on the lower left hand corner of the back side of the form)

- Open the Placenta and Umbilical Cord Collection Kit and place the DC label in the appropriate place on the data collection form.

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Part 2

Appendix 7-I

Infant Blood Spot Data Collection Form

Appendix 7-I. Infant Blood Spot Data Collection Form



37364



National Children's Study Infant Blood Spot Data Collection Form

Birth

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☐ on the wrong answer.
- ➔ It is important to print clearly, using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study (NCS), we are asking you to obtain capillary blood from the infant in conjunction with the routine heel stick. DO NOT perform an additional heel stick to collect the NCS blood spots. All the materials needed for this collection are included in the NCS Infant Blood Spot Collection Kit. Please follow the instructions in the kit and complete all relevant items on this form.

1. Mother's name: _____

2. Child's name: _____

3. Mother's date of birth:

m	m		d	d		y	y	y	y

4. Child's date of birth:

m	m		d	d		2	0		
						y	y	y	y

5. Time of child's birth:

h	h	:	m	m

☐ a.m. ☐ p.m.

6. Child's gender:

☐ Male ☐ Female

7. Has the child received a blood transfusion?

☐ Yes ☐ No

8. Date heel stick was performed:

m	m		d	d		2	0		
						y	y	y	y

9. Time heel stick was performed:

h	h	:	m	m

☐ a.m. ☐ p.m.

Please see back of page.



INBSDC01.00EN

Place Child's
Subject ID Label
Here

Appendix 7-I.
Infant Blood Spot Data Collection Form (continued)



37364

10. How was the blood obtained?

- ☐ Free flowing
☐ Milked

11. Number of spots filled on Protein Saver Card (0-4):

12. Number of spots filled on FTA Card (0-2):

13. If fewer than 6 total spots were filled (both cards completed), choose one reason that best describes why. (Mark one.)

- ☐ Participant refusal
☐ Parent/guardian refusal
☐ Quantity not sufficient
☐ Defective kit
☐ Other-specify: _____

Please do not write in this box.

NCS Data collector ID:

Place Infant Blood
Spot Collection
DC Label Here

Part 2

Appendix 7-J

Infant Blood Spot Data Collection Form: Field-by-Field Instructions

Appendix 7-J.
Infant Blood Spot Data Collection Form:
Field-by-Field Instructions

Infant Blood Spot Data Collection Form:
Field-by-Field Instructions

This form is to be completed with the collection of blood spot cards from the infant. Instructions for completing each item on the form are provided in this field-by-field instruction.



37364



National Children's Study Infant Blood Spot Data Collection Form

Birth

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☒ on the wrong answer.
- ➔ It is important to print clearly, using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study (NCS), we are asking you to obtain capillary blood from the infant in conjunction with the routine heel stick. DO NOT perform an additional heel stick to collect the NCS blood spots. All the materials needed for this collection are included in the NCS Infant Blood Spot Collection Kit. Please follow the instructions in the kit and complete all relevant items on this form.

1. Mother's name: _____

2. Child's name: _____

3. Mother's date of birth:

		/			/				
m	m		d	d		y	y	y	y

4. Child's date of birth:

		/			/	2	0		
m	m		d	d		y	y	y	y

5. Time of child's birth:

		:			☐ a.m.	☐ p.m.
h	h		m	m		

6. Child's gender:

☐ Male ☐ Female

7. Has the child received a blood transfusion?

☐ Yes ☐ No

8. Date heel stick was performed:

		/			/	2	0		
m	m		d	d		y	y	y	y

9. Time heel stick was performed:

		:			☐ a.m.	☐ p.m.
h	h		m	m		

Please see back of page.



INBSDC01.00EN

Place Child's
Subject ID Label
Here

1. *Mother's name*—This field will be used only if hospital staff are completing the form. The mother's name should be written clearly in the space provided.
2. *Child's name*—This field will be used only if hospital staff are completing the form. The child's name should be written clearly in the space provided.
3. *Mother's date of birth*—Record the mother's date of birth. The month, day, and the year should be recorded (e.g., 02/07/1968).
4. *Child's date of birth*—Record the child's date of birth. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
5. *Time of child's birth*—Record the time of the child's birth. Be sure to fill the space with a zero when necessary and to mark the box to indicate "a.m." or "p.m." For example, if the child was born at 2:05 p.m., record "02:05" and mark the box corresponding to "p.m."
6. *Child's gender*:
 - If the child is male, mark that box that corresponds to "Male."
 - If the child is female, mark the box that corresponds to "Female."
7. *Has the child received a blood transfusion?*
 - If the child has had a blood transfusion, mark that box that corresponds to "Yes."
 - If the child has *not* had a blood transfusion mark that box that corresponds to "No."
8. *Date heel stick was performed*—Record the date the heel stick was performed. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
9. *Time heel stick was performed*—Record the time the heel stick was performed. Be sure to fill the space with a zero when necessary and to mark the box to indicate "a.m." or "p.m." For example, if the heel stick was performed at 2:05 p.m., record "02:05" and mark the box corresponding to "p.m."



10. How was the blood obtained?

- ☐ Free flowing
☐ Milked

11. Number of spots filled on Protein Saver Card (0-4):

12. Number of spots filled on FTA Card (0-2):

13. If fewer than 6 total spots were filled (both cards completed), choose one reason that best describes why. (Mark one.)

- ☐ Participant refusal
☐ Parent/guardian refusal
☐ Quantity not sufficient
☐ Defective kit
☐ Other-specify: _____

Please do not write in this box.

NCS Data collector ID:

**Place Infant Blood
Spot Collection
DC Label Here**

10. *How was the blood obtained?*—Mark the correct box.
 - If the blood flowed freely from the heel without having to massage the foot, mark the box that corresponds to “Free flowing.”
 - If it is necessary to massage the foot to obtain blood from the heel, mark the box that corresponds to “Milked.”
11. *Number of spots filled on Protein Saver Card (0–4)*—Record the number of spots (0–4) filled on the Protein Saver Card.
12. *Number of spots filled on FTA Card (0–2)*—Record the number of spots (0–2) filled on the FTA Mini Card.
13. *If fewer than six total spots were filled (both cards completed), choose one reason that best describes why. (Mark one.)*
 - “Participant refusal”—Mark this box to indicate that the birth mother is unwilling to allow a sample of the child’s blood to be collected.
 - “Parent/guardian refusal”—Mark this box to indicate that the birth mother is younger than 18 years old and her parent or guardian refused to allow a sample of the child’s blood to be collected.
 - “Quantity not sufficient” —Mark this box to indicate that there was not enough blood for six blood spots on the two collection cards. Infants *will not* have a second heel stick to accommodate NCS collections.
 - “Defective kit”—Mark this box to indicate that the specimen was not collected because of a problem with the Infant Blood Spot Collection Kit. This includes not having the appropriate supplies available at the collection site.
 - “Other—specify”—Mark this box to indicate that the blood was not collected for a reason other than those listed and specify the reason in the space provided. Capital block letters are the best to use.

NCS Data Collector ID

- Record the data collector ID of the NCS staff member who completes the form. If the form and collection were completed by hospital staff, record the data collector ID of the NCS staff member reviewing the form for completeness.

Subject Label

- If a subject label was not affixed prior to completion, obtain one from the visit coordinator’s Biospecimen Folder and affix it to the bottom right corner of the data collection form. Immediately following the placement of the subject label on the form, both the mother’s and the child’s name must be removed completely from the front page of the form by using a black permanent marker.

Kit Label (placed on the lower left-hand corner of the back side of the form)

- Open the Infant Blood Spot Collection Kit and place the DC label in the appropriate place on the data collection form.

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Part 2

Appendix 7-K

Infant Blood Spot Collection Instructions

Appendix 7-K. Infant Blood Spot Collection Instructions

National Children's Study Infant Blood Spot Collection Instructions

The Infant Blood Spot Collection Kit contains the following materials:

- 1 Whatman 903 Protein saver card, prelabeled
 - 1 FTA Mini card, prelabeled
 - 1 Adhesive label for Infant Blood Spot Data Collection Form (DC label)
 - 1 Adhesive label for Transmittal Form (TM label)
-

To collect the infant blood spots, please follow the instructions below:

1. Use powder-free gloves when handling the blood spot cards.
2. Do NOT touch the sample area on the blood spot cards.
3. Immediately after blood spots are obtained from the child for routine testing, use the two National Children's Study (NCS) cards provided in the kit to collect blood spots from the same heel stick, following steps 4 and 5 below. Do NOT perform an additional heel stick to collect the NCS blood spots.
4. Follow the instructions indicated on the cards to open each card.
5. When collecting the blood spots, alternate between the Whatman 903 card and the FTA Mini card to ensure a minimum of one spot is collected on each card. Continue to alternate between the cards until all blood spots are collected or until blood flow stops. It may not be possible to fill some or all of the spots on the cards. If blood flow stops before all the spots are collected, do NOT perform an additional heel stick to collect the remaining blood spots.
6. Complete the Infant Blood Spot Data Collection Form. Place the DC label contained in the kit on the data collection form in the space indicated.
7. Allow the cards to air dry for a minimum of 3-4 hours. Once the cards are dry, fold the card covers over the samples and store them at room temperature until they are picked up by the NCS data collector.
8. Please keep the other collection kit label with the cards until the NCS data collector picks up the cards.

Thank you for collecting the sample!

INBSIN01.00EN

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Part 2

Appendix 7-L

Meconium Data Collection Form

Appendix 7-L. Meconium Data Collection Form



Draft



National Children's Study Meconium Data Collection Form

Birth

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☒ on the wrong answer.
- ➔ It is important to print clearly, using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study (NCS), we are asking you to collect at least one diaper containing the first available meconium. All the materials needed for this collection are included in the NCS Meconium Collection Kit. Please follow the instructions included in the kit and complete all relevant items on this form.

1. Mother's name: _____

2. Child's name: _____

3. Mother's date of birth:

m	m		d	d		y	y	y	y

4. Child's date of birth:

m	m		d	d		2	0		
						y	y	y	y

5. Time of child's birth:

h	h	:	m	m			
				☐ a.m. ☐ p.m.			

6. Child's gender:

☐ Male ☐ Female

7. Were any diapers containing meconium collected?

☐ Yes (Go to Q9) ☐ No

8. If not, please choose one reason that best describes why meconium was not collected (Mark one.)

- ☐ Defective Kit (END)
☐ Participant refusal (END)
☐ Parent/guardian refusal (END)
☐ Quantity not sufficient
☐ Other-specify: _____

9. How many diapers were collected?



MECODF00.03EN

**Place Child's
Subject ID Label
Here**

REVIEW

Appendix 7-L. Meconium Data Collection Form (continued)



Draft

10. Date the first diaper was collected:

m	m		d	d		2	0		
m m			d d			y y y y			

11. Time the first diaper was collected:

h	h	:	m	m		a.m.	p.m.
h h			m m				

12. Date the second diaper was collected:
(If applicable)

m	m		d	d		2	0		
m m			d d			y y y y			

13. Time the second diaper was collected:
(If applicable)

h	h	:	m	m		a.m.	p.m.
h h			m m				

Please do not write in this box.

14. Date the third diaper was collected:
(If applicable)

m	m		d	d		2	0		
m m			d d			y y y y			

15. Time the third diaper was collected:
(If applicable)

h	h	:	m	m		a.m.	p.m.
h h			m m				

16. Date the fourth diaper was collected:
(If applicable)

m	m		d	d		2	0		
m m			d d			y y y y			

17. Time the fourth diaper was collected:
(If applicable)

h	h	:	m	m		a.m.	p.m.
h h			m m				

18. Date the fifth diaper was collected:
(If applicable)

m	m		d	d		2	0		
m m			d d			y y y y			

19. Time the fifth diaper was collected:
(If applicable)

h	h	:	m	m		a.m.	p.m.
h h			m m				

Appendix 7-L.
Meconium Data Collection Form (continued)



Draft

20. Was any meconium scraped from the diaper/s into the collection vial at the hospital/birthing center?

☐ Yes

☐ No

21. If yes, from how many diapers was meconium scraped?

NCS Data collector ID:

For Reference Only

Place Meconium
Collection
DC Label Here

Place Child's
Subject ID Label
Here

This page deliberately blank.

Part 2

Appendix 7-M

Meconium Data Collection Form: Field-by-Field Instructions

**Appendix 7-M.
Meconium Data Collection Form:
Field-by-Field Instructions**

**Meconium Data Collection Form:
Field-by-Field Instructions**

This form is to be completed with the collection of meconium from the infant. Instructions for completing each item on the form are provided in this field-by-field instruction.



Draft



National Children's Study Meconium Data Collection Form

Birth

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☒ on the wrong answer.
- ➔ It is important to print clearly, using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study (NCS), we are asking you to collect at least one diaper containing the first available meconium. All the materials needed for this collection are included in the NCS Meconium Collection Kit. Please follow the instructions included in the kit and complete all relevant items on this form.

1. Mother's name: _____

2. Child's name: _____

3. Mother's date of birth:

m	m	d	d	y	y	y	y

4. Child's date of birth:

				2	0		
m	m	d	d	y	y	y	y

5. Time of child's birth:

		:		
h	h		m	m

☐ a.m. ☐ p.m.

6. Child's gender:

☐ Male ☐ Female

7. Were any diapers containing meconium collected?

☐ Yes (Go to Q9) ☐ No

8. If not, please choose one reason that best describes why meconium was not collected (Mark one.)

- ☐ Defective Kit (END)
☐ Participant refusal (END)
☐ Parent/guardian refusal (END)
☐ Quantity not sufficient
☐ Other-specify: _____

9. How many diapers were collected?



REVIEW

Place Child's
Subject ID Label
Here

1. *Mother's name*—This field will be used only if hospital staff are completing the form. The mother's name should be written clearly in the space provided.
2. *Child's name*—This field will be used only if hospital staff are completing the form. The child's name should be written clearly in the space provided.
3. *Mother's date of birth*—Record the mother's date of birth. The month, day, and the year should be recorded (e.g., 02/07/1968).
4. *Child's date of birth*—Record the child's date of birth. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
5. *Time of child's birth*—Record the time of the child's birth. Be sure to fill the space with a zero when necessary and to mark the box to indicate "a.m." or "p.m." For example, if the child was born at 2:05 p.m., record "02:05" and mark the box corresponding to "p.m."
6. *Child's gender:*
 - If the child is male, mark that box that corresponds to "Male."
 - If the child is female, mark the box that corresponds to "Female."
7. *Were any diapers containing meconium collected?*
 - If at least one diaper containing meconium was collected, mark the box that corresponds to "Yes" and continue with Question 8.
 - If no diapers containing meconium were collected, mark the box that corresponds to "No."
8. *If not, please choose one reason that best describes why meconium was not collected (Mark one.).*
 - "Defective kit"—Mark this box to indicate that the specimen was not collected because of a problem with the Meconium Collection Kit. This includes not having the appropriate supplies available at the collection site.
 - "Participant refusal"—Mark this box to indicate that the birth mother was unwilling to allow her infant's meconium to be collected.
 - "Parent/guardian refusal"—Mark this box to indicate that the birth mother is younger than 18 years old and her parent or guardian refused to allow the infant's meconium to be collected.
 - "Quantity not sufficient"—The amount of meconium available on diaper was less than the amount described in the Meconium Collection Instructions.
 - "Other—specify"—Mark this box to indicate that the meconium was not collected for a reason other than those listed and specify the reason in the space provided. Capital block letters are the best to use.
9. *How many diapers were collected?*—Record the number of diapers that were collected in the box provided.



10. Date the first diaper was collected:

m	m	/	d	d	/	2	0
						y	y

11. Time the first diaper was collected:

		:		
h	h		m	m

☐ a.m. ☐ p.m.

12. Date the second diaper was collected:
(If applicable)

m	m	/	d	d	/	2	0
						y	y

13. Time the second diaper was collected:
(If applicable)

		:		
h	h		m	m

☐ a.m. ☐ p.m.

Please do not write in this box.

14. Date the third diaper was collected:
(If applicable)

m	m	/	d	d	/	2	0
						y	y

15. Time the third diaper was collected:
(If applicable)

		:		
h	h		m	m

☐ a.m. ☐ p.m.

16. Date the fourth diaper was collected:
(If applicable)

m	m	/	d	d	/	2	0
						y	y

17. Time the fourth diaper was collected:
(If applicable)

		:		
h	h		m	m

☐ a.m. ☐ p.m.

18. Date the fifth diaper was collected:
(If applicable)

m	m	/	d	d	/	2	0
						y	y

19. Time the fifth diaper was collected:
(If applicable)

		:		
h	h		m	m

☐ a.m. ☐ p.m.

10. *Date the first diaper was collected*—Record the date that the first diaper was collected. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
11. *Time the first diaper was collected*—Record the time the first diaper was placed in the labeled biohazard bag. Be sure to fill the space with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the diaper was collected at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
12. *Date the second diaper was collected (if applicable)*—If a second diaper was collected, record the date that the second diaper was collected. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
13. *Time the second diaper was collected (if applicable)*—Record the time that the second diaper was placed in the labeled biohazard bag. Be sure to fill the space with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the diaper was collected at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
14. *Date the third diaper was collected (if applicable)*—If a third diaper was collected, record the date that the third diaper was collected. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
15. *Time the third diaper was collected (if applicable)*—Record the time that the third diaper was placed in the labeled biohazard bag. Be sure to fill the space with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the diaper was collected at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
16. *Date the fourth diaper was collected (if applicable)*—If a fourth diaper was collected, record the date that the fourth diaper was collected. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
17. *Time the fourth diaper was collected (if applicable)*—Record the time that the fourth diaper was placed in the labeled biohazard bag. Be sure to fill the space with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the diaper was collected at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
18. *Date the fifth diaper was collected (if applicable)*—If a fifth diaper was collected, record the date that the fifth diaper was collected. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).
19. *Time the fifth diaper was collected (if applicable)*—Record the time that the fifth diaper was placed in the labeled biohazard bag. Be sure to fill the space with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the diaper was collected at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”



Draft

20. Was any meconium scraped from the diaper/s into the collection vial at the hospital/birthing center?

☐ Yes

☐ No

21. If yes, from how many diapers was meconium scraped?

☐

NCS Data collector ID:

20. *Was any meconium scraped from the diaper/s into the collection vial at the hospital/birthing center?*

- If the collection vial contains meconium, mark the box that corresponds to “Yes.” This includes situations when more than one diaper was collected and the contents of at least one were scraped into the container.
- If the collection container is empty, mark the box that corresponds to “No.”

21. *If yes, from how many diapers was meconium scraped?*—Record the number of diapers from which meconium was scraped in the box provided.

NCS Data Collector ID

- Record the data collector ID of the NCS staff member who completes the form. If collection and completion of form was done by hospital staff, record the data collector ID of the NCS staff member reviewing the form for completeness.

Subject Label

- If a subject label was not affixed prior to completion, obtain one from the visit coordinator’s Biospecimen Folder and affix it to the bottom right corner of the data collection form. Immediately following the placement of the subject label on the form, both the mother’s and the child’s name must be removed completely from the front page of the form by using a black permanent marker.

Kit Label (placed on the lower left-hand corner of the back side of the form)

- Open the Meconium Collection Kit and place the DC label in the appropriate place on the data collection form.

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Part 2

Appendix 7-N

Meconium Collection Instructions

Appendix 7-N. Meconium Collection Instructions

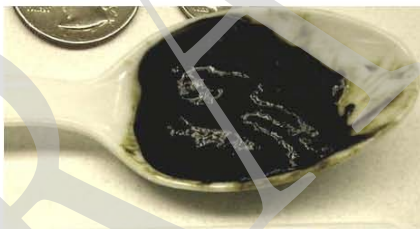
National Children's Study Meconium Collection Instructions

The Meconium Collection Kit contains the following materials:

- 1- 30 mL Para-pak collection vial with scoop lid, prelabeled
- 5 Wooden tongue depressors
- 5 Plastic biohazard collection bags, prelabeled (for diapers)
- 1 Plastic biohazard transport bag (for Para-pak vial)
- 1 Adhesive label for the Meconium Data Collection Form (DC label)
- 1 Adhesive label for the Transmittal form (TM label)
- 1 Extra adhesive label for the collection vial (EX label)

To collect the meconium sample, please follow these instructions.

1. Use powder-free gloves when handling the diaper(s) and collection vial.
2. Collect the first available diaper containing meconium. You may collect up to 5 diapers containing meconium if needed. This picture shows an example of the minimum quantity of meconium for collection.



3. Place one diaper in each prelabeled collection bag and seal the bag.
4. Complete the following information on the bag label:
 - Mother's name
 - Mother's date of birth
 - Child's name
 - Child's date of birth
 - Date and time of collection
5. Place the bag at 2-8 °C within 2 hours of collection.
6. Complete the Meconium Data Collection Form and record the date and time the diaper was collected.
7. If more than one diaper is collected, follow steps 2-5 for each additional diaper, placing each diaper into a separate prelabeled collection bag.
8. If you would like, you may transfer the meconium from the diaper(s) into the prelabeled collection vial at the hospital/birthing center. If not, the National Children's Study (NCS) data collector will perform this task after picking up the diaper(s).
 - To transfer the meconium, use the wooden tongue depressors provided or the scoop attached to the collection vial to scrape the meconium from the diaper(s) into the collection vial.
 - Dispose of the wooden tongue depressors and diapers appropriately.
 - Place the collection vial into the biohazard transport bag and store the bag at 2-8 °C until it can be picked up by NCS staff.
 - Wash your hands.
9. Keep the unused collection kit items with the completed form until the NCS data collector picks up the sample.

Thank you for collecting this sample!

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Breast Milk and Infant Formula Collection and Transport Procedures

8.1 Breast Milk and Infant Formula

Breast milk or infant formula will be self-collected by the mother or primary caregiver at approximately 1 month and 6 months post-delivery. The participant will self-collect a small sample of either breast milk or formula at home within the week prior to the scheduled pick-up visit. The participant will be asked to store the sample in the home freezer until it can be picked up by study staff.

If a study participant does not have a home freezer, the data collector should request that the participant store the sample in the refrigerator until it can be picked up by study staff. If a study participant does not have a refrigerator, the data collector should request that the participant store the sample at room temperature until it can be picked up by study staff. Information about storage temperature in the participant's home should be recorded on the Breast Milk Data Collection Form or the Infant Formula Data Collection Form.

Breast milk and infant formula samples will be analyzed to obtain information about nutritional analytes and a variety of environmental exposures including metals, pesticides, and other chemicals.

8.1.1 Overview of Study Event-Specific Collections

8.1.1.1 1-Month Study Event

Approximately 2 weeks after the delivery date, the Site Office will call the study participant. During this phone call the mother will be asked a few questions about her infant feeding practices to determine which type of collection kit she should receive. For detailed information about this telephone contact including the script and questions, see the Site Office training

materials on the NCS Collaboration Portal. The following considerations will help determine whether the participant will be requested to provide a breast milk sample or a formula sample:

- If the mother is primarily breastfeeding, she will be asked to provide a sample of her breast milk.
- If the mother is primarily using infant formula, she will be asked to provide a sample of the infant formula.
- If the mother both breast feeds and uses infant formula, she will be asked to provide a sample of her breast milk for the 1-month collection.
- If the mother has multiple children that are fed both breast milk and formula, she will be asked to provide a sample of her breast milk for the 1-month collection.

The Site Office then will schedule a date for the 1-month pick-up visit.

Approximately 10 days before the scheduled 1-month pick-up visit, the Site Office will mail the study participant either a Breast Milk Collection Kit or an Infant Formula Collection Kit along with the appropriate data collection form (see Appendices 8-A and 8-B). Each kit contains instructions for collecting and storing the sample in the home until it can be picked up by study staff (see Appendices 8-C and 8-D). Three days before the 1-month pick-up visit, the participant will receive a reminder call from the Site Office to remind her of her appointment, to ask if she has completed the breast milk or formula collection, and to encourage her to collect the sample if she has not already done so. At the 1-month pick-up visit, the breast milk or formula sample will be picked up by the data collector and transported back to the Specimen Shipping and Processing Center (SPSC).

8.1.1.2 6-Month Data Collection

For the breast milk/infant formula collection for the 6-Month data collection, the mother/primary caregiver will receive a Breast Milk Collection Kit or an Infant Formula Collection Kit at the time of the data collection visit. Collection kits will not be mailed to participants in advance of the 6 month data collection visit. During the visit, the data collector will administer the Biospecimen instrument from the Field-Administered Collection Environment (FACE) that includes questions about infant feeding practices to determine which type of collection kit the study participant should receive. The following considerations will help determine whether the participant will be requested to provide a breast milk sample or a formula sample:

- If the mother/primary caregiver is primarily breastfeeding, she will be asked to provide a sample of her breast milk.
- If the mother/primary caregiver is primarily using infant formula, she will be asked to provide a sample of the infant formula.
- If the mother/primary caregiver both breast feeds and uses infant formula, she will be asked to provide a sample of her breast milk for the 6-Month data collection.
- If the mother/primary caregiver has multiple children that are fed both breast milk and formula, she will be asked to provide a sample of her breast milk for the 6-Month data collection.

8.1.2 Mailing the Study Participant Breast Milk or Infant Formula Collection Materials (1-Month Study Event Only)

8.1.2.1 Supplies and Forms

Approximately 10 days prior to the scheduled 1-month pick-up visit, the Site Office will mail the breast milk or infant formula collection materials to the study participant. Either a Breast Milk or Infant Formula Collection Kit will be mailed depending on the participant's responses to the infant feeding questions that were asked during the phone call at 2 weeks post-delivery. The following supplies and forms should be mailed to the participant:

- Breast Milk Collection Kit *or* Infant Formula Collection Kit
- A prelabeled Breast Milk Data Collection Form *or* Infant Formula Data Collection Form. The data collection form is a Self-Administered Questionnaire (SAQ) to be completed by the participant at the time of collection (see Appendices 8-A and 8-B). The form must be prelabeled with the mother's subject label and the collection kit label (DC01 label).

8.1.2.2 Procedures for Mailing the Study Participant Breast Milk or Infant Formula Collection Materials (1-Month Study Event)

For detailed instructions on mailing breast milk or infant formula collection materials to study participants, refer to the Site Office training materials on the NCS Collaboration Portal.

8.1.3 Providing the Study Participant with Breast Milk or Infant Formula Collection Materials (6-Month Data Collection Only)

8.1.3.1 Equipment, Supplies, and Forms

The following equipment and supplies are required:

- Breast Milk Collection Kit *or* Infant Formula Collection Kit (kit contents are listed below);
- Breast Milk Data Collection Form *or* Infant Formula Data Collection Form. This is an SAQ to be completed by the participant at the time of collection (see Appendices 8-A and 8-B); and
- Computer tablet with bar code scanner.

The Breast Milk Collection Kit contains the following items:

- One prelabeled breast milk collection container with lid
- Two absorbent cloths
- One amber transport bag
- Two absorbent pads
- One adhesive label for appropriate Biospecimen Transmittal Form (TM01 label)
- One adhesive label for Breast Milk Data Collection Form (DC01 label)
- One additional adhesive label (EX label)
- Breast Milk Collection Instructions (see Appendix 8-C).

The Infant Formula Collection Kit contains the following items:

- One prelabeled infant formula collection vial
- One individually wrapped disposable transfer pipette
- One paper towel
- One amber transport bag

- One absorbent pad
- One adhesive label for appropriate Biospecimen Transmittal Form (TM01 label)
- One adhesive label for Infant Formula Data Collection Form (DC01 label)
- One additional adhesive label (EX label)
- Infant Formula Collection Instructions (see Appendix 8-D).

Breast milk or infant formula collection data will be documented in the Biospecimen instrument in FACE. If FACE is not available, the hard copy backup Breast Milk and Infant Formula Data Collection Form must be used to document collection data (see Appendices 8-E and 8-F for form and field-by-field instructions). Once the system becomes available, data must be entered in the system from the backup form. Instructions for entering data from backup forms into FACE can be found in the document *Guide to FACE Data Entry from Backup Biospecimen Data Collection Forms: Postnatal Data Collection* (located on the NCS Collaboration Portal).

8.1.3.2 Procedures for Providing the Study Participant with Breast Milk or Infant Formula Collection Materials (6-Month Data Collection)

For the 6-Month data collection, the breast milk or infant formula collection materials are given to the study participant during the data collection visit. The data collector will launch the Biospecimen instrument from FACE when providing the mother/primary caregiver with the collection materials. Detailed instructions for administering the Biospecimen instrument for breast milk or infant formula collection are found in Volume Appendix VIII-A.

For general guidance on how to use FACE for data collection activities, refer to the FACE User Guide.

1. Launch the Biospecimen instrument of FACE on the tablet.
 - If FACE is not available, the hard copy backup Breast Milk and Infant Formula Data Collection Form should be used. Place an extra Subject label (from the visit coordinator's supplies) in the appropriate place on the form.
2. Read the breast milk/infant formula collection question to the participant from FACE and enter the response. If FACE is not available, read the collection question in Part B of the hard copy backup Breast Milk and Infant Formula Data Collection Form and record the response.

3. Based on the participant's response to the collection question, locate the Breast Milk Collection Kit *or* the Infant Formula Collection Kit, and the Breast Milk Data Collection Form *or* the Infant Formula Data Collection Form
4. Wand the collection kit bar code into FACE and validate the kit type and expiration date. If FACE is not available, validate the kit type and expiration date manually.
5. If the kit type is valid and the kit is not expired, open the kit and remove the kit contents.
6. Instruct the participant in the breast milk or infant formula self-collection procedures using the Breast Milk Collection Instructions *or* the Infant Formula Collection Instructions.
7. Place the DC label in the appropriate place on the Breast Milk Data Collection Form *or* the Infant Formula Data Collection Form.
8. If FACE is not available, manually record the collection kit ID number in the appropriate place on the hard copy backup Breast Milk and Infant Formula Data Collection Form.
9. Review the data collection form and the contents of the kit with the participant. Ask the participant to keep the remaining adhesive labels in the amber transport bag when freezing the sample.
10. Give the collection kit and labeled data collection form to the participant.
11. Record in FACE that the collection kit was given to the participant.
12. If a Breast Milk Collection Kit or Infant Formula Collection Kit was given to the participant, break off the FACE session by selecting "Break Off" and click on the End Exam button () at the top of the screen. Select "Planned Break" at the End of Section screen.

8.1.4 Pick-Up of Breast Milk or Infant Formula (1-Month Study Event Only)

The breast milk or infant formula sample will be picked up at the study participant's home during the scheduled 1-month pick-up visit by a data collector and then will be transported to the SPSC. If the sample is not picked up during the 1-month visit, another pick-up visit should not be scheduled. The pick-up of the breast milk or infant formula sample for the 1-month study visit does not require the use of a tablet.

8.1.4.1 Equipment, Supplies, and Forms

The following equipment, supplies, and forms are needed to pick up a 1-month breast milk or infant formula sample from a study participant's home and to transport the sample to the SPSC:

- Specimen collection tray (optional)
- Disposable laboratory coat
- Gloves
- Hand sanitizer
- Biohazard waste bag
- Biospecimen transport cooler
- Dry ice
- Biospecimen Transmittal Form–1 Month (see volume Appendix VIII-I).

8.1.4.2 Procedures for Pick-Up of Breast Milk or Infant Formula (1-Month Study Event)

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

1. Put on a laboratory coat.
2. Locate the 1-Month Biospecimen Transmittal Form.
3. Ask the study participant to retrieve the breast milk or formula sample from the freezer, as well as the completed data collection form and the remaining labels from the collection kit.
4. Put on a clean pair of gloves.
5. Place the specimen collection tray on a flat surface.
6. When the study participant returns with the sample, do the following:

- Thank the participant for providing the sample and ask her to place the plastic amber bag containing the sample on the specimen collection tray.
 - Locate the kit TM label and place it on the Biospecimen Transmittal Form.
 - Check the lid or cap on the collection container to make sure it is securely closed.
 - Ensure the absorbent pad is in the amber bag and seal the bag.
7. Place the bag securely on dry ice in the transport cooler.

8.1.4.3 Documenting Breast Milk or Infant Formula Pick-Up (1-Month Study Event)

1. Review the Breast Milk or Infant Formula Data Collection Form for legibility and completeness and verify that the DC label from the collection kit is affixed to the form. If the DC label was not affixed to the form and is no longer available, manually record the collection kit ID with the suffix “DC01” onto the form (for example, “AB1234567-DC01”). The kit ID is the 9-digit sequence before the item ID. Because the form is a Teleform, this information should be written in block letters above the label box.
2. Record the following data on the back of the form in the “For Data Collector’s Use” box:
 - Data collector ID
 - Date of pick-up
 - Sample condition at pick-up
 - Time placed in cooler.
3. Record the collection status on the Biospecimen Transmittal Form.
4. If an incident occurs during the pick-up procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

8.1.5 Pick-Up of Breast Milk or Infant Formula (6-Month Data Collection Only)

The breast milk or infant formula sample will be picked up at the study participant's home by a data collector approximately a week after the collection and then will be transported to the SPSC. The pick-up of the breast milk or infant formula sample for the 6-Month data collection requires the use of a tablet.

8.1.5.1 Equipment, Supplies, and Forms

The following equipment, supplies, and forms are needed to pick up a 6-Month breast milk or infant formula sample from a study participant's home and to transport the sample to the SPSC:

- Specimen collection tray
- Disposable laboratory coat
- Gloves
- Hand sanitizer
- Biohazard waste bag
- Biospecimen transport cooler
- Dry ice
- Computer tablet with bar code scanner
- Computer keyboard cover
- Biospecimen Transmittal Form–6 Month (see volume Appendix VIII-J).

8.1.5.2 Procedures for Pick-Up of Breast Milk or Infant Formula (6-Month Data Collection)

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

1. Put on a laboratory coat.

2. Place the computer keyboard cover on the keyboard if you have not already done so. This will prevent contamination of the keyboard when handling specimens during the visit.
3. Locate the 6-Month Biospecimen Transmittal Form.
4. Launch the Biospecimen instrument from FACE.
5. Ask the study participant to retrieve the breast milk or formula sample from the freezer, as well as the completed data collection form and the remaining labels from the collection kit.
6. Put on a clean pair of gloves.
7. Place the specimen collection tray on a flat surface.
8. When the study participant returns with the sample, do the following:
 - Thank the participant for providing the sample and ask her to place the plastic amber bag containing the sample on the specimen collection tray.
 - Remove the TM label from the amber transport bag and place it on the Biospecimen Transmittal Form.
 - Check the lid or cap on the collection container to make sure it is securely closed.

8.1.5.3 Documenting Breast Milk or Infant Formula Pick-Up (6-Month Data Collection)

1. Record the breast milk or infant formula collection status in FACE and wand the bar code label on the collection container.
2. Immediately place the collection container back into the amber transport bag with the absorbent pad. Seal the bag and place the bag securely on dry ice in the transport cooler.
3. Review the Breast Milk or Infant Formula Data Collection Form for legibility and completeness and verify that the DC label from the collection kit is affixed to the form. If the DC label was not affixed to the form and is no longer available, manually record the collection kit ID with the suffix “DC01” onto the form (for example, “AB1234567-DC01”). The kit ID is the 9-digit sequence before the item ID. Because the form is a Teleform, this information should be written in block letters above the label box.

4. Record the following data on the back of the form in the “For Data Collector’s Use” box:
 - Data collector ID
 - Date of pick-up
 - Sample condition at pick-up
 - Time placed in cooler.
5. Record the collection status on the Biospecimen Transmittal Form.
6. If an incident occurs during the pick-up procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

8.1.6 Clean-Up Procedures

1. Clean the work area and pack all supplies. If a spill has occurred, clean the tray with a bleach wipe and discard in the biohazard waste bag.
2. Remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer.
3. Be sure to pack the biohazard waste bag appropriately for transport so that it is not visible upon leaving the site of data collection. The biohazard waste bag must be disposed of properly at the SPSC.

8.1.7 Transport Procedures

Breast milk or infant formula samples will be transported to the SPSC in the dry ice chamber of the biospecimen transport cooler. The Breast Milk or Infant Formula Data Collection Form will be transported with other SAQs and forms to the Site Office by the visit coordinator.

1. Ensure that the Biospecimen Transmittal Form is complete. Place the completed form in the zippered document pouch inside the lid of the transport cooler.
2. Secure the amber transport bag containing the collection container in the dry ice and confirm the cooler is properly closed for transport.
3. Transport any remaining kit labels to the SPSC.

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Part 2

Appendix 8-A

Breast Milk Data Collection Form

Appendix 8-A. Breast Milk Data Collection Form



National Children's Study Breast Milk Data Collection Form

1 Mo, 6 Mo

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☐ on the wrong answer.
- ➔ Your answers are important. Please print clearly using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study, we are asking you to provide a breast milk sample. You have been provided with a collection kit to collect a breast milk sample. Please follow the instructions provided in the kit. After you have collected the breast milk sample, please complete the information below.

1. On what date did you collect the sample?

		/			/	2	0		
m	m		d	d		y	y	y	y

2. At what time did you collect the sample?

		:			
h	h		m	m	☐ a.m. ☐ p.m.

3. During the 2 hours prior to collecting the breast milk, have you done any of the following:

Consumed a caffeinated beverage or food
(for example, coffee, tea, soda, chocolate)?

☐ Yes ☐ No

Consumed alcohol?

☐ Yes ☐ No

4. Please write down the name of any prescription or over the counter medications you have taken in the last 24 hours (including prenatal vitamins). Please be specific. For example, if you took Robitussin DM®, write Robitussin DM®, not Robitussin®. If you did not take any prescription or over the counter medications in the last 24 hours, please mark None.

☐ None

5. How long did you pump to collect this sample?

 minutes

6. The instructions asked you to collect the breast milk sample from one breast only. At approximately what time did you last breast feed your baby or pump milk from this breast?

		:			
h	h		m	m	☐ a.m. ☐ p.m.



BMLKDF01.00EN

Place Mother's
Subject ID Label
Here

Appendix 8-A. Breast Milk Data Collection Form (continued)



7. Did you completely empty the breast when collecting the sample?

- ☐ Yes
☐ No

8. Did you squeeze out the milk by hand?

- ☐ Yes (Go to 11)
☐ No

9. What type of pump did you use to collect the sample?

- ☐ Electric pump
☐ Hand pump

10. What is the brand of the pump you used to collect the sample? (Mark one)

- ☐ medela® ☐ AVENT® ☐ Dr. Brown's Natural Flow®
☐ Ameda® ☐ evenflo® ☐ Don't know
☐ Other-specify: _____

11. What time did you place your breast milk sample in the freezer?

: ☐ a.m.
h h m m ☐ p.m.

Please call the Study Center number on your Local Contact Sheet if you have any questions.

Thank you for taking the time to provide this information today.

For Data Collector's Use

Data collector ID:

Date breast milk sample picked up: / /
m m d d y y y y

Was the breast milk sample frozen when received from the participant? ☐ Yes ☐ No

Time breast milk sample was placed in the cooler: : ☐ a.m.
h h m m ☐ p.m.

Place Breast Milk
DC Label Here

Part 2

Appendix 8-B

Infant Formula Data Collection Form

Appendix 8-B. Infant Formula Data Collection Form



National Children's Study Infant Formula Data Collection Form

1 Mo, 6 Mo

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☐ on the wrong answer.
- ➔ Your answers are important. Please print clearly using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study, we are asking you to provide a sample of the formula that you typically use to feed your baby.

You have been provided with a collection kit to collect the formula sample. Please follow the instructions provided in the kit. After you have collected the formula sample, please complete the information below.

1. On what date did you prepare the sample?

m	m	d	d	y	y	y	y

2. At what time did you prepare the sample?

		:			☐ a.m.
h	h		m	m	☐ p.m.

3. Did you use organic formula to prepare the sample? ☐ Yes ☐ No

4. What type of formula was used?

- ☐ Soy based
☐ Cow's milk based

5. Which of the following best describes the formula used to make this sample?

- ☐ Ready-to-feed
☐ Liquid concentrate
☐ Powder from multiple-serving can
☐ Powder from a single serving packet

6. Was the formula mixed according to the directions on the formula label?

- ☐ Yes (Go to 8)
☐ No



INFFOR01.00EN

**Place Mother's
Subject ID Label
Here**

Appendix 8-B. Infant Formula Data Collection Form (continued)



20802

7. When the formula was mixed, how much formula (powder or liquid concentrate) and how much water were used?

	Amount	Measurement Units
Formula		☐ Teaspoons ☐ Tablespoons ☐ Ounces ☐ Cups
Water		☐ Ounces ☐ Cups ☐ Milliliters (mL)

8. What type of water was used to make this sample?

- ☐ Cold tap water
☐ Warm tap water
☐ Hot tap water
☐ Bottled water (drinking water)
☐ Bottled water (spring water)
☐ Filtered water
☐ No water used (END)

9. Is this the water source that you usually use to mix infant formula?

☐ Yes ☐ No

10. Does your tap water come from a well?

☐ Yes ☐ No

Please call the Study Center number on your Local Contact Sheet if you have any questions.

Thank you for taking the time to provide this information today.

For Data Collector's Use

Data collector ID:

Date formula sample picked up:

 / /

m m d d y y y y

Was the formula sample frozen when received from the participant? ☐ Yes ☐ No

Time formula sample was placed in the cooler:

 : ☐ a.m.
☐ p.m.

h h m m

Place Infant Formula
Collection DC Label
Here

Part 2

Appendix 8-C

Breast Milk Collection Instructions

Appendix 8-C. Breast Milk Collection Instructions

OMB Control Number: 0925-0593
Expiration Date: 09/30/2011

National Children's Study Breast Milk Collection Instructions

As part of the National Children's Study, we are asking you to collect a sample of your breast milk. We are asking you to provide about 3 ounces of breast milk (about 6 tablespoons).

This kit includes everything you will need to collect the sample:

- 2 absorbent cloths
- 1 Plastic collection container, prelabeled
- 1 Plastic amber bag with absorbent pad

Important instructions before getting started

Please collect this sample as close to the time of your NCS pick up visit as possible.

- **For this sample collection, you are asked to collect breast milk from *one breast only*, and to *completely drain the breast*. You may not have enough milk left after the collection to satisfy your baby. For this reason, please make sure to pump milk ahead of time so that you have enough milk to feed your baby after the sample is taken.**
- **Please do not breast-feed your baby or pump breast milk from the breast you will use to provide this sample for 2 hours prior to the sample collection. Please do not eat food or take medication for 2 hours prior to the sample collection.**
- **Please collect the breast milk sample sometime in the morning, preferably between 9:00 a.m. – 12:00 p.m. (noon). You will be asked to write down the time you collected the sample on the Breast Milk Data Collection Form.**
- **Please use your own breast pump to collect this sample. If you choose, you may also squeeze out the breast milk by hand in order to collect this sample.**
- **Please do not use any soaps, cleansers, lotions, or creams on the breast or nipple prior to the sample collection.**
- **Be sure to drink plenty of water before and after the sample collection.**

Collection Instructions

1. Thoroughly wash your hands with soap and water and dry with a clean towel.
2. Wash one breast and nipple *with warm tap water only*, using one of the two absorbent cloths provided. Please do not use any soap or other cleanser to clean the area, and do not apply any lotion or cream. Gently dry the area with the second absorbent cloth.
3. Follow the manufacturer's instructions for your breast pump in order to safely collect the sample.
4. If you choose to squeeze out the breast milk by hand, you can either collect the milk directly in the plastic container provided or in your own collection container.

Immediately after collection

1. Gently mix the milk in the container you used to collect the sample by swirling the container. This is important in order to thoroughly mix the different components of the breast milk.
2. Remove the lid from the prelabeled plastic container provided in the Breast Milk Collection Kit. After you have gently mixed the sample, pour the milk into the container so that the total volume in the container is approximately to the 80 mL mark on the container. If you did not collect enough milk to fill the container to the 80 mL mark, pour whatever you have collected into the container. Place the lid on the container.
3. If there is any milk left over in the container you used to collect the sample, you can save it for your baby.
4. Place the prelabeled plastic container into the plastic amber bag with the absorbent pad, seal the bag, and place it in the freezer until it can be picked up by the Study staff. Please keep the labels that came with the kit inside the bag.
5. Complete the Breast Milk Data Collection Form.

Please call the Study Center phone number on your Local Contact Sheet if you have any questions.

Thank you for providing this sample!

Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

BMLKIN02.00DU

Appendix 8-C. Breast Milk Collection Instructions (continued)

Número de control de OMB: 0925-0593
Fecha de vencimiento: 09/30/2011

Estudio Nacional de los Niños

Instrucciones para tomar la muestra de leche materna

Como parte del Estudio Nacional de los Niños, quisiéramos pedirle que tome una muestra de su leche materna. Le estamos pidiendo más o menos unas 3 onzas de su leche (6 cucharadas más o menos).

Estos materiales incluyen todo lo que va a necesitar para tomar la muestra:

- 2 paños de tela absorbente
- 1 tubito de plástico pre-etiquetado
- 1 bolsa de plástico color ámbar con una almohadilla absorbente

Instrucciones importantes para antes de empezar

Por favor tome esta muestra lo más cerca posible de la fecha de la visita del NCS para recoger sus muestras.

- Para tomar esta muestra, le pedimos que se saque leche de *un seno solamente* y que se saque *toda la leche de ese seno*. Después de tomar la muestra posiblemente no le quede leche suficiente para satisfacer a su bebé. Por este motivo, por favor asegúrese de sacarse la leche con anticipación para tener leche suficiente para alimentar a su bebé después de tomar la muestra.
- Por favor, durante 2 horas antes de tomar la muestra, no le dé pecho al bebé ni se saque leche con un extractor del seno del que se sacará la leche para tomar esta muestra. Por favor no coma ningún alimento ni tome ningún medicamento durante 2 horas antes de tomar la muestra.
- Por favor tome la muestra de leche en algún momento en la mañana, preferiblemente entre las 9:00 de la mañana y las 12 del mediodía. Le pediremos que anote la hora en que tomó la muestra en el Formulario de información de la muestra de leche materna.
- Por favor use su propio extractor de leche para tomar la muestra. Si prefiere, también puede sacarse la leche exprimiéndose el seno manualmente para tomar esta muestra.
- Por favor no use ningún tipo de jabón, lociones ni cremas en el seno ni en el pezón antes de tomar la muestra.
- Asegúrese de tomar bastante agua antes y después de tomar la muestra.

Instrucciones para tomar la muestra

5. Lávese bien las manos con jabón y agua y séquese con una toalla limpia.
6. Lávese un seno y el pezón *solamente con agua tibia de la llave*, usando uno de los dos paños de tela absorbente. Por favor no use ningún jabón ni otro limpiador para limpiar el área y no se ponga ninguna loción ni crema. Séquese el área delicadamente con el otro paño de tela absorbente.
7. Siga las instrucciones del fabricante de su extractor de leche para tomar la muestra en forma segura.
8. Si decide sacarse la leche exprimiéndose el seno manualmente, puede echar la leche directamente en el tubito de plástico proporcionado o en su propio envase para echar la leche.

Inmediatamente después de tomar la muestra

6. Agite delicadamente el envase que usó para tomar la muestra para mezclar la leche. Esto es importante para mezclar totalmente los diferentes componentes de la leche materna.
7. Destape el tubito de plástico pre-etiquetado que se incluyó con los materiales para tomar la muestra de leche. Después de mezclar delicadamente la muestra, eche la leche en el tubito hasta que el volumen total en el tubito llegue aproximadamente a la marca de 80 ml. Si no sacó suficiente leche para llenar el tubito hasta la marca de 80 ml, eche en el tubito toda la cantidad de leche que se haya sacado. Póngale la tapa al tubito.
8. Si sobra algo de leche en el envase que usó para tomar la muestra, la puede guardar para su bebé.
9. Ponga el tubito de plástico pre-etiquetado para la muestra dentro de la bolsa de plástico de color ámbar con la almohadilla absorbente, cierre la bolsa y póngala en el congelador hasta que la pueda ir a buscar un miembro del personal del Estudio. Por favor mantenga las etiquetas que venían con los materiales dentro de la bolsa.
10. Complete el Formulario de información de la muestra de leche materna.

Por favor llame al número del Centro del Estudio que hay en su Hoja de Contactos Locales si tiene alguna pregunta.

¡Gracias por darnos esta muestra!

Se calcula que el promedio de tiempo necesario para esta recolección de información es de 20 minutos por entrevista, incluyendo el tiempo para leer las instrucciones, buscar fuentes de información existentes, reunir y mantener la información necesaria y completar y revisar la recolección de información. **Ninguna agencia puede llevar a cabo ni patrocinar una recolección de información y ninguna persona está obligada a responder a dicha recolección a menos que ésta muestre un número de control vigente de OMB.** Envíe los comentarios acerca de este cálculo de tiempo necesario, incluyendo sugerencias sobre cómo reducirlo, o acerca de cualquier otro aspecto de esta recolección de información a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). No devuelva el formulario contestado a esta dirección.

BMLKIN02.00DU

Part 2

Appendix 8-D

Infant Formula Collection Instructions

Appendix 8-D. Infant Formula Collection Instructions

OMB Control Number: 0925-0593
Expiration Date: 09/30/2011

National Children's Study Infant Formula Collection Instructions

As part of the National Children's Study, we are asking you to collect a sample of your infant's formula. We are asking you to provide about 5 milliliters (mL) of formula (about 1 teaspoon).

This kit includes everything you will need to collect the sample:

- 1 Plastic collection container, prelabeled
- 1 Paper towel
- 1 Sterile plastic dropper
- 1 Plastic amber bag with absorbent pad

Important instructions before getting started

- **Please collect this sample as close to the time of your NCS pick-up visit as possible.**
- **Please be sure to prepare your baby's formula as you would normally prepare it to feed your baby.**
- **We are asking you to provide a small amount of formula and the rest can be used to feed your baby.**

Collection Instructions

1. Thoroughly wash your hands with soap and water and dry with a clean towel.
2. Prepare the formula the way you normally prepare it to feed your baby.
3. Remove the cap from the prelabeled plastic collection container and place it on the paper towel. The inside of the cap should be face down on the paper towel. Do not touch the inside of the cap or the collection container.
4. Remove the sterile plastic dropper from the package. The plastic dropper (pictured below) resembles an eye dropper and should be used in the same manner.



5. Use the plastic dropper to place 5 milliliters (mL) (or about 1 teaspoon) of formula into the container. To do so,
 - Hold the plastic dropper by the bulb and squeeze the bulb.
 - Insert the tip of the dropper into the formula and release the bulb. This will cause the formula to be pulled up into the dropper.
 - Place the tip into the collection container and squeeze the bulb again. This will release the formula into the collection container.
 - Repeat until the collection container has been filled up to the fill line, as indicated in the picture below. Any remaining formula can be used to feed your baby.



6. Place the prelabeled plastic collection container into the plastic amber bag with the absorbent pad, seal the bag, and place it in the freezer until it can be picked up by the Study staff. Please keep the labels that came with the kit inside the bag.
7. Complete the Infant Formula Data Collection Form.

Please call the Study Center phone number on your Local Contact Sheet if you have any questions.

Thank you for providing this sample!

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

INFOIN02.00DU

Appendix 8-D. Infant Formula Collection Instructions (continued)

Número de control de OMB: 0925-0593
Fecha de vencimiento: 09/30/2011

Estudio Nacional de los Niños Instrucciones para tomar la muestra de leche de fórmula para lactantes

Como parte del Estudio Nacional de los Niños, quisiéramos pedirle que tome una muestra de la leche de fórmula para lactantes. Le estamos pidiendo que dé más o menos 5 mililitros (ml) de fórmula (1 cucharadita más o menos).

Estos materiales incluyen todo lo que va a necesitar para tomar la muestra:

- 1 tubito de plástico pre-etiquetado para la muestra
- 1 toalla de papel
- 1 gotero de plástico esterilizado
- 1 bolsa de plástico de color ámbar con una almohadilla absorbente

Instrucciones importantes para antes de empezar

Por favor tome esta muestra lo más cerca posible de la fecha de la visita del NCS para recoger sus muestras.

- Por favor asegúrese de preparar la fórmula tal como la prepararía normalmente para alimentar a su bebé.
- Le estamos pidiendo que dé una pequeña cantidad de fórmula. Puede usar el resto para alimentar a su bebé.

Instrucciones para tomar la muestra

8. Lávese bien las manos con jabón y agua y séquese con una toalla limpia.
9. Prepare la fórmula de la manera que normalmente la prepara para alimentar a su bebé.
10. Destape el tubito de plástico pre-etiquetado para la muestra y ponga la tapa sobre la toalla de papel. El interior de la tapa debe quedar boca abajo sobre la toalla de papel. No toque el interior de la tapa ni el interior del tubito para la muestra.
11. Saque el gotero de plástico esterilizado del paquete. El gotero de plástico (dibujo a continuación) se parece a un gotero para los ojos y se debe usar de la misma manera.



12. Use el gotero de plástico para poner 5 mililitros (ml) (o 1 cucharadita más o menos) de fórmula dentro del tubito. Para hacer esto:
 - Sujete el gotero de plástico por la cabeza y apriétela.
 - Meta la punta del gotero en la fórmula y suelte la cabeza. Esto hará que la fórmula suba y entre al gotero.
 - Ponga la punta del gotero dentro del tubito para la muestra y apriete la cabeza nuevamente. Esto hará que la fórmula caiga dentro del tubito.
 - Repita hasta que el tubito de la muestra se haya llenado con fórmula hasta la línea que indica lleno, como se muestra en el dibujo a continuación. Puede usar la fórmula que sobre para alimentar a su bebé.

Llene hasta aquí



13. Ponga el tubito de plástico pre-etiquetado para la muestra dentro de la bolsa de plástico de color ámbar con la almohadilla absorbente, cierre la bolsa y póngala en el congelador hasta que la pueda ir a buscar un miembro del personal del Estudio. Por favor mantenga las etiquetas que venían con los materiales dentro de la bolsa.
14. Complete el Formulario de información de la muestra de leche de fórmula para lactantes.

Por favor llame al número del Centro del Estudio que hay en su Hoja de Contactos Locales si tiene alguna pregunta.

¡Gracias por darnos esta muestra!

Se calcula que el promedio de tiempo necesario para esta recolección de información es de 5 minutos por entrevista, incluyendo el tiempo para leer las instrucciones, buscar fuentes de información existentes, reunir y mantener la información necesaria y completar y revisar la recolección de información. **Ninguna agencia puede llevar a cabo ni patrocinar una recolección de información y ninguna persona está obligada a responder a dicha recolección a menos que ésta muestre un número de control vigente de OMB.** Envíe los comentarios acerca de este cálculo de tiempo necesario, incluyendo sugerencias sobre cómo reducirlo, o acerca de cualquier otro aspecto de esta recolección de información a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). No devuelva el formulario contestado a esta dirección.

INFOIN02.00DU



New
Appendix

Part 2

Appendix 8-E

Breast Milk and Infant Formula Data Collection Form

Appendix 8-E. Breast Milk and Infant Formula Data Collection Form

 National Children's Study Breast Milk and Infant Formula Data Collection Form 6-Mo	
(Only for use when FACE is not available)	
Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office PLEASE WRITE KIT NUMBER HERE	Collection Status: (Mark one.) ☐ Complete ☐ Partial ☐ Not done Reason for Not Done/Partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitation ☐ Quantity not sufficient ☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/Guardian refusal ☐ Other—specify: _____
Part B: Collection Questions	
1. DATA COLLECTOR: PHRASE THE QUESTION BELOW AS APPROPRIATE TO THE SITUATION. IF THE PARTICIPANT SAYS FEEDING OF BREAST MILK AND FORMULA ARE EQUAL, CHOOSE 'MOSTLY BREAST MILK'. SINGLETON: Are you currently feeding (name/your child) mostly breast milk, including pumped or expressed milk, or mostly formula? <i>¿Está usted alimentando actualmente a (name/su bebé) principalmente con leche materna, incluyendo leche extraída manualmente o con un extractor, o principalmente con leche de fórmula?</i> MULTIPLES: Are you currently feeding your children mostly breast milk, including pumped or expressed milk, or mostly formula? <i>¿Está usted alimentando actualmente a sus bebés principalmente con leche materna, incluyendo leche extraída manualmente o con un extractor, o principalmente con leche de fórmula?</i> ☐ Mostly breast milk (Go to Q3) <i>Principalmente leche materna</i> ☐ Mostly formula (Go to Q3) <i>Principalmente fórmula</i> ☐ Neither breast milk nor formula <i>Ni leche materna ni fórmula</i> ☐ Refused ☐ Don't know	
2. You said that you are not currently feeding your (child/children) breast milk or formula. Can you tell me what you feed your (child/children)? <i>Usted dijo que actualmente no está alimentando a (su bebé/sus bebés) ni con leche materna ni con fórmula. ¿Podría decirme con qué alimenta a (su bebé/sus bebés)?</i>	

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Primary Caregiver Subject Label

Assignment ID,
Subject ID, Event Type

Appendix 8-E.
Breast Milk and Infant Formula Data Collection Form (continued)

3. DATA COLLECTOR: INDICATE THE TYPE OF KIT PROVIDED TO THE PARTICIPANT.
☐ Breast Milk Collection Kit ☐ Infant Formula Collection Kit
Comments:

Data collector ID for field QC:

Date entered into FACE: / /20 m m d d y y y y
ID of data collector who entered the form:



New
Appendix

Part 2

Appendix 8-F

Breast Milk and Infant Formula Data Collection Form:
Field-by-Field Instructions

Appendix 8-F.
Breast Milk and Infant Formula Data Collection Form: Field-by-Field Instructions

**BREAST MILK AND INFANT FORMULA
DATA COLLECTION FORM:
FIELD-BY-FIELD INSTRUCTIONS**

This form is only to be used when the Field-Administered Collection Environment (FACE) is not available and should be completed by the postnatal biospecimen data collector for the 6-Month data collection. The form should only be completed if FACE is not available at the visit where the collection materials are distributed to the participant (i.e., the form is not required for the pick-up of the breast milk or infant formula sample). Instructions for completing each item on the form are provided in this field-by-field.

After Completing the Form

- Within 2 hours of the visit, the form should be checked to make sure that it is accurate, legible, and complete.
- Make sure that all of the appropriate boxes are completely filled. Comments should be limited to the area provided.
- The data collector who checks the form for completeness should write his or her data collector ID in the space provided at the bottom of the last page.
- The data collector who enters the data in FACE will record the date of data entry and his or her data collector ID in the space provided on the last page of the form.

 National Children's Study Breast Milk and Infant Formula Data Collection Form 6-Mo	
(Only for use when FACE is not available)	
Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office PLEASE WRITE KIT NUMBER HERE	Collection Status: (Mark one.) ☐ Complete ☐ Partial ☐ Not done Reason for Not Done/Partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitation ☐ Quantity not sufficient ☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/Guardian refusal ☐ Other—specify: _____
Part B: Collection Questions	
1. DATA COLLECTOR: PHRASE THE QUESTION BELOW AS APPROPRIATE TO THE SITUATION. IF THE PARTICIPANT SAYS FEEDING OF BREAST MILK AND FORMULA ARE EQUAL, CHOOSE 'MOSTLY BREAST MILK'. SINGLETON: Are you currently feeding (name/your child) mostly breast milk, including pumped or expressed milk, or mostly formula? <i>¿Está usted alimentando actualmente a (name/su bebé) principalmente con leche materna, incluyendo leche extraída manualmente o con un extractor, o principalmente con leche de fórmula?</i> MULTIPLES: Are you currently feeding your children mostly breast milk, including pumped or expressed milk, or mostly formula? <i>¿Está usted alimentando actualmente a sus bebés principalmente con leche materna, incluyendo leche extraída manualmente o con un extractor, o principalmente con leche de fórmula?</i> ☐ Mostly breast milk (Go to Q3) <i>Principalmente leche materna</i> ☐ Mostly formula (Go to Q3) <i>Principalmente fórmula</i> ☐ Neither breast milk nor formula <i>Ni leche materna ni fórmula</i> ☐ Refused ☐ Don't know 2. You said that you are not currently feeding your (child/children) breast milk or formula. Can you tell me what you feed your (child/children)? <i>Usted dijo que actualmente no está alimentando a (su bebé/sus bebés) ni con leche materna ni con fórmula. ¿Podría decirme con qué alimenta a (su bebé/sus bebés)?</i> _____	
BMIFDC01.00DU Primary Caregiver Subject Label Assignment ID, Subject ID, Event Type	

Part A: Administrative Section

- *Date*—Record the date of the visit during which the collection questions are asked and if applicable, the appropriate breast milk or infant formula collection materials are distributed to the participant. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002). The date should not be recorded in advance of the participant’s study visit.
- *Data collector ID*—Record the data collector ID of the person who completes the form.
- *Visit location*—Mark the box corresponding to the location of the visit.
- *Collection status* (Mark one)—For the purpose of this form, the term “collection status” is used to refer to the status of the breast milk/infant formula collection activities performed at Day 1 of the 6-Month data collection. These activities include asking the participant the collection questions in Part B, and distributing the appropriate collection kit and data collection form to the participant. Mark the box that corresponds to the status of the breast milk/infant formula collection activities performed during Day 1 of the 6-Month data collection.
 - “Complete”—Mark this box to indicate that the breast milk/infant formula collection activities were completed at the visit.
 - “Partial”—Mark this box to indicate that the breast milk/infant formula collection activities were partially completed at the visit. When this box is marked, indicate the reason the breast milk/infant formula collection activities were partially completed.
 - “Not done”—Mark this box to indicate that none of the breast milk/infant formula collection activities were completed at the visit.
- *Reason for Not Done/Partial* (Mark one)—If applicable, mark the box that corresponds to the choice that best explains why the status is partial or not done.
 - “Participant refusal”—Mark this box to indicate that the participant refused to complete the breast milk/infant formula collection.
 - “Participant ill/emergency”—Mark this box to indicate that the participant was ill during the visit and was unable to complete the breast milk/infant formula collection activities. This box also is marked if the participant/parent has an emergency that required termination of the visit prior to completion of the breast milk/infant formula collection activities. Record a brief description of the nature of the emergency or illness in the Comments section in Part B.
 - “No time”—Mark this box to indicate that the breast milk/infant formula collection activities were not completed because the visit was ended ahead of schedule. Record a brief description of the reason the visit was ended in the Comments section on Part B.
 - “Safety exclusion”—This code does not apply to this biospecimen collection activity.

 National Children's Study Breast Milk and Infant Formula Data Collection Form	
6-Mo	
(Only for use when FACE is not available)	
Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office PLEASE WRITE KIT NUMBER HERE 	Collection Status: (Mark one.) ☐ Complete ☐ Partial ☐ Not done Reason for Not Done/Partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitation ☐ Quantity not sufficient ☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/Guardian refusal ☐ Other—specify: _____
Part B: Collection Questions	
1. DATA COLLECTOR: PHRASE THE QUESTION BELOW AS APPROPRIATE TO THE SITUATION. IF THE PARTICIPANT SAYS FEEDING OF BREAST MILK AND FORMULA ARE EQUAL, CHOOSE 'MOSTLY BREAST MILK'. SINGLETON: Are you currently feeding (name/your child) mostly breast milk, including pumped or expressed milk, or mostly formula? <i>¿Está usted alimentando actualmente a (name/su bebé) principalmente con leche materna, incluyendo leche extraída manualmente o con un extractor, o principalmente con leche de fórmula?</i> MULTIPLES: Are you currently feeding your children mostly breast milk, including pumped or expressed milk, or mostly formula? <i>¿Está usted alimentando actualmente a sus bebés principalmente con leche materna, incluyendo leche extraída manualmente o con un extractor, o principalmente con leche de fórmula?</i> ☐ Mostly breast milk (Go to Q3) <i>Principalmente leche materna</i> ☐ Mostly formula (Go to Q3) <i>Principalmente fórmula</i> ☐ Neither breast milk nor formula <i>Ni leche materna ni fórmula</i> ☐ Refused ☐ Don't know	
2. You said that you are not currently feeding your (child/children) breast milk or formula. Can you tell me what you feed your (child/children)? <i>Usted dijo que actualmente no está alimentando a (su bebé/sus bebés) ni con leche materna ni con fórmula. ¿Podría decirme con qué alimenta a (su bebé/sus bebés)?</i>	

BMIFDC01.00DU

Primary Caregiver Subject Label

Assignment ID,
Subject ID, Event Type

- “Physical limitation”—Mark this box to indicate that the participant has a physical limitation that prevents collection of a breast milk or infant formula sample. Record a brief description of the type of physical limitation in the Comments section in Part B.
 - “Quantity not sufficient”—This code does not apply to this biospecimen collection activity.
 - “Defective collection kit”—Mark this box to indicate that the breast milk/infant formula collection activities were not completed due to a problem with the collection kit. This includes not having the appropriate supplies available.
 - “Language issue, Spanish”—Mark this box to indicate that breast milk/infant formula collection activities were not completed because the data collector did not speak Spanish well enough to communicate with the participant regarding the breast milk or infant formula collection procedures.
 - “Language issue, non-Spanish”—Mark this box to indicate that the breast milk/infant formula collection activities were not completed because the data collector was unable to communicate with the participant regarding the breast milk or infant formula collection procedures.
 - “Cognitive disability”—Mark this box to indicate that the breast milk/infant formula collection activities were not completed because the participant is cognitively or developmentally impaired and therefore unable to understand the breast milk or infant formula collection procedures.
 - “Parent/Guardian refusal”—Mark this box to indicate that the participant is younger than 18 years old and her parent or guardian refused to allow the breast milk or infant formula collection.
 - “Other—specify”—Mark this box to indicate that the breast milk/infant formula collection activities were not completed for a reason other than those listed; specify the reason in the space provided.
- *Please Write Kit Number Here*—Record the 9-digit collection kit ID of the breast milk or infant formula collection kit that was distributed to the participant in the spaces provided.

 National Children's Study Breast Milk and Infant Formula Data Collection Form 6-Mo	
(Only for use when FACE is not available)	
Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office	Collection Status: (Mark one.) ☐ Complete ☐ Partial ☐ Not done Reason for Not Done/Partial: (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitation ☐ Quantity not sufficient ☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/Guardian refusal ☐ Other—specify: _____
PLEASE WRITE KIT NUMBER HERE 	
Part B: Collection Questions	
1. DATA COLLECTOR: PHRASE THE QUESTION BELOW AS APPROPRIATE TO THE SITUATION. IF THE PARTICIPANT SAYS FEEDING OF BREAST MILK AND FORMULA ARE EQUAL, CHOOSE 'MOSTLY BREAST MILK'. SINGLETON: Are you currently feeding (name/your child) mostly breast milk, including pumped or expressed milk, or mostly formula? <i>¿Está usted alimentando actualmente a (name/su bebé) principalmente con leche materna, incluyendo leche extraída manualmente o con un extractor, o principalmente con leche de fórmula?</i> MULTIPLES: Are you currently feeding your children mostly breast milk, including pumped or expressed milk, or mostly formula? <i>¿Está usted alimentando actualmente a sus bebés principalmente con leche materna, incluyendo leche extraída manualmente o con un extractor, o principalmente con leche de fórmula?</i> ☐ Mostly breast milk (Go to Q3) <i>Principalmente leche materna</i> ☐ Mostly formula (Go to Q3) <i>Principalmente fórmula</i> ☐ Neither breast milk nor formula <i>Ni leche materna ni fórmula</i> ☐ Refused ☐ Don't know	
2. You said that you are not currently feeding your (child/children) breast milk or formula. Can you tell me what you feed your (child/children)? <i>Usted dijo que actualmente no está alimentando a (su bebé/sus bebés) ni con leche materna ni con fórmula. ¿Podría decirme con qué alimenta a (su bebé/sus bebés)?</i>	
Primary Caregiver Subject Label Assignment ID, Subject ID, Event Type	

BMIFDC01.00DU

Part B: Collection Questions

1. DATA COLLECTOR: PHRASE THE QUESTION BELOW AS APPROPRIATE TO THE SITUATION. IF THE PARTICIPANT SAYS FEEDING OF BREAST MILK AND FORMULA ARE EQUAL, CHOOSE “MOSTLY BREAST MILK.”
 - SINGLETON: Are you currently feeding (name/your child) mostly breast milk, including pumped or expressed milk, or mostly formula?
 - MULTIPLES: Are you currently feeding your children mostly breast milk, including pumped or expressed milk, or mostly formula?
 - *Mostly breast milk (Go to Q3)*—Mark this box if the participant responds that the child or children are currently fed mostly breast milk. Also mark this box if the participant responds that the child or children are currently fed breast milk and infant formula in equal amounts. Continue to Question 3.
 - *Mostly formula (Go to Q3)*—Mark this box if the participant responds that the child or children are currently fed mostly infant formula. Continue to Question 3.
 - *Neither breast milk nor formula*—Mark this box if the participant responds that she is not currently feeding the child or children breast milk or infant formula.
 - If the participant either refuses to answer or does not know, mark the corresponding box.
2. *You said that you are not currently feeding your (child/children) breast milk or formula. Can you tell me what you feed your (child/children)?*
 - Record the participant’s response in the space provided.

Primary Caregiver Subject Label

Affix a subject label for the primary caregiver assignment to the bottom right corner of the data collection form in the space provided.

3. DATA COLLECTOR: INDICATE THE TYPE OF KIT PROVIDED TO THE PARTICIPANT.

- ☐ Breast Milk Collection Kit
☐ Infant Formula Collection Kit

Comments:

Data collector ID for field QC:

Date entered into FACE: //20
m m d d y y y y

ID of data collector who entered the form:

3. DATA COLLECTOR: INDICATE THE TYPE OF KIT PROVIDED TO THE PARTICIPANT.

- Breast Milk Collection Kit
- Infant Formula Collection Kit
- *Comments*—Additional comments may include reasons why the breast milk/infant formula collection activities were not completed or any issues encountered when completing the form.

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Part 2

Addendum 2-A

Group 2 Version of Chapter 2, Part 2 Urine Collection and Transport Procedures



Urine Collection and Transport Procedures

2.1 Adult Urine (Group 2 Vanguard Center Only)

Adult urine specimens will be collected at the P1 mother, T1 mother, T1 father, and T3 mother study events. Adult urine specimens will be analyzed to obtain information about physiological conditions and environmental exposures.

A participant may provide a urine specimen at any time during a specified visit. However, for visits during which both urine and vaginal specimens are collected, it is preferred that the participant self-collects the vaginal specimens at the same time (i.e., during the same bathroom visit) as the urine specimen.

Adult urine collection procedures are the same for all study events with the exception of the T3 mother study event (for Group 2 Vanguard Centers only). For the T3 mother study event, a different version of the adult urine collection kit will be used (i.e., the Adult Urine 2-Cup Collection Kit). Urine will be transferred into a second collection container for transport at two different temperatures. Collection procedures are described separately for the T3 study event in the sections that follow.

2.1.1 Equipment, Supplies, and Forms

2.1.1.1 P1 Mother, T1 Mother, T1 Father

The following equipment and supplies are required to collect and transport adult urine for the P1 mother, T1 mother, and T1 father data collection visits:

- Adult Urine Collection Kit (kit contents are in the next list)
- Specimen collection tray
- Disposable laboratory coat

- Gloves
- Hand sanitizer
- Biohazard waste bag
- Biospecimen transport cooler
- Dry ice
- Dry ice glove
- Computer tablet with bar code scanner
- Computer keyboard cover.

The Adult Urine Collection Kit contains the following items:

- One prelabeled urine collection container with lid
- One biohazard transport bag
- Two absorbent pads
- Two paper towels
- Adult Urine Collection Instructions
- One adhesive label for Biospecimen Transmittal Form (TM label)
- One adhesive label for hard copy backup Adult Urine Data Collection Form (DC label)
- Three additional adhesive labels for collection container (EX labels).

The following form is required to collect and transport adult urine specimens:

- Event-specific Biospecimen Transmittal Form (see volume Appendices VIII-B through VIII-G for forms and field-by-field instructions).

Urine collection data will be documented in the Biospecimen instrument in the Field-Administered Collection Environment (FACE). If FACE is not available, then the appropriate hard copy backup Adult Urine Data Collection Form must be used to document collection data (see Appendices 2-A and 2-B for form and field-by-field instructions). Once the system becomes available, data must be entered in the system from the backup form.

2.1.1.2 T3 Mother (Group 2 Vanguard Centers Only)

The following equipment and supplies are required to collect and transport adult urine for the T3 mother data collection visit:

- Adult Urine 2-Cup Collection Kit
- Specimen collection tray
- Disposable laboratory coat
- Gloves
- Sterile disposable plastic transfer pipette (optional)
- Hand sanitizer
- Biohazard waste bag
- Biospecimen transport cooler
- Dry ice (for UR02)
- Dry ice glove
- Four -1 °C cold packs (for UR03)
- Computer tablet with bar code scanner
- Computer keyboard cover.

The Adult Urine 2-Cup Collection Kit contains the following items:

- Two prelabeled urine collection containers with lids (UR02 and UR03)
- Two biohazard transport bags
- Two absorbent pads
- Two paper towels
- Adult Urine Collection Instructions
- One adhesive label for Biospecimen Transmittal Form (TM label)
- One adhesive label for hard copy backup Adult Urine Data Collection Form (DC label)

- One adhesive label for Urine Preservative Aliquot (4265 label)
- One adhesive label for Urine Aliquot (4266 label)
- One additional adhesive label for collection container (EX label).

The following form is required to collect and transport adult urine 2-cup specimens:

- T3 Mother Biospecimen Transmittal Form (see volume Appendices VIII-E and VIII-G for form and field-by-field instructions).

Urine collection data will be documented in the Biospecimen instrument in FACE. If FACE is not available, then the hard copy backup Adult Urine Data Collection Form must be used to document collection data (see Appendices 2-A and 2-B for form and field-by-field instructions). Once the system becomes available, data must be entered in the system from the backup form.

2.1.2 Step-by-Step Procedures for Adult Urine Collection

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following procedures are to be used for adult urine collection. For general guidance on how to use FACE for data collection activities, refer to the FACE User Guide. For detailed question-by-question specifications for administering the Biospecimen instrument, refer to the appropriate section in volume Appendix VIII-A.

2.1.2.1 P1 Mother, T1 Mother, T1 Father

1. Put on a disposable laboratory coat.
2. Place the computer keyboard cover on the keyboard if you have not already done so. This will prevent the keyboard from contamination when handling specimens during the visit. One keyboard cover will be used for the duration of the biospecimen collection.
3. Launch the Biospecimen Data Collection instrument of FACE on the tablet. If FACE is not available, the hard copy backup Adult Urine Data Collection Form should be used.

P1 Mother, T1 Mother

Follow the prompt in FACE to give the participant the option of collecting the vaginal swabs at the same time she is collecting the urine specimen (i.e., during the same bathroom visit).

4. Read the urine collection questions to the participant from FACE and enter the responses. If FACE is not available, read the collection questions in Part B of the hard copy backup Adult Urine Data Collection Form and record the responses.

P1 Mother, T1 Mother

If both urine and vaginal swabs are to be collected during the same bathroom visit, FACE will prompt the user to ask the vaginal swab collection questions at this time. If FACE is not available read the collection questions in Part B of the hard copy backup Vaginal Swab Data Collection Form and record the responses.

5. Locate the Adult Urine Collection Kit and event-specific Biospecimen Transmittal Form.

P1 Mother, T1 Mother

If both urine and vaginal swabs are to be collected during the same bathroom visit, also locate the Vaginal Swab Collection Kit. Follow the procedures in Chapter 3 of this part and volume to provide the participant with the Vaginal Swab Collection Kit and instructions simultaneously with the urine kit and instructions.

6. Wand the collection kit bar code into FACE and validate the kit type and expiration date.
7. If the kit type is valid and the kit is not expired, open the kit and remove the urine collection container, instructions, and labels.
8. Give the labeled urine collection container to the participant for collection.
9. Instruct the participant in the urine self-collection procedures using the Adult Urine Collection Instructions (see Appendix 2-C). The participant may refer to the collection instructions when collecting the specimen.
10. While the participant is in the bathroom collecting the specimens, do the following:
 - a. Place the TM label on the Biospecimen Transmittal Form.

- b. If FACE is not available during the collection procedures, the hard copy backup Adult Urine Data Collection Form should be used. Place an extra subject label (from the visit coordinator's supplies) in the appropriate place on the form and place the DC label in the appropriate place on the form.
 - c. Put on gloves.
11. Place the specimen collection tray on a flat surface.
12. When the participant returns with the specimen:
 - a. Thank the participant for providing the specimen and ask him or her to place it on the specimen collection tray, and
 - b. Check the lid of the urine collection container to make sure it is securely closed.
13. Record the urine collection status in FACE and wand in the bar code label on the urine collection container.
14. Place the urine specimen in the biohazard transport bag with the absorbent pad and seal the bag. Wearing the dry ice glove, immediately place the sealed bag on dry ice in the transport cooler.

2.1.2.2 T3 Mother (Group 2 Vanguard Centers Only)

The following procedures are to be used for adult urine collection for the T3 mother data collection visit. After the study participant collects the urine specimen, the data collector will transfer a small amount of urine to a second urine collection container, using the following procedures. The second urine specimen will be stored and transported at refrigerated temperatures to allow for the testing of specific analytes in the specimen.

Please note that the second urine specimen (UR03) should be transported to the Specimen Processing and Shipping Center (SPSC) in order for the specimen to be processed (aliquotted and stored) at the SPSC within 2 hours of collection. If it is not possible to process the UR03 urine specimen within 2 hours of collection, ensure that the processing is completed within 4 hours of collection.

1. Put on a disposable laboratory coat.
2. Place the computer keyboard cover on the keyboard if you have not already done so. This will prevent the keyboard from contamination when handling specimens during

the visit. One keyboard cover will be used for the duration of the biospecimen collection.

3. Launch the Biospecimen Data Collection instrument of FACE on the tablet. If FACE is not available, the hard copy backup Adult Urine Data Collection Form should be used.
4. Follow the prompt in FACE to give the participant the option of collecting the vaginal swabs at the same time she is collecting the urine specimen (i.e., during the same bathroom visit).
5. Read the urine collection questions to the participant from FACE and enter the responses. If both urine and vaginal swabs are to be collected during the same bathroom visit, FACE will prompt you to ask the vaginal swab collection questions at this time. If FACE is not available, read the collection questions in Part B of the hard copy backup Adult Urine Data Collection Form and Vaginal Swab Data Collection Form and record the responses.
6. Locate the Adult Urine 2-Cup Collection Kit and the T3 Mother Biospecimen Transmittal Form. If both urine and vaginal swabs are to be collected during the same bathroom visit, also locate the Vaginal Swab Collection Kit. Follow the procedures in Chapter 3 of this part and volume to provide the participant with the Vaginal Swab Collection Kit and instructions simultaneously with the urine kit and instructions.
7. Wand the collection kit bar code into FACE and validate the kit type and expiration date. Be sure to use the Adult Urine 2-Cup Collection Kit for the collection.
8. If the kit type is valid and the kit is not expired, open the kit and remove the urine collection containers, instructions, and labels.
9. Give the labeled urine collection container with the UR02 extension to the participant for collection. *Be sure to give the participant the correct collection container (UR02) for the collection.*
10. Instruct the participant in the urine self-collection procedures by using the Adult Urine Collection Instructions (see Appendix 2-C). The participant may refer to the collection instructions when collecting the specimen.
11. While the participant is in the bathroom collecting the specimen, do the following:
 - a. Place the TM label on the Biospecimen Transmittal Form.
 - b. If FACE is not available during the collection procedures, the hard copy backup Adult Urine Data Collection Form should be used. Place an extra subject label (from the visit coordinator's supplies) in the appropriate place on the form and place the DC label in the appropriate place on the form.

- c. Put on gloves.
12. Place the specimen collection tray on a flat surface.
13. Place the second urine collection container (UR03) on the specimen collection tray. If using a disposable transfer pipette to transfer the urine, have one readily accessible and leave it inside the package until ready for use, ensuring that it does come in contact with any surface.
14. When the participant returns with the specimen, thank her for providing the specimen and ask her to place it on the specimen collection tray.
15. Record the UR02 urine collection status in FACE and wand the bar code label on the UR02 urine collection container.
16. A minimum of 20 mL of urine is required in the UR02 urine collection container in order to transfer urine to the UR03 collection container. If at least 20 mL of urine was collected, perform the following steps to transfer the urine:
 - Unscrew the lid from the empty UR03 collection container and place the lid loosely on the container, to minimize exposure of the container to the air.
 - Unscrew and remove the lid from the UR02 collection container.
 - Transfer 5–7 mL of urine from the UR02 collection container into the UR03 collection container, being careful to minimize exposure to the air. The urine may be transferred by pouring or by using the plastic transfer pipette.
 - Immediately replace the lids on both the UR02 and the UR03 collection containers and close them securely.
17. Record the UR03 urine collection status in FACE and wand in the bar code label on the UR03 urine collection container if urine was transferred. If less than 20 mL of urine was collected in the UR02 collection container, record that the UR03 collection container was not collected.
18. Place the UR02 urine specimen in a biohazard transport bag with an absorbent pad and seal the bag. Wearing the dry ice glove, immediately place the sealed bag on dry ice in the transport cooler.
19. Place the UR03 urine specimen in a biohazard transport bag with an absorbent pad. Place the remaining labels (i.e., the 4265 aliquot label, 4266 aliquot label, and other unused labels) inside the biohazard transport bag and seal the bag. Immediately place the sealed bag in the refrigerated chamber of the transport cooler, positioning the container securely and upright on the cold packs.

Please note that in order for the UR03 urine specimen to be processed and stored properly at the SPSC, the 4265 and 4266 aliquot labels must accompany the specimen to the SPSC.

2.1.3 Documenting Adult Urine Collection

1. Record any comments pertaining to the urine specimen collection in FACE (up to a 250-character limit) or on the hard copy backup Adult Urine Data Collection Form. If using the backup form, ensure the form is complete.
2. Record the urine collection status on the Biospecimen Transmittal Form.
3. If an incident occurs during the urine collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

2.1.4 Clean-Up Procedures

- After completing the urine collection procedures, make sure the work area is clean and reusable.
 - If a plastic transfer pipette was used, dispose of the pipette in the biohazard waste bag.
 - The work area is reusable if contamination, such as a spill, has *not* occurred.
 - If a spill has occurred, clean the tray with a bleach wipe. Discard items in the biohazard waste bag.
 - If the urine specimen is the last biospecimen collected at the visit, remove the computer keyboard cover, clean the work area and pack all collection supplies.
- After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer. Be sure to pack the biohazard waste bag appropriately for transport so that it is not visible upon leaving the site of data collection. The biohazard waste bag must be disposed of properly at the SPSC.

2.1.5 Transport Procedures

UR01 and UR02 urine specimens will be transported to the SPSC in the dry ice chamber of the biospecimen transport cooler. UR03 urine specimens will be transported to the SPSC in the refrigerated chamber of the biospecimen transport cooler.

- Ensure the Biospecimen Transmittal Form is complete. If this is the last biospecimen type collected at the visit, place the completed form in the zippered document pouch inside the lid of the transport cooler.
- Secure the biohazard transport bags containing the urine containers in the transport cooler and confirm the cooler is properly closed for transport.

2.2 Pregnancy Testing and Pregnancy Urine

At the P1 mother data collection visit, the data collector will collect a urine specimen from the study participant. At the same visit, participants in the High Tryer Pregnancy Probability Group¹ will receive a Pregnancy Test and Urine Collection Kit. The kit contains materials and instructions for performing pregnancy tests and for collecting and storing a urine specimen after a positive pregnancy test.

Pregnancy urine specimens will be analyzed to obtain information about physiological conditions and environmental exposures.

2.2.1 Providing Participant with Pregnancy Test and Urine Collection Materials (P1 Study Event)

2.2.1.1 Equipment, Supplies, and Forms

The following equipment, supplies and forms are required:

- Pregnancy Test and Urine Collection Kit (kit contents are in the next list)

¹ Information from the Pregnancy Screener is used to assign study participants to one of five pregnancy probability groups. At the P1 data collection visit, FACE will prompt the data collector to give the participant a Pregnancy Test and Urine Collection Kit if she has been assigned to the High Tryer Pregnancy Probability Group. Participants in the other groups *will not* receive this kit at the P1 data collection visit. For detailed information regarding assignment of participants to pregnancy probability groups, refer to Chapter 5 of Part 2, Volume III.

- Prelabeled Pregnancy Test and Urine Data Collection Form. This is a self-administered questionnaire (SAQ) to be completed by the participant at the time of collection (see Appendices 2-D and 2-E). The form must be prelabeled with the subject label.
- Computer tablet with bar code scanner.

The Pregnancy Test and Urine Collection Kit contains the following items:

- Five First Response[®] pregnancy tests
- Five plastic cups
- NCS Pregnancy Test Instructions (see Appendix 2-F)
- First Response manufacturer pregnancy test instructions
- An inner bag containing the following:
 - One prelabeled urine collection container with lid
 - One biohazard transport bag
 - Two absorbent pads
 - Two paper towels
 - Adult Urine Collection Instructions
 - One adhesive label for Biospecimen Transmittal Form (TM label)
 - One adhesive label for Pregnancy Test and Urine Data Collection Form (DC label)
 - One additional adhesive label for collection container (EX label).

2.2.1.2 Procedures for Providing Participant with Pregnancy Test and Urine Collection Materials

For study participants in the High Tryer Pregnancy Probability Group, pregnancy tests and pregnancy urine collection materials are given to them during the P1 data collection visit.

For general guidance on how to use FACE for data collection activities, refer to the FACE User's Guide. Detailed instructions for administering the Biospecimen instrument are found in Appendix VIII-A.

1. Locate the Pregnancy Test and Urine Collection Kit and Pregnancy Test and Urine Data Collection Form. Launch the Biospecimen instrument from FACE on the tablet.
2. Wand the collection kit bar code into FACE and validate the kit type and expiration date. If FACE is not available, validate the kit type and expiration date manually.
3. If the kit type is valid and the kit is not expired, open the kit.
4. Instruct the study participant in the pregnancy test procedures using the NCS Pregnancy Test Instructions. After reviewing the instructions, review the relevant contents of the kit with the participant. The participant may refer to the NCS Pregnancy Test Instructions when performing the pregnancy tests.
5. Explain to the study participant that if she has a positive pregnancy test, she then will be asked to self-collect a urine sample. The urine should be collected the following morning after the positive pregnancy test and should be stored in the participant's freezer until it can be picked up by study staff. If the participant learns of her pregnancy from a healthcare provider without using a home pregnancy test, she is asked to collect a urine sample the following morning after learning about the pregnancy.

If a study participant does not have a home freezer, the data collector should request that the participant store the urine specimen in the refrigerator until it can be picked up by study staff. If a study participant does not have a refrigerator, the data collector should request that the participant store the urine specimen at room temperature until it can be picked up by study staff. Information about storage temperature in the participant's home should be recorded appropriately on the Pregnancy Test and Urine Data Collection Form at the time of pick-up.

6. Instruct the study participant in the pregnancy urine collection instructions using the Adult Urine Collection Instructions. After reviewing the instructions, review the contents of the kit with her. The participant may refer to the Adult Urine Collection Instructions when performing the pregnancy urine collection.
7. Verify that the participant's subject label is affixed to the Pregnancy Test and Urine Data Collection Form. If not, place the subject label in the appropriate place on the form.
8. Open the inner bag and remove the adhesive labels. Place the DC label in the appropriate place on the Pregnancy Test and Urine Data Collection Form.

9. Place the remaining labels (TM and EX labels) inside the biohazard transport bag. Ask the study participant to keep the remaining adhesive labels in the biohazard transport bag when storing the urine specimen.
10. Review the Pregnancy Test and Urine Data Collection Form with the study participant, emphasizing the following instructions:
 - The morning after a positive pregnancy test, she should collect a pregnancy urine specimen using the collection kit.
 - She should place the urine specimen inside the biohazard transport bag and freeze the specimen immediately in her home freezer.
 - She should contact the Study Center to inform the Study Center about her pregnancy and to schedule a pick-up for the urine specimen.
11. Give the Pregnancy Test and Urine Collection Kit and labeled Pregnancy Test and Urine Data Collection Form to the study participant.

2.2.2 Mailing the Participant Pregnancy Test and Urine Collection Materials (Post-P1)

After the P1 data collection visit, study participants will receive follow-up calls from the Site Office. During these telephone contacts, or if a study participant contacts the Site Office at another time to request additional pregnancy tests, the Site Office may mail an additional Pregnancy Test and Urine Collection Kit to participants in the High Tryer Pregnancy Probability Group.

2.2.2.1 Supplies and Forms

The following supplies and forms should be mailed to the study participant:

- Pregnancy Test and Urine Collection Kit
- Prelabeled Pregnancy Test and Urine Data Collection Form. This SAQ is to be completed by the participant at the time of collection (see Appendices 2-D and 2-E). The form must be prelabeled with the subject label *and* the collection kit label (DC label).

2.2.2.2 Procedures for Mailing the Participant Pregnancy Test and Urine Collection Materials

For detailed instructions regarding mailing pregnancy test and urine collection materials to study participants, refer to Volume II.

2.2.3 Pick-Up and Transport of Pregnancy Urine

After a study participant has a positive pregnancy test, she is instructed to collect a pregnancy urine specimen and to contact the Study Center to inform them about her pregnancy. The Site Office then will schedule a date and time to pick up the urine specimen within 7 days (preferably within 7 days of collection, depending on when the study participant contacts the Study Center). The pregnancy urine specimen will be picked up from the participant's home by study staff and transported to the SPSC.

2.2.3.1 Equipment, Supplies, and Forms

The following equipment, supplies, and forms are required to pick up pregnancy urine from a participant's home and to transport the specimen to the SPSC:

- Specimen collection tray
- Disposable laboratory coat
- Gloves
- Hand sanitizer
- Biohazard waste bag
- Biospecimen transport cooler
- Dry ice
- Dry ice glove
- P1 Mother Biospecimen Transmittal Form (see volume Appendices VIII-B and VIII-G for form and field-by-field instructions).

2.2.3.2 Step-by-Step Procedures for Pick-Up of Pregnancy Urine

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

A computer tablet is not required to pick up pregnancy urine specimens from the study participant's home. Pick-up of pregnancy urine specimens will be documented on the hard copy data collection form and the P1 Mother Biospecimen Transmittal Form.

1. Ask the participant to retrieve the urine specimen from the freezer and the Pregnancy Test and Urine Data Collection Form.
2. Locate the P1 Mother Biospecimen Transmittal Form.
3. Put on a laboratory coat and gloves.
4. Place the specimen collection tray on a flat surface.
5. When the participant returns with the specimen, do the following:
 - Thank the participant for providing the specimen and ask her to place the biohazard transport bag containing the specimen on the specimen collection tray.
 - Remove the TM label from the biohazard bag and place it on the Biospecimen Transmittal Form.
 - Check the lid on the collection container to make sure it is securely closed and then seal the biohazard bag.
6. Wearing the dry ice glove, immediately place the sealed bag on dry ice in the transport cooler.

2.2.4 Documenting Pick-Up of Pregnancy Urine

1. Review the Pregnancy Test and Urine Data Collection Form for legibility and completeness. Verify that the DC label is affixed to the form and is legible. If not, affix an additional adhesive label (EX label) or record the collection kit ID manually if no EX labels are available. Record your data collector ID and other specimen pick-up information on the back of the form in the spaces provided.
2. Record the pregnancy urine collection status on the Biospecimen Transmittal Form.

3. If an incident occurs during the urine pick-up procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

2.2.5 Clean-Up Procedures

After completing the pregnancy urine pick-up procedures, make sure the work area is clean.

- The work area is clean if contamination, such as a spill, has *not* occurred.
- If a spill has occurred, clean the tray with a bleach wipe. Discard the wipe in the biohazard waste bag.
- Clean the work area and pack all supplies.

After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer. Be sure to pack the biohazard waste bag appropriately for transport so that it is not visible when leaving the site of data collection. The biohazard waste bag must be disposed of properly at the SPSC.

2.2.6 Transport Procedures

Pregnancy urine specimens will be transported to the SPSC in the dry ice chamber of the biospecimen transport cooler.

1. Ensure that the Biospecimen Transmittal Form is complete. Place the completed form in the zippered document pouch, inside the lid of the transport cooler along with any unused labels.
2. Secure the biohazard transport bag containing the urine container in the dry ice and confirm the cooler is properly closed for transport.

The Pregnancy Test and Urine Data Collection Form will be transported to the Site Office.

2.3 Infant Urine

Infant urine specimens will be collected for the 6-Month and 12-Month data collections. These specimens will be analyzed to obtain information about physiological conditions and environmental exposures.

The parent will be told at the beginning of the visit that the visit includes collecting a urine sample from the child. If the parent agrees to the collection, the data collector will place a urine collection bag on the child towards the beginning of the visit. The urine collection bag will remain on the child while the data collector proceeds with other data collection activities and periodically checks to see if urine has collected in the bag. The urine collection bag should remain on the child for at least 1 hour and 15 minutes to allow for urine to collect in the bag, but as soon as the child has urinated, the bag should be removed. The data collector will then transfer the sample from the urine collection bag into the urine collection container and prepare the specimen for transport to the SPSC.

2.3.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to collect and transport infant urine using the urine collection bag method:

- Infant Urine Bag Collection Kit (kit contents are in the next list)
- Pediatric urine collection bag for demonstration
- Specimen collection tray
- Chux pads
- Soap cleansing towelette
- Disposable laboratory coat
- Gloves
- Hand sanitizer
- Biohazard waste bag
- Biospecimen transport cooler

- Dry ice
- Dry ice glove
- Computer tablet with bar code scanner
- Computer keyboard cover.

The Infant Urine Bag Collection Kit contains the following items:

- One sterile pediatric urine collection bag, prescreened
- One sterile prelabeled urine collection container with lid
- One adhesive remover wipe
- One biohazard transport bag with absorbent pads
- Two paper towels
- One diaper
- Infant Urine Bag Collection Instructions
- One adhesive label for Biospecimen Transmittal Form (TM label)
- One adhesive label for hard copy backup Infant Urine Data Collection Form (DC label)
- One additional adhesive label for collection container (EX label).

The following form is required to collect and transport infant urine specimens:

- Event-specific Biospecimen Transmittal Form (see appendices at the end of this volume for forms and field-by-field instructions).

Infant urine collection data will be documented in the Biospecimen instrument in FACE. If FACE is not available, then the appropriate hard copy backup Infant Urine Data Collection Form must be used to document collection data (see Appendices 2-G and 2-H, respectively, for form and field-by-field instructions). Once the system becomes available, data must be entered in the system from the backup form. Instructions for entering data from backup forms into FACE can be found in the document *Guide to FACE Data Entry From Backup Biospecimen Data Collection Forms: Postnatal Data Collection* (located on the NCS Collaboration Portal).

2.3.2 Step-by-Step Procedures for Infant Urine Collection

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following procedures are to be used for infant urine collection using the urine collection bag method. For general guidance on how to use FACE for data collection activities, refer to the FACE User's Guide. For detailed question-by-question specifications for administering the Biospecimen instrument, refer to the document Instructions for Documenting Biospecimen Collection in FACE (located on the NCS Collaboration Portal).

2.3.2.1 Application of the Urine Collection Bag

1. Put on a disposable laboratory coat.
2. Launch the Biospecimen instrument of FACE on the tablet. If FACE is not available, the hard copy backup Infant Urine Data Collection Form should be used.
3. Review the infant urine bag collection procedures with the parent, using the Infant Urine Bag Collection Instructions as a guide (see Appendix 2-I).
 - Be sure to emphasize that the parent must be present during both the application and the removal of the urine collection bag.
 - Inform the parent that the adhesive on the bag may cause mild skin irritation upon removal of the bag.
 - Show the parent the demo pediatric urine collection bag from the Biospecimen Auxiliary Bag supplies when explaining the procedures.
 - If the parent objects or is uncomfortable with the data collector cleansing the child's diaper area and applying the urine collection bag, the parent may perform these procedures with guided instruction from the data collector.
4. If the parent refuses to allow the collection, document the refusal in FACE or on the Infant Urine Data Collection Form.
5. Read the infant urine collection questions to the parent from FACE and enter the responses. If FACE is not available, read the collection questions in Part B of the hard copy backup Infant Urine Data Collection Form and record the responses.

6. Place the specimen collection tray on a flat surface.
7. Locate the Infant Urine Bag Collection Kit and Biospecimen Transmittal Form.
8. Wand the collection kit bar code into FACE and validate the kit type and expiration date.
9. If the kit type is valid and the kit is not expired, open the kit and place the kit contents on the tray.
10. Place the TM label on the Biospecimen Transmittal Form
11. If the hard copy backup Infant Urine Data Collection Form is being used during the collection procedures, place the DC label in the appropriate place on the form and place an extra subject label (from the visit coordinator's supplies) in the appropriate place on the form.
12. Select an appropriate location in the participant's home to perform the urine bag application. The child will need to be lying on his or her back while the procedures are being performed. A changing table is ideal for this purpose, but dependent on the circumstances, a changing pad, Chux, or other suitable absorbent material may be placed on a flat surface. If the bag application will be performed in another room, use the specimen collection tray to transport the necessary materials to the selected location.
13. Cleanse your hands and put on gloves.
14. Lay the child on his or her back on a changing table or other suitable flat surface. Do not leave the child unattended at any time during these procedures to avoid accidental falls.
15. Remove the child's diaper. If preferred, the parent may remove the child's diaper.
16. If the parent will perform the procedures, instruct the parent on the procedures for cleansing the genital area and placing the collection bag on the child (steps 17-25), using the Infant Urine Bag Collection Instructions as a guide.
17. The child's genital area will need to be cleaned based on how the parent responds to the question regarding product use in the Biospecimen instrument (or Question 3 in Part B of the hard copy backup Infant Urine Data Collection Form). The four products asked about are
 - Diaper cream or ointment,
 - Vaseline,
 - Infant lotion, and

- Baby oil.

If the parent indicated that any of the products were used on the child's diaper area in the past 24 hours, perform the following two steps to cleanse the child's genital area:

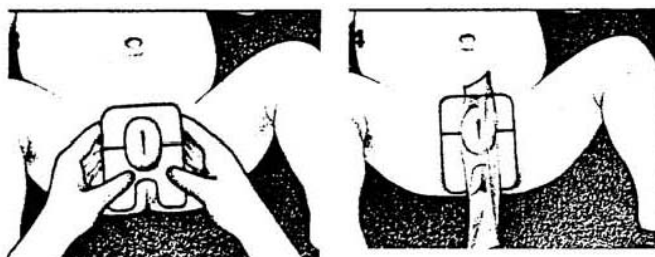
- First cleanse the area from front to back with a soap towelette to remove any product residue.
- Follow by cleansing the area from front to back with the water and/or wipe provided by the study.

If the parent indicated that none of the four products were used on the child's diaper area in the past 24 hours, cleanse the area from front to back only with the water and/or wipe provided by the study. Do not cleanse the area with a soap towelette.

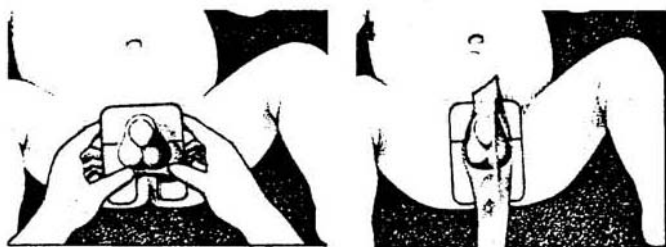
If the parent did not know whether any of the four products were used in the past 24 hours, or if the parent refused to answer the question, then perform the following two steps to cleanse the child's genital area:

- First cleanse the area from front to back with a soap towelette to remove any product residue.
- Follow by cleansing the area from front to back with the water and/or wipe provided by the study.

18. Allow the newly cleansed area to air dry. Do not wipe the area to speed drying. The skin must be completely dry before applying the collection bag.
19. Remove the paper backing from the bottom half of the adhesive patch. Leave the top half of the adhesive covered until the bottom section has been applied to the skin.
20. Open the child's legs to expose the genital area.
21. Begin application of the adhesive on the tiny area of skin between the genitals and the anus, smoothing any folds of skin if necessary.
22. For girls, it is best to apply the adhesive so that the urethral opening is at the top of the bag opening (see following image).



23. For boys, the adhesive can be placed on or below the scrotum. Ensure that the penis is inside the opening of the collection bag (see following image).



24. Press the adhesive firmly against the skin, avoiding wrinkles. When the bottom section of the adhesive is in place, remove the paper backing from the upper portion of the adhesive patch. Work upward to complete application of the bag.
25. After the collection bag is securely in place, carefully place a diaper on the child over the collection bag. A diaper is provided in the collection kit, or if preferred, the parent may use one of the child's own diapers. If the diaper that was removed is not soiled, the diaper can be re-used.
26. Remove your gloves and cleanse your hands.
27. Record in FACE that the urine collection was initiated.
28. On the next FACE screen break off the FACE session by selecting "Break Off" and click on the End Exam button () at the top of the screen. Select "Planned Break" at the End of Section screen.

After placement of the collection bag is complete, the data collector may proceed with other data collection activities and should periodically check the collection bag to see if urine has collected in the bag. If preferred, the parent may check the child's diaper periodically instead of the data collector. The urine collection bag should remain on the child for at least one hour and 15 minutes to allow for urine to collect in the bag, but as soon as the child has urinated, the bag should be removed.

If the child has a bowel movement while the bag is in place, if the bag leaks, or if the bag is pulled off by the child, promptly remove the bag and follow the procedures to transfer any collected urine to the collection container if possible.

If a second urine collection bag will be applied to the child, ask the parent if he or she agrees to a second application before repeating the procedure with a new collection bag from the Biospecimen Auxiliary Bag supplies.

2.3.2.2 Removal of the Urine Collection Bag and Transfer of Urine

The urine collection bag should be removed from the child by the data collector as soon as possible after the child has urinated. If the parent objects or is uncomfortable with the data collector removing the urine collection bag, the parent may perform this procedure with guided instruction from the data collector. The data collector will then transfer the urine from the collection bag into the urine collection container and prepare the specimen for transport to the SPSC.

1. Put on a disposable laboratory coat.
2. Place the computer keyboard cover on the keyboard if you have not already done so. This will prevent the keyboard from contamination when handling specimens during the visit.
3. Launch the Biospecimen instrument of FACE on the tablet. If FACE is not available, the hard copy backup Infant Urine Data Collection Form should be used.
4. Continue the FACE session by selecting “Collect Specimen.”
5. Select an appropriate location in the participant’s home to perform the urine bag removal. The child will need to be lying on his or her back while the bag removal procedure is performed. A changing table is ideal for this purpose, but depending on the circumstances a changing pad, Chux, or other suitable absorbent material may be placed on a flat surface.
6. To prepare the transfer of the urine, place the specimen collection tray on a flat surface and gather the materials needed (i.e., paper towels, urine collection container with lid). Unfold a paper towel on the specimen collection tray.
7. Cleanse your hands and put on gloves.
8. Lay the child on his or her back on a changing table or other suitable flat surface.
9. Remove the child’s diaper. If preferred, the parent may remove the child’s diaper.
10. If the parent will perform the bag removal procedure, instruct the parent on the procedures for removing the collection bag from the child (steps 11 and 12) using the Infant Urine Bag Collection Instructions as a guide.
11. Carefully remove the urine collection bag from the child, being careful not to spill the bag contents. Slowly remove the adhesive from the skin, beginning at the top of the adhesive patch and working downward. Avoid discomfort to the child by pushing the skin away from the adhesive rather than pulling the adhesive from the skin.

12. If necessary, use the adhesive remover wipe to aid in removing the adhesive patch from the skin.
13. Re-diaper or ask the parent to re-diaper the child after the urine collection bag has been removed.
14. As soon as possible after removing the urine collection bag, perform the following steps to transfer the urine into the sterile prelabeled urine collection container provided in the Infant Urine Bag Collection kit:
 - Unscrew the lid from the empty collection container and place the lid face down on the paper towel.
 - Tilt the collection bag so the urine is away from the blue tab.
 - Remove the blue tab and carefully drain the contents of the urine collection bag into the collection container, being careful not to touch the inside of the sterile container or the lid.
 - Immediately replace the lid on the collection container and close it securely.
 - Dispose of the empty urine collection bag in the biohazard waste bag.

2.3.3 Documenting Infant Urine Collection

1. Record the urine collection status in FACE and record the required collection information by following the prompts.
2. Wand the bar code label on the urine collection container.
3. Place the urine specimen in the biohazard transport bag with the absorbent pads and seal the bag. Wearing the dry ice glove, immediately place the sealed transport bag on dry ice in the transport cooler.
4. Record any comments pertaining to the infant urine collection in FACE (up to a 250-character limit) or on the hard copy backup Infant Urine Data Collection Form. If using the backup form, ensure the form is complete.
5. Record the urine collection status on the Biospecimen Transmittal Form.
6. If an incident occurs during the urine collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

2.3.4 Clean-Up Procedures

1. After completing the infant urine collection procedures, make sure the work area is clean and reusable.
 - The work area is reusable if contamination, such as a spill, has *not* occurred.
 - If a spill has occurred, clean the tray with a bleach wipe. Discard items in the biohazard waste bag.
 - Remove the computer keyboard cover, clean the work area, and pack all collection supplies.
2. After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer. Be sure to pack the biohazard waste bag appropriately for transport so that it is not visible upon leaving the site of data collection. The biohazard waste bag must be disposed of properly at the SPSC.

2.3.5 Transport Procedures

Infant urine specimens will be transported to the SPSC in the dry ice chamber of the biospecimen transport cooler.

- Ensure the Biospecimen Transmittal Form is complete. Place the completed form in the zippered document pouch inside the lid of the transport cooler along with any unused labels.
- Secure the biohazard transport bag containing the urine container in the dry ice and confirm the cooler is properly closed for transport.

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Part 2

Appendix 2-A

Adult Urine Data Collection Form

Appendix 2-A. Adult Urine Data Collection Form

	National Children's Study Adult Urine Data Collection Form
	T1-1 st , T1-Prior, P1, T3-1 st , T3 Prior, T1 Dad

(Only for use when FACE is not available)

Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office Time collection kit opened: : ☐ a.m. ☐ p.m. h h m m Place Adult Urine Collection DC Label Here	Collection Status (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for Not Done/Partial (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient ☐ Defective collection kit ☐ Slide broken ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other-specify: _____
Part B: Adult Urine Collection Questions	
1. When did you last urinate? <i>¿A qué hora orinó por última vez?</i> : ☐ a.m. ☐ p.m. h h m m ☐ Refused ☐ Don't know	
2. When was the last time you had anything to eat or drink other than water? <i>¿A que hora comió o bebió algo por última vez, aparte de agua?</i> : ☐ a.m. ☐ p.m. h h m m ☐ Refused ☐ Don't know	

Subject Label

 Assignment ID,
 Subject ID, Event Type

ADUCPT02.00DU

Appendix 2-A. Adult Urine Data Collection Form (continued)

3. The last time that you ate, how much of what you ate was beef, pork, cod, tuna, or salmon? <i>La última vez que comió, ¿qué tanto de lo que comió era carne de res, cerdo, bacalao, atún o salmón?</i> ☐ None / Nada ☐ Less than one quarter of the meal / Menos de un cuarto de la comida ☐ One quarter to one half of the meal / De un cuarto a la mitad de la comida ☐ Less than three quarters of the meal / Menos de tres cuartos de la comida ☐ Three quarters to all of the meal / De tres cuartos a toda la comida ☐ All of the meal / Toda la comida ☐ Refused ☐ Don't know	
4. Do you take creatine supplements? ☐ Yes ☐ No <i>¿Toma suplementos de creatina?</i> ☐ Refused ☐ Don't know	
Part C: Adult Urine Collection	
UR01 or UR02 Urine collection container	Collection Status (Mark one.) ☐ Collected (END) ☐ Not collected Reason not collected (Mark one.) ☐ Quantity not sufficient ☐ Other-specify: _____ ☐ Refused
UR03 Urine collection container For Urine 2 Cup Kit Only	Collection Status (Mark one.) ☐ Collected (END) ☐ N/A ☐ Not collected Reason not collected (Mark one.) ☐ Quantity not sufficient ☐ Other-specify: _____ ☐ Refused
Comments:	

Data collector ID for field QC:

Date entered into FACE: / / 20

m m d d y y y y

ID of data collector who entered the form:

Part 2

Appendix 2-B

Adult Urine Data Collection Form: Field-by-Field Instructions

Appendix 2-B.
Adult Urine Data Collection Form: Field-by-Field Instructions

ADULT URINE DATA COLLECTION FORM: FIELD-BY-FIELD INSTRUCTIONS

This form is only to be used when the Field-Administration Collection Environment (FACE) is not available and should be completed by the biospecimen data collector at the P1 mother, T1 mother, T1 father and T3 mother data collection visits. Instructions for completing each item on the form are provided in this field-by-field.

After Completing the Form

- Within 2 hours of the visit, the form should be checked to make sure that it is accurate, legible, and complete.
- Make sure that all of the appropriate boxes are completely filled. Comments should be limited to the area provided.
- The biospecimen data collector who checks the form for completion should write her data collector ID in the space provided at the bottom of the last page.
- The data collector who enters the data in FACE should record the date of data entry and her data collector ID in the spaces provided on the last page of the form.



National Children's Study Adult Urine Data Collection Form

T1-1st, T1-Prior, P1, T3-1st, T3 Prior, T1 Dad

(Only for use when FACE is not available)

Part A: Administrative	
Date: / / 2 0 m m d d y y y y	Collection Status (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done
Data collector ID:	Reason for Not Done/Partial (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient ☐ Defective collection kit ☐ Slide broken ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other-specify: _____
Visit location: ☐ Home ☐ Clinic/Office	
Time collection kit opened: : ☐ a.m. h h m m ☐ p.m.	
Place Adult Urine Collection DC Label Here	
Part B: Adult Urine Collection Questions	
1. When did you last urinate? : ☐ a.m. h h m m ☐ p.m. ¿A qué hora orinó por última vez?	
☐ Refused ☐ Don't know	
2. When was the last time you had anything to eat or drink other than water? : ☐ a.m. h h m m ☐ p.m. ¿A que hora comió o bebió algo por última vez, aparte de agua?	
☐ Refused ☐ Don't know	

ADUCPT02.00DU

Subject Label

Assignment ID,
Subject ID, Event Type

Part A: Administrative Section

- *Date*—Record the date that the adult urine collection was completed or attempted. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002). The date of collection should not be recorded in advance of the participant’s study visit.
- *Data Collector ID*—Record the data collector ID of the person who completes the form.
- *Visit location*—Mark the box corresponding to the location of the visit.
- *Collection status (Select one)*—Mark the box that corresponds to the status of the adult urine collection.
 - “Complete”—Mark this box to indicate that the specimen was collected.
 - “Partial complete”—Mark this box to indicate that the urine collection was attempted but the participant did not collect any urine.
 - “Not done”—Mark this box to indicate that the participant did not provide a urine specimen. When this box is marked indicate the reason that the urine specimen was not collected.
- *Reason for Not Done/Partial (Mark one)*—Mark the box that corresponds to the choice that best explains why the urine specimen was not done or was partially completed. If the reason is determined prior to giving the Adult Urine Collection Kit to the participant, complete this section and the items in Part A as described; however, do not open the Adult Urine Collection Kit or complete Parts B and C.
 - “Participant refusal”—Mark this box to indicate that the participant was unwilling to provide a urine specimen.
 - “Participant Ill/emergency”—Mark this box to indicate that the participant became ill during the visit and was unable to provide a urine specimen. This box also is marked if the participant has an emergency that requires termination of the visit prior to the collection of the urine specimen. Record a brief description of the nature of the emergency or illness in the Comments section of Part C.
 - “No time”—Mark this box to indicate that the urine specimen was not collected because the visit is ended ahead of schedule. Record a brief description of the reason that the visit was ended in the Comments section in Part C.



**THE NATIONAL
CHILDREN'S
STUDY**

National Children's Study

Adult Urine Data Collection Form

T1-1st, T1-Prior, P1, T3-1st, T3 Prior, T1 Dad

(Only for use when FACE is not available)

Part A: Administrative

Date: / / 20 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office	Collection Status (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for Not Done/Partial (Mark one.) ☐ Participant refusal ☐ Participant Ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient ☐ Defective collection kit ☐ Slide broken ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other-specify: _____

Time collection kit opened: : ☐ a.m. ☐ p.m.

h h m m

Place Adult Urine Collection DC Label Here

Part B: Adult Urine Collection Questions

1. When did you last urinate? <i>¿A qué hora orinó por última vez?</i>	 : ☐ a.m. ☐ p.m. ☐ Refused ☐ Don't know
2. When was the last time you had anything to eat or drink other than water? <i>¿A que hora comió o bebió algo por última vez, aparte de agua?</i>	 : ☐ a.m. ☐ p.m. ☐ Refused ☐ Don't know

ADUCPT02.00DU

Subject Label

Assignment ID,
Subject ID, Event Type

- “Safety exclusion”—This code does not apply to this biospecimen collection activity.
 - “Physical limitations”—Mark this box to indicate that the participant has a physical limitation that prevented him or her from providing a urine specimen. Record a brief description of the type of physical limitation in the Comments section in Part C.
 - “Quantity not sufficient”—This code does not apply to this biospecimen collection activity.
 - “Defective collection kit”—Mark this box to indicate that the urine specimen was not collected because of a problem with the Adult Urine Collection Kit. This includes not having the appropriate supplies available in the home or clinic.
 - “Slide broken”—This code does not apply to this biospecimen collection activity.
 - “Language issue, Spanish”—Mark this box to indicate that the urine specimen was not collected because the biospecimen data collector does not speak Spanish well enough to communicate the necessary instructions to the participant.
 - “Language issue, non-Spanish”—Mark this box to indicate that the urine specimen was not collected because the biospecimen data collector is unable to communicate the necessary instructions to the participant.
 - “Cognitive disability”—Mark this box to indicate that the urine specimen was not collected because the participant is cognitively or developmentally impaired and therefore unable to understand the specimen collection instructions.
 - “Parent/guardian refusal”—Mark this box to indicate that the participant is younger than 18 years old and his or her parent or guardian refused to allow her to provide a urine specimen.
 - “Other—specify”—Mark this box to indicate that the urine specimen was not collected for a reason other than those listed; specify the reason in the space provided.
- *Time collection kit opened*—Record the time the Adult Urine Collection Kit was opened. Be sure to zero fill the spaces when necessary and to mark the box to indicate “a.m.” or “p.m.” For example if data collection kit is opened at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”

	National Children's Study Adult Urine Data Collection Form T1-1st, T1-Prior, P1, T3-1st, T3 Prior, T1 Dad

(Only for use when FACE is not available)

Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID: Visit location: ☐ Home ☐ Clinic/Office Time collection kit opened: : ☐ a.m. h h m m ☐ p.m. Place Adult Urine Collection DC Label Here	Collection Status (Mark one.) ☐ Complete ☐ Partial complete ☐ Not done Reason for Not Done/Partial (Mark one.) ☐ Participant refusal ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitations ☐ Quantity not sufficient ☐ Defective collection kit ☐ Slide broken ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/guardian refusal ☐ Other-specify: _____
Part B: Adult Urine Collection Questions	
1. When did you last urinate? : ☐ a.m. <i>¿A qué hora orinó por última vez?</i> h h m m ☐ p.m. ☐ Refused ☐ Don't know	
2. When was the last time you had anything to eat or drink other than water? : ☐ a.m. <i>¿A que hora comió o bebió algo por última vez, aparte de agua?</i> h h m m ☐ p.m. ☐ Refused ☐ Don't know	

ADUCPT02.00DU

Subject Label

Assignment ID,
Subject ID, Event Type

- **Kit Label**—Before reviewing the Adult Urine Collection Instructions with the participant, open the Adult Urine Collection Kit and place the “DC” label in the appropriate place on the form.

Part B: Adult Urine Collection Questions

1. *When did you last urinate?*

Record the time of the participant’s last urination prior to collecting the specimen. Be sure to zero fill the spaces when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the participant last urinated at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.” If the participant refuses to answer or does not know, mark the corresponding box.

2. *When was the last time you had anything to eat or drink other than water?*

Record the time that the participant reports last eating or drinking anything other than water. Be sure to zero fill the spaces when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the kit is opened at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”

Subject Label

Obtain a subject label from the visit coordinator’s biospecimen folder and affix it to the bottom right corner of the data collection form.

3. The last time that you ate, how much of what you ate was beef, pork, cod, tuna, or salmon? <i>La última vez que comió, ¿qué tanto de lo que comió era carne de res, cerdo, bacalao, atún o salmón?</i> ☐ None / <i>Nada</i> ☐ Less than one quarter of the meal / <i>Menos de un cuarto de la comida</i> ☐ One quarter to one half of the meal / <i>De un cuarto a la mitad de la comida</i> ☐ Less than three quarters of the meal / <i>Menos de tres cuartos de la comida</i> ☐ Three quarters to all of the meal / <i>De tres cuartos a toda la comida</i> ☐ All of the meal / <i>Toda la comida</i> ☐ Refused ☐ Don't know	
4. Do you take creatine supplements? <i>¿Toma suplementos de creatina?</i> ☐ Yes ☐ No ☐ Refused ☐ Don't know	
Part C: Adult Urine Collection	
UR01 or UR02 Urine collection container	Collection Status (Mark one.) ☐ Collected (END) ☐ Not collected Reason not collected (Mark one.) ☐ Quantity not sufficient ☐ Other-specify: _____ ☐ Refused
UR03 Urine collection container For Urine 2 Cup Kit Only	Collection Status (Mark one.) ☐ Collected (END) ☐ N/A ☐ Not collected Reason not collected (Mark one.) ☐ Quantity not sufficient ☐ Other-specify: _____ ☐ Refused
Comments: _____ _____	

Data collector ID for field QC:

Date entered into FACE: //20

m m d d y y y y

ID of data collector who entered the form:

3. *The last time that you ate, how much of what you ate was beef, pork, cod, tuna, or salmon?*

Read each of the responses and mark the box that corresponds to the participant's response. If the participant refuses to answer or does not know, mark the corresponding box.

4. *Do you take creatine supplements?*

Mark the box that corresponds to the participant's response. If the participant refuses to answer or does not know, mark the corresponding box.

Part C: Adult Urine Collection

- *Collection Status* (Mark one)—Mark the box that corresponds to the status of the adult urine collection.
 - “Collected”—Mark this box to indicate that the specimen was collected. When the specimen is collected, no additional information is required and the form is complete.
 - “Not collected”—Mark this box to indicate that the specimen was not collected. When this box is marked, indicate the reason that the urine specimen was not collected.
 - “N/A” (UR03 only)—Mark this box to indicate that the collection status is not applicable. UR03 will only be collected if using the Urine 2 Cup Collection Kit.
- *Reason for Not Collected* (Mark one)—Mark the box that corresponds to the choice that best explains why the specimen was not collected.
 - “Quantity not sufficient”—Choose one of the following:
 1. “UR01 or UR02”—Mark this box to indicate that the urine specimen was not collected because the study participant did not have enough urine to be able to provide a specimen.
 2. “UR03” (If using the Urine 2 Cup Collection Kit only)—Mark this box to indicate that no urine was transferred from the UR02 collection cup into the UR03 collection cup either because UR02 was not collected or because ≤ 20 mL of urine was collected in UR02. A minimum of 20 mL of urine is required in UR02 in order to collect UR03.
 - “Other—specify”—Mark this box to indicate that the adult urine specimen was not collected for a reason other than those listed; specify the reason in the space provided.

3. The last time that you ate, how much of what you ate was beef, pork, cod, tuna, or salmon? <i>La última vez que comió, ¿qué tanto de lo que comió era carne de res, cerdo, bacalao, atún o salmón?</i> ☐ None / <i>Nada</i> ☐ Less than one quarter of the meal / <i>Menos de un cuarto de la comida</i> ☐ One quarter to one half of the meal / <i>De un cuarto a la mitad de la comida</i> ☐ Less than three quarters of the meal / <i>Menos de tres cuartos de la comida</i>		☐ Three quarters to all of the meal / <i>De tres cuartos a toda la comida</i> ☐ All of the meal / <i>Toda la comida</i> ☐ Refused ☐ Don't know	
4. Do you take creatine supplements? <i>¿Toma suplementos de creatina?</i>		☐ Yes ☐ Refused	☐ No ☐ Don't know
Part C: Adult Urine Collection			
UR01 or UR02 Urine collection container		Collection Status (Mark one.) ☐ Collected (END) ☐ Not collected Reason not collected (Mark one.) ☐ Quantity not sufficient ☐ Other-specify: _____ ☐ Refused	
UR03 Urine collection container For Urine 2 Cup Kit Only		Collection Status (Mark one.) ☐ Collected (END) ☐ N/A ☐ Not collected Reason not collected (Mark one.) ☐ Quantity not sufficient ☐ Other-specify: _____ ☐ Refused	
Comments: _____ _____			

Data collector ID for field QC:

Date entered into FACE: / /

m m d d y y y y

ID of data collector who entered the form:

- “Refused”—Mark this box to indicate that the participant is unwilling to provide a urine specimen.
- *Comments*—Additional comments may include reasons that the urine specimen was not collected or problems encountered during the collection that may affect analysis. Problems with post-collection processing also should be recorded here.

This page deliberately blank.

Part 2

Appendix 2-C

Adult Urine Collection Instructions

Appendix 2-C. Adult Urine Collection Instructions

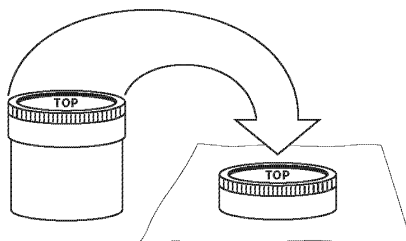
OMB Control Number: 0925-0593
Expiration Date: 09/30/2011

National Children's Study Adult Urine Collection Instructions

As part of the National Children's Study, we ask you to collect a sample of your urine.
This kit includes everything you will need to collect the sample: a prelabeled urine collection cup with lid and 2 paper towels.

Instructions

1. Wash your hands with soap and water.
2. Lay one paper towel on a flat surface. Unscrew the lid from the collection cup and place it on the paper towel. The inside of the lid should be placed face down on the paper towel. Do not touch the inside of the lid or the collection cup. Do not allow the inside of the collection cup or the inside of the lid to come in contact with any part of your body, clothing, or bathroom surfaces.



3. Start urinating into the toilet, then urinate directly into the collection cup. If possible, fill the cup at least half full. Do not fill to overflowing.
4. Screw the lid on the collection cup immediately so that the urine is only briefly exposed to the air.
5. Use the other paper towel to wipe any urine from the outside of the cup.
6. Remember to wash your hands with soap and water after collecting the sample.
7. Give the collection cup back to the study staff.

If you have any questions please ask study staff.

Thank you for providing this sample!

Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

ADUCIN01.00DU

Appendix 2-C. Adult Urine Collection Instructions (continued)

Número de control de OMB: 0925-0593
Fecha de vencimiento: 09/30/2011

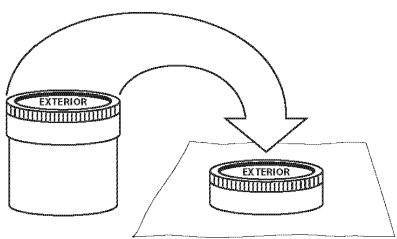
Estudio Nacional de los Niños Instrucciones para tomar la muestra de orina de un adulto

Como parte del Estudio Nacional de los Niños queremos pedirle que tome una muestra de su orina.

Con estos materiales usted tendrá todo lo que necesita para tomar la muestra, incluyendo un envase con tapa para muestras de orina previamente etiquetado y 2 toallas de papel.

Instrucciones

1. Lávese las manos con agua y jabón.
2. Extienda una toalla de papel en una superficie plana. Quite la tapa del envase y póngala sobre la toalla. El interior de la tapa debe quedar boca abajo sobre la toalla. No toque el interior de la tapa ni el interior del envase. Tampoco permita que el interior del envase ni el de la tapa toquen ninguna parte de su cuerpo, ropa o las superficies del baño.



3. Comience a orinar en el inodoro o excusado y continúe orinando directamente dentro del envase para la muestra. Si es posible, llene el envase al menos hasta la mitad. No permita que se derrame.
 4. Ajuste la tapa del envase de inmediato para que la orina no esté en contacto con el aire más que por unos breves momentos.
 5. Con la otra toalla de papel, limpie el exterior del envase.
 6. Recuerde lavarse bien las manos con agua y jabón después de tomar la muestra.
 7. Entregue el envase al personal del estudio.
-

Si tiene alguna pregunta, por favor pregunte al personal del estudio.

¡Gracias por darnos esta muestra!

Se calcula que el promedio de tiempo necesario para esta recolección de información es de 7 minutos por entrevista, incluyendo el tiempo para leer las instrucciones, buscar fuentes de información existentes, reunir y mantener la información necesaria y completar y revisar la recolección de información. **Ninguna agencia puede llevar a cabo ni patrocinar una recolección de información y ninguna persona está obligada a responder a dicha recolección a menos que ésta muestre un número de control vigente de OMB.** Envíe los comentarios acerca de este cálculo de tiempo necesario, incluyendo sugerencias sobre cómo reducirlo, o acerca de cualquier otro aspecto de esta recolección de información a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). No devuelva el formulario contestado a esta dirección.

ADUCIN01.00DU

Part 2

Appendix 2-D

Pregnancy Test and Urine Data Collection Form (English)

Appendix 2-D.
Pregnancy Test and Urine Data Collection Form (English)


 6761



National Children's Study

Pregnancy Test and Urine Data Collection Form

P1

Instructions

- ➔ Please use a black or blue pen to complete this form. Do not use a felt-tip pen or a pencil.
- ➔ Mark ☒ to indicate your answer.
- ➔ If you want to change your answer, mark ☐ on the wrong answer.
- ➔ Your answers are important. Please print clearly using uppercase, block letters (for example, "WEDNESDAY").

As part of the National Children's Study, we are asking you to collect a urine sample the morning after your positive pregnancy test. This should be an early morning sample, collected the first time you urinate after you wake up to start your day. Only collect this urine sample if you had a positive pregnancy test.

You have been provided with:

- A prelabeled urine collection cup with lid
- 2 paper towels
- A sealable plastic bag
- Instructions you will need to collect your urine sample.

Please follow the instructions provided.

1. What was the date of your positive pregnancy test?

/

/

2

0

m m
d d
y y y y

2. What is today's date?

/

/

2

0

m m
d d
y y y y

3. What time did you collect your sample?

:

a.m. ☐

p.m. ☐

h h
m m

4. Was this the first time you urinated after you woke up?

☐ Yes

☐ No

☐ Not sure, explain: _____

5. At what time did you last urinate before this collection?

:

a.m. ☐

p.m. ☐

h h
m m

Please complete the question on the back.


 URPREG01.00EN

**For
Office Use
Only**

**Place Subject ID
Label Here**

**Appendix 2-D.
Pregnancy Test and Urine Data Collection Form (English) (continued)**



6. What time did you place your urine sample in the freezer?

: ☐ a.m. ☐ p.m.
 h h m m

Contact the Study Center to let them know you are pregnant and that you have a urine sample ready for pick up.

Please call the Study Center number on your Local Contact Sheet if you have any questions.

Thank you for taking the time to provide this information today.

For Data Collector's Use

Date kit provided to participant:

/ /
 m m d d y y y y

Data collector ID:

Date urine specimen picked up:

/ /
 m m d d y y y y

Was the urine specimen frozen when received from the participant? ☐ Yes ☐ No

Time urine specimen was placed in the cooler:

: ☐ a.m. ☐ p.m.
 h h m m

**Pregnancy Test
Kit ID**

Part 2

Appendix 2-E

Pregnancy Test and Urine Data Collection Form (Spanish)

Appendix 2-E. Pregnancy Test and Urine Data Collection Form (Spanish)



Número de control de OMB: 0925-0593
Fecha de vencimiento: 09/30/2011



THE NATIONAL
CHILDREN'S
STUDY

SALUD · CRECIMIENTO · AMBIENTE

Estudio Nacional de los Niños

Formulario de información de la muestra de orina y la prueba de embarazo

P1

Instrucciones

- ➔ Por favor use una pluma o bolígrafo de tinta negra o azul para completar este formulario. No use marcador ni lápiz.
- ➔ Marque con una ☒ para indicar su respuesta.
- ➔ Si desea cambiar su respuesta, tache la respuesta errónea así: ✕.
- ➔ Sus respuestas son importantes. Por favor escriba en letra clara, en letras de imprenta mayúsculas (por ejemplo, "MIÉRCOLES").

Como parte del Estudio Nacional de los Niños, queremos pedirle que tome una muestra de orina a la mañana siguiente de haber obtenido un resultado positivo en su prueba de embarazo. Esta muestra se debe tomar temprano en la mañana, la primera vez que orine después de despertarse para comenzar el día. Tome esta muestra solamente si obtuvo un resultado positivo en la prueba de embarazo.

Se incluyen los siguientes materiales:

- Un envase con tapa para muestras de orina previamente etiquetado
- 2 toallas de papel
- Una bolsa de plástico sellable
- Las instrucciones que necesitará para tomar su muestra de orina.

Por favor siga las instrucciones que se incluyen.

1. ¿En qué fecha obtuvo un resultado positivo en su prueba de embarazo?

		/			/	2	0		
m	m		d	d		a	a	a	a

2. ¿Cuál es la fecha de hoy?

		/			/	2	0		
m	m		d	d		a	a	a	a

3. ¿A qué hora tomó su muestra?

		:				
h	h		m	m		

☐ a.m. ☐ p.m.

4. ¿Fue ésta la primera vez que orinó desde que se despertó?

- ☐ Sí
- ☐ No
- ☐ No está segura, explique: _____

Por favor responda las preguntas al otro lado de la página.



URPREG00.03SP

REVIEW

**For
Office Use
Only**

Place Subject ID
Label Here

Appendix 2-E.
Pregnancy Test and Urine Data Collection Form (Spanish) (continued)



Draft

5. ¿A qué hora orinó por última vez antes de tomar esta muestra?

: ☐ a.m. ☐ p.m.
 h h m m

6. ¿A qué hora puso la muestra de orina en el congelador?

: ☐ a.m. ☐ p.m.
 h h m m

Comuníquese con el Centro del Estudio y avíseles que está embarazada y que su muestra de orina está lista para que la pasen a buscar.

Por favor si desea hacer alguna pregunta llame al número del Centro del Estudio que hay en su Hoja de Contactos Locales.

Gracias por tomarse el tiempo hoy para darnos esta información.

For Data Collector's Use

Date kit provided to participant:

/ /
 m m d d y y y y

Data collector ID:

Date urine specimen picked up:

/ /
 m m d d y y y y

Was the urine specimen frozen when received from the participant? ☐ Yes ☐ No

Time urine specimen was placed in the cooler:

: ☐ a.m. ☐ p.m.
 h h m m

**Pregnancy Test
Kit ID**

Part 2

Appendix 2-F

Pregnancy Test Instructions

Appendix 2-F. Pregnancy Test Instructions

OMB Control Number: 0925-0593
Expiration Date: 09/30/2011

National Children's Study Pregnancy Test Instructions

As part of the National Children's Study, we are asking you to take a pregnancy test the first day of your missed period. For example, if you expect your period on the 20th day of the month and have not started your period by the 21st day, please take the test.

The kit includes:

- 5 Pregnancy tests
- 5 Plastic cups
- 1 Urine collection kit to be used the morning after a positive pregnancy test

Pregnancy Test Instructions

For the most accurate results, the pregnancy test should be done the first time you urinate in the morning. Follow the instructions below. You may also refer to the First Response instructions included in the kit.

1. Collect your urine in one of the clean plastic cups included in the pregnancy test kit. The cup should be at least half full.
2. Remove the overcap from the absorbent tip.
3. Immerse the entire absorbent tip in the urine for **5 seconds only**.
4. Remove the absorbent tip from the urine.
5. With the tip still pointing down toward the urine, replace the overcap and lay the test stick on a flat surface with the result window facing up. (The test will still work if you do not replace the overcap.)
6. Read the result after **3 minutes**.
 - o **Positive Test (pregnant)** – You will see **two parallel pink lines** in the result window. One line may be lighter than the other.
 - o **Negative Test (not pregnant)** – You will see **one pink line** in the result window.



Important Notes

- There should be at least one pink line in the result window after 5 minutes to indicate that the test is complete and was done correctly. If one pink line does not appear after 5 minutes, the test is invalid.
- Reasons for an invalid test:
 - o Not enough urine on the absorbent tip.
 - o Not holding the test stick with the absorbent tip pointing downward while replacing the cap.
- If the test is invalid, retest by carefully following the instructions above using a new test stick.
- A positive result will last for 48 hours. A negative result cannot be read after 10 minutes.
- The test results may be affected by medications that contain the pregnancy hormone (hCG). Examples of these types of medications include but are not limited to: A.P.L.[™], Pregnyl[™], Profasi[™], and Pergonal[™].

After conducting the test, follow the directions below:

- If the test is positive:
 - o Collect a urine sample tomorrow morning. This should be an early morning sample that you will collect the first time you urinate after you wake up.
 - o Be sure to record the date of the positive pregnancy test on the Pregnancy Test and Urine Data Collection Form.
- If the test is negative, and you do not begin your period within 2 days, take another test.
- If the tests continue to be negative and you do not begin your period in 7 days, call your doctor or other health care provider.

Please call the Study Center number on your Local Contact Sheet if you have any questions.

Thank you for your important contribution to the National Children's Study.

Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

PGTIN01.00DU

Appendix 2-F. Pregnancy Test Instructions (continued)

Número de control de OMB: 0925-0593
Fecha de vencimiento: 09/30/2011

Estudio Nacional de los Niños Instrucciones para la prueba de embarazo

Como parte del Estudio Nacional de los Niños, queremos pedirle que se haga una prueba de embarazo el primer día que se atrase su menstruación. Por ejemplo, si espera la menstruación el día 20 del mes y no ha empezado a menstruar el día 21, por favor hágase la prueba.

Los materiales incluyen:

- 5 pruebas de embarazo
- 5 envases de plástico
- 1 paquete con los materiales para tomar una muestra de orina que deberá usarse la mañana siguiente después de haber obtenido una prueba de embarazo positiva.

Instrucciones para la prueba de embarazo

Para mayor precisión en los resultados, la prueba de embarazo debe hacerse cuando orine por primera vez en la mañana. Siga las instrucciones a continuación. También puede usar las instrucciones de First Response que se incluyen en los materiales.

1. Orine en uno de los envases de plástico sin usar que se incluyen en el paquete de materiales para la prueba de embarazo. Debe llenar al menos la mitad del envase.
2. Quite la tapa protectora de la punta absorbente.
3. Sumerja completamente la punta absorbente en la orina **solamente durante 5 segundos**.
4. **Saque la punta absorbente de la orina.**
5. Con la punta todavía apuntando hacia abajo, hacia la orina, ponga la tapa protectora y coloque la prueba sobre una superficie plana con la ventana de resultados mirando hacia arriba. (La prueba funcionará correctamente aun sin poner la tapa.)
6. Lea el resultado después de **3 minutos**.
 - **Prueba positiva (embarazada)** – Verá dos líneas paralelas de color rosado en la ventana de resultados. Una línea puede estar más clara que la otra.
 - **Prueba negativa (no está embarazada)** – Verá una línea de color rosado en la ventana de resultados.



Información importante

- Debe haber al menos una línea de color rosado en la ventana de resultados después de 5 minutos para indicar que la prueba se ha completado y que se hizo de manera correcta. Si no aparece una línea de color rosado después de 5 minutos, la prueba no es válida.
- Razones para una prueba inválida:
 - No hubo suficiente orina en la punta absorbente.
 - No sujetó la prueba con la punta absorbente hacia abajo mientras puso la tapa.
- No sujetó la prueba con la punta absorbente hacia abajo mientras puso la tapa. Si la prueba no es válida, vuelva a hacerla, siguiendo las instrucciones anteriores con atención y utilizando una nueva prueba.
- Un resultado positivo se podrá ver por 48 horas. Un resultado negativo no se puede leer después de 10 minutos.
- Los resultados de la prueba pueden verse afectados por medicamentos que contienen la hormona del embarazo (hCG). Ejemplos de este tipo de medicamentos incluyen pero no se limitan a: A.P.L.TM, PregnylTM, ProfasiTM y PergonalTM.

Después de hacer la prueba, siga las instrucciones a continuación:

- Si la prueba es positiva:
 - Tome una muestra de orina mañana en la mañana. Debe tomar esta muestra temprano en la mañana, la primera vez que orine después de despertarse.
 - Asegúrese de anotar la fecha de la prueba de embarazo positiva en el Formulario de información de la muestra de orina y la prueba de embarazo.
- Si la prueba es negativa y no le ha llegado la menstruación en un plazo de 2 días, hágase otra prueba.
- Si la prueba continúa siendo negativa y no le ha llegado la menstruación en 7 días, llame a su médico o a otro proveedor de cuidado de salud.

Por favor llame al número del Centro del Estudio que se encuentra en su Hoja de Contactos Locales si tiene alguna pregunta.

Gracias por su importante contribución al Estudio Nacional de los Niños.

Se calcula que el promedio de tiempo necesario para esta recolección de información es de 7 minutos por entrevista, incluyendo el tiempo para leer las instrucciones, buscar fuentes de información existentes, reunir y mantener la información necesaria y completar y revisar la recolección de información. Ninguna agencia puede llevar a cabo ni patrocinar una recolección de información y ninguna persona está obligada a responder a dicha recolección a menos que ésta muestre un número de control vigente de OMB. Envíe los comentarios acerca de este cálculo de tiempo necesario, incluyendo sugerencias sobre cómo reducirlo, o acerca de cualquier otro aspecto de esta recolección de información a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). No devuelva el formulario contestado a esta dirección.



New
Appendix

Part 2

Appendix 2-G

Infant Urine Data Collection Form

Appendix 2-G. Infant Urine Data Collection Form

	National Children's Study Infant Urine Data Collection Form	6-Mo

(Only for use when the FACE is not available)

Part A: Administrative	
Date: / / 2 0 m m d d y y y y	Visit location: ☐ Home ☐ Clinic/Office
Data collector ID:	Collection Status: (Mark one.) ☐ Complete ☐ Partial ☐ Not done
Place Infant Urine Bag Collection Kit DC Label Here	Reason for Not Done/Partial: (Mark one.) ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitation ☐ Quantity not sufficient ☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/Guardian refusal ☐ Other—specify: _____
READ ONLY WHEN PARENT REFUSES TO ALLOW URINE COLLECTION. I am sorry that you have chosen not to participate in this collection. Can you tell me why? <i>Lamento que haya decidido no participar en la toma de esta muestra. ¿Podría decirme por qué?</i>	
☐ Concerned about allergic reaction/Skin irritation <i>Le preocupan las reacciones alérgicas/la irritación de la piel</i> ☐ Child has a diaper rash <i>El niño tiene rozadura a causa del pañal</i> ☐ Other—specify: _____ <i>Otro—especifique:</i>	
Part B: Infant Urine Collection Questions	
1. When did you last change (name/your child's) diaper? : ☐ a.m. <i>¿A qué hora fue la última vez que le cambió el pañal a (name/su bebé)?</i> h h m m ☐ p.m.	
☐ Refused ☐ Don't know	

Child Subject LabelAssignment ID,
Subject ID, Event Type

URDC6M01.00DU

Appendix 2-G.
Infant Urine Data Collection Form (continued)

2. When was the last time he/she had anything to drink? <i>¿A qué hora fue la última vez que él/ella bebió algo?</i>	: h h m m ☐ a.m. ☐ p.m. ☐ Refused ☐ Don't know																				
3. Have you or anyone else used any of the following products on your child's diaper area in the past 24 hours? (Mark all that apply.) <i>En las últimas 24 horas, ¿ha aplicado usted u otra persona alguno de los siguientes productos en la piel de su bebé, en las zonas donde lo toca el pañal? (Marque todo lo que corresponda).</i> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">None (<i>Nada</i>)</td> <td style="width: 30%; text-align: center;">☐</td> </tr> <tr> <td>Infant powder/Talc/Cornstarch (<i>talcos para niños/talcos/maizena</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Diaper cream/Ointment (<i>crema/ungüento para la rozadura de pañal</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Vaseline (<i>vaselina</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Infant wipes (<i>pañitos para bebés</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Infant shampoo (<i>champú para bebés</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Infant lotion (<i>crema para bebés</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Baby oil (<i>aceite para bebés</i>)</td> <td style="text-align: center;">☐</td> </tr> <tr> <td>Other—please describe: _____</td> <td style="text-align: center;">☐</td> </tr> <tr> <td><i>Otro – por favor describa:</i> _____</td> <td></td> </tr> </table> ☐ Refused ☐ Don't know		None (<i>Nada</i>)	☐	Infant powder/Talc/Cornstarch (<i>talcos para niños/talcos/maizena</i>)	☐	Diaper cream/Ointment (<i>crema/ungüento para la rozadura de pañal</i>)	☐	Vaseline (<i>vaselina</i>)	☐	Infant wipes (<i>pañitos para bebés</i>)	☐	Infant shampoo (<i>champú para bebés</i>)	☐	Infant lotion (<i>crema para bebés</i>)	☐	Baby oil (<i>aceite para bebés</i>)	☐	Other—please describe: _____	☐	<i>Otro – por favor describa:</i> _____	
None (<i>Nada</i>)	☐																				
Infant powder/Talc/Cornstarch (<i>talcos para niños/talcos/maizena</i>)	☐																				
Diaper cream/Ointment (<i>crema/ungüento para la rozadura de pañal</i>)	☐																				
Vaseline (<i>vaselina</i>)	☐																				
Infant wipes (<i>pañitos para bebés</i>)	☐																				
Infant shampoo (<i>champú para bebés</i>)	☐																				
Infant lotion (<i>crema para bebés</i>)	☐																				
Baby oil (<i>aceite para bebés</i>)	☐																				
Other—please describe: _____	☐																				
<i>Otro – por favor describa:</i> _____																					
Part C: Infant Urine Collection																					
BU01 Urine collection container	Collection Status: (Mark one.) ☐ Collected ☐ Not collected Reason for Not Collected: (Mark one.) <table style="width: 100%;"> <tr> <td>☐ Bag leaked</td> <td>☐ Bag spilled</td> </tr> <tr> <td>☐ Bag torn/Pulled off</td> <td>☐ Sample contaminated</td> </tr> <tr> <td>☐ Quantity not sufficient</td> <td>☐ Refused</td> </tr> <tr> <td colspan="2">☐ Other—specify: _____</td> </tr> </table>	☐ Bag leaked	☐ Bag spilled	☐ Bag torn/Pulled off	☐ Sample contaminated	☐ Quantity not sufficient	☐ Refused	☐ Other—specify: _____													
☐ Bag leaked	☐ Bag spilled																				
☐ Bag torn/Pulled off	☐ Sample contaminated																				
☐ Quantity not sufficient	☐ Refused																				
☐ Other—specify: _____																					
Who placed the urine bag on the child?	☐ Data collector ☐ Parent ☐ Other—specify: _____																				
If a second bag was applied, who placed the second bag on the child?	☐ Second bag not required ☐ Data collector ☐ Parent ☐ Other—specify: _____																				
Comments:																					

Data collector ID for field QC:	Date entered into FACE:
	/ / m m d d y y y y
	ID of data collector who entered the form:



New
Appendix

Part 2

Appendix 2-H

Infant Urine Data Collection Form: Field-By-Field Instructions

Appendix 2-H.
Infant Urine Data Collection Form: Field-by-Field Instructions

**INFANT URINE DATA COLLECTION FORM:
FIELD-BY-FIELD INSTRUCTIONS**

This form is only to be used when the Field-Administration Collection Environment (FACE) is not available and should be completed by the postnatal biospecimen data collector for the 6-Month and 12-Month data collection. Instructions for completing each item on the form are provided in this field-by-field.

After Completing the Form

- Within 2 hours of the visit, the form should be checked to make sure that it is accurate, legible, and complete.
- Make sure that all of the appropriate boxes are completely filled. Comments should be limited to the area provided.
- The data collector who checks the form for completeness should write her data collector ID in the space provided at the bottom of the last page.
- The data collector who enters the data in FACE will record the date of data entry and her data collector ID in the space provided on the last page of the form.

	National Children's Study Infant Urine Data Collection Form	6-Mo

(Only for use when the FACE is not available)

Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID:	Visit location: ☐ Home ☐ Clinic/Office Collection Status: (Mark one.) ☐ Complete ☐ Partial ☐ Not done Reason for Not Done/Partial: (Mark one.) ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitation ☐ Quantity not sufficient ☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/Guardian refusal ☐ Other—specify: _____
Place Infant Urine Bag Collection Kit DC Label Here	
READ ONLY WHEN PARENT REFUSES TO ALLOW URINE COLLECTION. I am sorry that you have chosen not to participate in this collection. Can you tell me why? <i>Lamento que haya decidido no participar en la toma de esta muestra. ¿Podría decirme por qué?</i> ☐ Concerned about allergic reaction/Skin irritation <i>Le preocupan las reacciones alérgicas/la irritación de la piel</i> ☐ Child has a diaper rash <i>El niño tiene rozadura a causa del pañal</i> ☐ Other—specify: _____ <i>Otro—especifique:</i> _____	
Part B: Infant Urine Collection Questions	
1. When did you last change (name/your child's) diaper? : ☐ a.m. <i>¿A qué hora fue la última vez que le cambió el pañal a (name/su bebé)?</i> h h m m ☐ p.m. ☐ Refused ☐ Don't know	

Child Subject Label

 Assignment ID,
 Subject ID, Event Type

URDC6M01.00DU

Part A: Administrative Section

- *Date*—Record the date that the infant urine collection was completed or attempted. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002). The date of collection should not be recorded in advance of the participant’s study visit.
- *Data collector ID*—Record the data collector ID of the person who completes the form.
- *Visit location*—Mark the box corresponding to the location of the visit.
- *Collection status* (Mark one)—Mark the box that corresponds to the status of the infant urine collection.
 - “Complete”—Mark this box to indicate that the infant urine was collected.
 - “Partial”—Mark this box to indicate that the infant urine collection was initiated but the specimen was not collected. When this box is marked, indicate the reason the infant urine collection is partially complete.
 - “Not done”—Mark this box to indicate that an infant urine collection was not initiated. When this box is marked indicate the reason the collection was not initiated.
- *Reason for Not Done/Partial* (Mark one)—Mark the box that corresponds to the choice that best explains why the specimen was not collected or the collection was partially complete.
 - “Participant ill/ Emergency”—Mark this box to indicate that the child participant was ill during the visit and was unable to provide an infant urine specimen. This box also is marked if the participant/parent has an emergency that required termination of the visit prior to the collection of the infant urine specimen. Record a brief description of the nature of the emergency or illness in the Comments section in Part C.
 - “No time”—Mark this box to indicate that the infant urine specimen was not collected because the visit was ended ahead of schedule. Record a brief description of the reason the visit was ended in the Comments section on Part C.
 - “Safety exclusion”—This code does not apply to this biospecimen collection activity.
 - “Physical limitation”—Mark this box to indicate that the child participant has a physical limitation that prevents collection of an infant urine specimen. Record a brief description of the type of physical limitation in the Comments section in Part C.
 - “Quantity not sufficient”—Mark this box to indicate that the specimen was not collected because the child did not urinate into the collection bag or there was not enough urine to transfer to the collection container (i.e., a few drops).

 National Children's Study Infant Urine Data Collection Form 6-Mo	
(Only for use when the FACE is not available)	
Part A: Administrative	
Date: / / 2 0 m m d d y y y y Data collector ID:	Visit location: ☐ Home ☐ Clinic/Office Collection Status: (Mark one.) ☐ Complete ☐ Partial ☐ Not done Reason for Not Done/Partial: (Mark one.) ☐ Participant ill/emergency ☐ No time ☐ Safety exclusion ☐ Physical limitation ☐ Quantity not sufficient ☐ Defective collection kit ☐ Language issue, Spanish ☐ Language issue, non-Spanish ☐ Cognitive disability ☐ Parent/Guardian refusal ☐ Other—specify: _____
Place Infant Urine Bag Collection Kit DC Label Here	
READ ONLY WHEN PARENT REFUSES TO ALLOW URINE COLLECTION. I am sorry that you have chosen not to participate in this collection. Can you tell me why? <i>Lamento que haya decidido no participar en la toma de esta muestra. ¿Podría decirme por qué?</i> ☐ Concerned about allergic reaction/Skin irritation <i>Le preocupan las reacciones alérgicas/la irritación de la piel</i> ☐ Child has a diaper rash <i>El niño tiene rozadura a causa del pañal</i> ☐ Other—specify: _____ <i>Otro—especifique:</i> _____	
Part B: Infant Urine Collection Questions	
1. When did you last change (name/your child's) diaper? : ☐ a.m. <i>¿A qué hora fue la última vez que le cambió el pañal a (name/su bebé)?</i> h h m m ☐ p.m. ☐ Refused ☐ Don't know	

URDC6M01.00DU

Child Subject Label

Assignment ID,
Subject ID, Event Type

- “Defective collection kit”—Mark this box to indicate that the infant urine specimen was not collected due to a problem with the collection kit. This includes not having the appropriate supplies available.
- “Language issue, Spanish”—Mark this box to indicate that the infant urine specimen was not collected because the data collector did not speak Spanish well enough to communicate with the parent regarding the infant urine collection procedures.
- “Language issue, non-Spanish”—Mark this box to indicate that the infant urine specimen was not collected because the data collector was unable to communicate with the parent regarding the infant urine collection procedures.
- “Cognitive disability”—Mark this box to indicate that the infant urine specimen was not collected because the parent is cognitively or developmentally impaired and therefore unable to understand the infant urine collection procedures.
- “Parent/Guardian refusal”—Mark this box to indicate that the child’s parent or guardian refused to allow the infant urine collection. Go to the next section in Part A titled “READ ONLY WHEN PARENT REFUSES TO ALLOW URINE COLLECTION.”
- “Other—specify”—Mark this box to indicate that the infant urine specimen was not collected for a reason other than those listed; specify the reason in the space provided.
- Place Infant Urine Bag Collection Kit DC Label Here—Place the kit DC label in the appropriate place on the form, if the kit was opened and the collection was initiated.
- READ ONLY WHEN PARENT REFUSES TO ALLOW URINE COLLECTION.

I am sorry that you have chosen not to participate in this collection. Can you tell me why?

- “Concerned about allergic reaction/Skin irritation”—Mark this box to indicate that the parent refused to allow the infant urine collection because he or she is concerned that application and/or removal of the urine collection bag may cause an allergic reaction or skin irritation for the child.
- “Child has a diaper rash”—Mark this box to indicate that the child’s parent or guardian refused to allow the infant urine collection because the child has a diaper rash.
- “Other—specify”—Mark this box to indicate that the child’s parent or guardian refused to allow the infant urine collection for a reason other than those listed; specify the reason in the space provided.

Child Subject Label

Affix a subject label for the child assignment to the bottom right corner of the data collection form in the space provided.

2. When was the last time he/she had anything to drink? <i>¿A qué hora fue la última vez que él/ella bebió algo?</i>	: h h m m ☐ a.m. ☐ p.m. ☐ Refused ☐ Don't know																														
3. Have you or anyone else used any of the following products on your child's diaper area in the past 24 hours? (Mark all that apply.) <i>En las últimas 24 horas, ¿ha aplicado usted u otra persona alguno de los siguientes productos en la piel de su bebé, en las zonas donde lo toca el pañal? (Marque todo lo que corresponda).</i> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">None (<i>Nada</i>)</td> <td style="width: 5%; text-align: center;">☐</td> <td style="width: 35%;"></td> </tr> <tr> <td>Infant powder/Talc/Cornstarch (<i>talcos para niños/talcos/maizena</i>)</td> <td style="text-align: center;">☐</td> <td></td> </tr> <tr> <td>Diaper cream/Ointment (<i>crema/ungüento para la rozadura de pañal</i>)</td> <td style="text-align: center;">☐</td> <td></td> </tr> <tr> <td>Vaseline (<i>vaselina</i>)</td> <td style="text-align: center;">☐</td> <td></td> </tr> <tr> <td>Infant wipes (<i>pañitos para bebés</i>)</td> <td style="text-align: center;">☐</td> <td></td> </tr> <tr> <td>Infant shampoo (<i>champú para bebés</i>)</td> <td style="text-align: center;">☐</td> <td></td> </tr> <tr> <td>Infant lotion (<i>crema para bebés</i>)</td> <td style="text-align: center;">☐</td> <td></td> </tr> <tr> <td>Baby oil (<i>aceite para bebés</i>)</td> <td style="text-align: center;">☐</td> <td></td> </tr> <tr> <td>Other—please describe: _____</td> <td style="text-align: center;">☐</td> <td></td> </tr> <tr> <td><i>Otro – por favor describa:</i> _____</td> <td></td> <td></td> </tr> </table> ☐ Refused ☐ Don't know		None (<i>Nada</i>)	☐		Infant powder/Talc/Cornstarch (<i>talcos para niños/talcos/maizena</i>)	☐		Diaper cream/Ointment (<i>crema/ungüento para la rozadura de pañal</i>)	☐		Vaseline (<i>vaselina</i>)	☐		Infant wipes (<i>pañitos para bebés</i>)	☐		Infant shampoo (<i>champú para bebés</i>)	☐		Infant lotion (<i>crema para bebés</i>)	☐		Baby oil (<i>aceite para bebés</i>)	☐		Other—please describe: _____	☐		<i>Otro – por favor describa:</i> _____		
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Part C: Infant Urine Collection																															
BU01 Urine collection container	Collection Status: (Mark one.) ☐ Collected ☐ Not collected Reason for Not Collected: (Mark one.) <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">☐ Bag leaked</td> <td style="width: 50%;">☐ Bag spilled</td> </tr> <tr> <td>☐ Bag torn/Pulled off</td> <td>☐ Sample contaminated</td> </tr> <tr> <td>☐ Quantity not sufficient</td> <td>☐ Refused</td> </tr> <tr> <td colspan="2">☐ Other—specify: _____</td> </tr> </table>	☐ Bag leaked	☐ Bag spilled	☐ Bag torn/Pulled off	☐ Sample contaminated	☐ Quantity not sufficient	☐ Refused	☐ Other—specify: _____																							
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Who placed the urine bag on the child?	☐ Data collector ☐ Parent ☐ Other—specify: _____																														
If a second bag was applied, who placed the second bag on the child?	☐ Second bag not required ☐ Data collector ☐ Parent ☐ Other—specify: _____																														
Comments:																															

Data collector ID for field QC:	Date entered into FACE: / / m m d d y y y y ID of data collector who entered the form:

Part B: Infant Urine Collection Questions

1. *When did you last change (name/your child's) diaper?*
 - *Time*—Record the time the parent states in his or her response. Be sure to complete the fields with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the child's diaper was last changed at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.” If the parent refuses to answer or does not know, mark the corresponding box.
2. *When was the last time he/she had anything to drink?*
 - *Time*—Record the time the parent states in his or her response. Be sure to complete the fields with a zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the child was last fed breast milk at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.” If the parent refuses to answer or does not know, mark the corresponding box.
3. *Have you or anyone else used any of the following products on your child's diaper area in the past 24 hours? (Mark all that apply.)*
 - Read each of the choices and mark the boxes that correspond to the parent's responses. Mark all choices that apply. For example, if the parent used diaper ointment and infant wipes on the child's diaper area in the past 24 hours, mark both boxes corresponding to these responses.
 - If the parent responds that a product was used on the child's diaper area within the past 24 hours that is not listed, mark “Other” and record the product that was used in the space provided.
 - If the parent refuses to answer or does not know, mark the corresponding box.

Part C: Infant Urine Collection

Complete the following information for the infant urine collection:

- *Collection status* (Mark one)—Mark the box that corresponds to the status of the infant urine collection.
 - “Collected”—Mark this box to indicate that the infant urine specimen was collected and transferred from the urine collection bag to the collection container.
 - “Not Collected”—Mark this box to indicate that the infant urine specimen was not collected. When this box is marked, indicate the reason the infant urine specimen was not collected.
- *Reason for Not Collected* (Mark one)—Mark the box that corresponds to the choice that best explains why the specimen was not collected.
 - “Bag leaked” —Mark this box to indicate that the urine collection bag leaked after the bag was applied to the child's genital area.
 - “Bag torn/Pulled off”—Mark this box to indicate that the urine collection bag was torn or the child pulled the bag off after it was applied to the child's genital area.

2. When was the last time he/she had anything to drink? <i>¿A qué hora fue la última vez que él/ella bebió algo?</i>	: h h m m ☐ a.m. ☐ p.m. ☐ Refused ☐ Don't know
3. Have you or anyone else used any of the following products on your child's diaper area in the past 24 hours? (Mark all that apply.) <i>En las últimas 24 horas, ¿ha aplicado usted u otra persona alguno de los siguientes productos en la piel de su bebé, en las zonas donde lo toca el pañal? (Marque todo lo que corresponda).</i>	
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Part C: Infant Urine Collection	
BU01 Urine collection container	Collection Status: (Mark one.) ☐ Collected ☐ Not collected Reason for Not Collected: (Mark one.) ☐ Bag leaked ☐ Bag torn/Pulled off ☐ Quantity not sufficient ☐ Other—specify: _____ ☐ Bag spilled ☐ Sample contaminated ☐ Refused
Who placed the urine bag on the child?	☐ Data collector ☐ Parent ☐ Other—specify: _____
If a second bag was applied, who placed the second bag on the child?	☐ Second bag not required ☐ Data collector ☐ Parent ☐ Other—specify: _____
Comments: 	

Data collector ID for field QC: 	Date entered into FACE: / / m m d d y y y y ID of data collector who entered the form:

- “Quantity not sufficient”—Mark this box to indicate that the specimen was not collected because the child did not urinate into the collection bag or there was not enough urine to transfer to the collection container (i.e., a few drops).
- “Bag spilled”—Mark this box to indicate that the contents of the urine collection bag were spilled after the bag was removed from the child’s genital area.
- “Sample contaminated”—Mark this box to indicate that the infant urine specimen was contaminated because the child had a bowel movement while the collection bag was applied and it was not possible to obtain an uncontaminated sample.
- “Refused”—Mark this box to indicate that the parent is unwilling to allow the infant urine collection.
- “Other—specify:”—Mark this box to indicate that the infant urine specimen was not collected for a reason other than those listed; specify the reason in the space provided.

1. *Who placed the urine bag on the child?*

- Mark the box that corresponds to the appropriate choice.
 - “Data collector”—Mark this box to indicate that the data collector applied the urine collection bag to the child.
 - “Parent”—Mark this box to indicate that the parent applied the urine collection bag to the child.
 - “Other-specify:”—Mark this box to indicate that someone other than the data collector or the parent applied the urine collection bag to the child; specify who in the space provided.

2. *If a second bag was applied, who placed the second bag on the child?*

- Mark the box that corresponds to the appropriate choice.
 - “Second bag not required”—Mark this box to indicate that a second urine collection bag was not applied to the child to collect the specimen.
 - “Data collector”—Mark this box to indicate that the data collector applied the second urine collection bag to the child.
 - “Parent”—Mark this box to indicate that the parent applied the second urine collection bag to the child.
 - “Other-specify:”—Mark this box to indicate that someone other than the data collector or the parent applied the second urine collection bag to the child; specify who in the space provided.

- *Comments*—Additional comments may include reasons why the infant urine specimen was not collected or problems encountered during the collection that may affect analysis. Problems with post collection processing should also be recorded here.

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New
Appendix

Part 2

Appendix 2-I

Infant Urine Bag Collection Instructions

Appendix 2-I Infant Urine Bag Collection Instructions

OMB Control Number: 0925-0593
Expiration Date: 09/30/2011

National Children's Study Infant Urine Bag Collection Instructions

As part of the National Children's Study, we are asking you to allow us to collect a sample of your child's urine. This kit contains the following items:

- 1 diaper
- 1 wipe
- 1 urine specimen collection bag
- 1 adhesive remover wipe
- 1 sterile prelabeled collection container.

Important Instructions before getting started

- **The parent must be present during both the application and the removal of the urine collection bag.**
- **Inform the parent that the adhesive on the bag may cause mild irritation.**

Instructions for Placing Urine Bag on Child

1. Cleanse your hands and put on gloves.
2. Lay the child on his or her back.
3. Remove the child's diaper.
4. Cleanse the child's entire genital area.
5. Ensure that the skin is dry before applying the collection bag.
6. Remove the paper backing from the bottom half of the adhesive patch. *Note:* It is easier to leave the top half of the adhesive covered until the bottom section has been applied to the skin.
7. Open the child's legs to expose the genital area. Begin application of the adhesive on the tiny area of skin between the anus and genitals, smoothing any folds of skin if necessary.
8. For girls, it is best to place the adhesive so that the urethral opening is at the top of the bag opening (see the following figure).



9. For boys, the adhesive can be placed on or below the scrotum. Ensure that the penis is inside the bag opening (see the following figure).



10. Press the adhesive firmly against the skin, avoiding wrinkles. When the bottom section is in place, remove the paper backing from the upper portion of the adhesive patch. Work upward to complete application.
11. Place a diaper on the child over the collection bag.

Instructions for Removing Urine Bag and Transferring Sample

1. Periodically check the collection bag for urine.
2. Remove the urine bag as soon as possible after the child has urinated.
3. Remove the bag, beginning at the top and working downward. Avoid discomfort to the child by pushing the skin away from the adhesive rather than pulling the adhesive from the skin.
4. If necessary use the adhesive remover wipe to aid in removing the bag from the child.
5. Transfer the urine into the sterile urine collection container. Be careful not to touch the inside of the sterile collection container or the lid. Put the lid on the collection cup immediately so that the urine is only briefly exposed to the air.

Public reporting burden for this collection of information is estimated to average **XX** minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

URCIN601.00DU

Appendix 2-I Infant Urine Bag Collection Instructions (continued)

Número de control de OMB: 0925-0593
Fecha de vencimiento: 09/30/2011

Estudio Nacional de los Niños Instrucciones para tomar la muestra de orina del bebé con una bolsa

Como parte del Estudio Nacional de los Niños, quisiéramos pedirle que nos permita tomar una muestra de orina de su hijo. Los materiales incluyen:

- 1 pañal
- 1 pañito
- 1 bolsa para la muestra de orina
- 1 pañito para quitar adhesivos
- 1 recipiente para muestras esterilizado y previamente etiquetado.

Instrucciones importantes para antes de empezar

- El padre o la madre debe estar presente tanto al momento de poner la bolsa para la muestra de orina como al momento de quitarla.
- Avísele al padre o a la madre que el adhesivo de la bolsa puede causar una leve irritación.

Instrucciones para ponerle al niño la bolsa para la muestra de orina

12. Lávese las manos y póngase los guantes.
13. Acueste al niño boca arriba.
14. Quítele el pañal al niño.
15. Limpie toda la zona de los genitales del niño.
16. Asegúrese de que la piel esté seca antes de poner la bolsa para la muestra.
17. Quite el papel que cubre la parte de abajo del parche adhesivo. *Nota:* Es más fácil no quitar la parte de arriba del adhesivo hasta que haya pegado la parte de abajo a la piel.
18. Abra las piernas del niño para que la zona genital quede expuesta. Comience a pegar el adhesivo en la pequeña zona de piel entre el ano y los genitales, estirando la piel con cuidado para que no haya pliegues.
19. Para las niñas, es mejor pegar el adhesivo de manera que la abertura de la uretra (de donde sale la orina) quede en la parte de arriba de la abertura de la bolsa (ver el siguiente dibujo).



20. Para los niños, el adhesivo se puede pegar en o debajo del escroto. Asegúrese de que el pene quede dentro de la abertura de la bolsa (ver el siguiente dibujo).



21. Oprima el adhesivo firmemente contra la piel, tratando de que no se formen arrugas. Cuando haya pegado la parte de abajo, quite el papel de la parte de arriba del parche adhesivo. Vaya pegando la bolsa desde abajo hacia arriba.
22. Póngale un pañal al niño por encima de la bolsa para la muestra.

Instrucciones para quitar la bolsa de orina y transferir la muestra

6. Revise la bolsa periódicamente para ver si se ha recogido orina.
7. Quite la bolsa tan pronto como sea posible después de que el niño haya orinado.
8. Para quitar la bolsa, comience estirándola desde arriba hacia abajo. Para no causarle molestias al niño, es mejor ir despegando la piel del adhesivo, en lugar de tirar directamente del adhesivo.
9. Si es necesario use el pañito para quitar adhesivos para ayudar a quitarle la bolsa al niño.
10. Pase la muestra de orina al recipiente esterilizado para muestras de orina. Asegúrese de no tocar la parte de adentro del recipiente ni de la tapa. Para que la orina esté expuesta al aire sólo por unos segundos, tape el recipiente de inmediato.

Se calcula que el promedio de tiempo necesario para esta recolección de información es de XX minutos por entrevista, incluyendo el tiempo para leer las instrucciones, buscar fuentes de información existentes, reunir y mantener la información necesaria y completar y revisar la recolección de información. Ninguna agencia puede llevar a cabo ni patrocinar una recolección de información y ninguna persona está obligada a responder a dicha recolección a menos que ésta muestre un número de control vigente de OMB. Envíe los comentarios acerca de este cálculo de tiempo necesario, incluyendo sugerencias sobre cómo reducirlo, o acerca de cualquier otro aspecto de esta recolección de información a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). No devuelva el formulario contestado a esta dirección.

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