

# Volume VIII

## Part 4. Blood Procedures (Collection to Storage)



November 30, 2009



# Adult Blood Collection Procedures

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

Fasting is not required before any blood draw except for the T3 study event. For the T3 study event, the participant will be asked to fast for a minimum of 8 hours prior to the data collection visit. After the blood collection is complete, the study participant may be encouraged to eat a snack before continuing with the remaining data collection activities.

This chapter describes step-by-step procedures for the collection of adult blood specimens, including general instructions for the documentation of collection activities using the Field-Administered Collection Environment (FACE). Detailed specifications for administering the Biospecimen Blood Collection instrument in FACE are found in volume Appendix VIII-A. If FACE is unavailable at the time of blood collection, the appropriate hard copy backup form should be used to document collection data until data can be entered in the system. 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 blood collection are located in Appendix I-F in General Resource Documents of Volume I.

Before a data collector may obtain blood specimens from a study participant during a data collection visit, the participant must sign a biological and environmental sample collection consent. This consent form need be signed only once for each participant during the first visit in which biospecimens are collected. The visit coordinator will use FACE to launch the consent instrument to administer the biological and environmental sample collection 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 in Volume I.

Participants will be asked a set of prescreening questions before every blood draw. These questions will be administered by the data collector by following the prompts in the data collection instrument during the visit. If a participant refuses or is unable to provide a blood specimen because he or she meets one of the exclusion criteria, the participant will be asked to provide a saliva specimen for the purpose of obtaining a source of DNA. The blood not collected (BNC) saliva specimen is in addition to the 2-day saliva specimens that are collected at specified study visits. Collection and transport procedures for adult BNC saliva are found in Section 4.2 in Part 3 of this volume.

All study events where adult blood specimens are collected require centrifugation of specific blood tubes. Centrifugation of all blood tubes except those collected from the mother at the birth must be completed within 2 hours of collection, and this may be performed at the location where blood is collected (e.g., participant's home, study clinic) or at a satellite location. Depending on the location where centrifugation will be performed, Study Centers may choose to modify the visit flow and change the timing of the blood collection component of the data collection visit as needed to meet the 2-hour time requirement. For more information about blood centrifugation requirements, see Chapter 2 of this part and volume. For more detailed information regarding the flow of data collection components within study events, refer to Volume V.

## 1.1 Adult Blood Collection Procedures

### 1.1.1 Equipment, Supplies, and Forms

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

- Event-specific Adult Blood Collection Kit (kit contents are in the next list)
- Specimen collection tray
- Chux pads
- Disposable laboratory coat
- Gloves
- Hand sanitizer
- Phlebotomy ball

- Biohazard waste bag
- Sharps container
- Adult BNC Saliva Collection Kit (BNC saliva will be collected only if the participant refuses or is unable to provide a blood specimen)
- Computer tablet with bar code scanner
- Computer keyboard cover.

Adult Blood Collection Kits are customized for each study event. Each kit contains the same general collection supplies and a specific number and type of blood tubes depending on the event type. Table 1-1 lists the Adult Blood Collection Kits that will be used throughout the NCS. The data collector should ensure that the appropriate collection kit is used for each study event.

Table 1-1. Adult blood collection kits by event type

<b>Event Type</b>	<b>Kit Name</b>
P1 Mother	Adult Blood Collection Kit- P1 Mother
T1 Mother	Adult Blood Collection Kit- T1 Mother
T1 Father	Adult Blood Collection Kit- T1 Father
T3 Mother	Adult Blood Collection Kit- T3 Mother
Birth Mother	Adult Blood Collection Kit- Birth Mother

Each Adult Blood Collection Kit contains the following items:

- Blood tubes specific for the study event type packaged in plastic clamshells (see Appendix 1-A for a complete listing of blood tubes by kit type)
- 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)
- One Blood Tube Reference Card

- Amber transport bags with absorbent pads
- 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 are required to collect adult blood specimens:

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

Adult blood collection data will be documented in the Biospecimen Blood instrument that is launched from 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 for forms and field-by-field instructions). Once the system becomes available, data must be entered into the system from the backup form.

## 1.2 Step-by-Step Procedures for Adult Phlebotomy

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

If centrifugation will be performed at the home, it is recommended that the data collector sets up the centrifuge prior to the blood draw. Refer to Section 2.5 for home centrifugation procedures. 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 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 from FACE on the tablet. If FACE is not available, the hard copy backup Adult Blood Data Collection Form should be used.

4. Use the prompts in FACE to guide the discussion with the participant.
5. Read the adult blood collection prescreening questions to the participant and enter the responses. If FACE is not available, read the questions in Part B of the hard copy backup Adult Blood Data Collection Form and record the responses.
6. If the participant refused or was unable to provide a blood specimen in Module 1, FACE 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.

Refer to Section 4.2 in Part 2 of this volume for adult BNC saliva collection procedures.

7. Find a place for the participant to sit while the blood draw is being done. The participant should be able to rest his or her *left* arm comfortably while holding it straight at the elbow, palm up on a flat surface. There also should be room for the specimen collection tray within easy reach.
8. Cover the area where the participant will rest his or her *left* arm with a chux pad (absorbent side up).
9. Place the specimen collection tray in the selected work area.
10. Locate the appropriate Adult Blood Collection Kit and event-specific Biospecimen Transmittal Form.
11. Scan the collection kit bar code into FACE and validate the kit type and expiration date.
12. If the kit type is valid and the kit is not expired, open the kit and remove the extra labels.
13. 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.
14. Cleanse hands thoroughly with hand sanitizer and put on gloves.
15. Remove the blood tubes from the clamshells and organize the blood tubes in the appropriate draw order. Refer to the Blood Tube Reference Card inside the blood collection kit and the prompts in FACE as needed.
16. Have the participant extend his or her *left* arm on the chux pad, palm up and straight at the elbow.
17. Position the arm on the work area so that the veins are readily accessible. Be sure the arm is in a *downward* position, with the elbow lower than the heart. If necessary,

- place a prop under the elbow to achieve this position. Rolled-up chux can be used for this purpose.
18. Inspect the *left* arm being used for venipuncture. The veins of choice are those located in the antecubital area. *Do not draw blood from an arm that has a rash, open sore, is swollen, or shows signs of a recent venipuncture or hematoma. Do not draw blood from an arm that contains an arterial access such as a fistula or shunt.* If the *left* arm is not appropriate, inspect the *right* arm.
  19. Apply the tourniquet several inches above the elbow and palpate for a suitable vein.
  20. Select a vein that is palpable and well-fixed to surrounding tissue. Palpate even when the vein can be seen. *Note:* If the veins do not distend rather quickly, the following techniques may be used:
    - a. Massage the arm from wrist to elbow. This forces blood into the veins.
    - b. Tap the area sharply with the index and second finger two or three times; this causes the veins to dilate.
    - c. The arm to be used for venipuncture may be hung at the participant's side without a tourniquet. This allows the veins to fill with blood to their capacity.
    - d. Examine the other arm. Sometimes the veins in one arm are larger than in the other.
  21. Check carefully for scar tissue or the presence of tendons near the vein and avoid these areas.
  22. Open the butterfly needle assembly unit and attach it to the needle holder. If veins appear to require a smaller needle gauge, substitute the 21 gauge needle assembly with the 23 gauge needle kit found in the auxiliary bag.
  23. If the tourniquet has been applied for more than 1 minute while searching for a vein, release the tourniquet. Prolonged obstruction of blood flow by the tourniquet is unnecessary and uncomfortable for the participant and may alter certain results. After 2–3 minutes, reapply the tourniquet but not too tightly.
  24. Ask the participant to squeeze the phlebotomy ball or make a tight fist.
  25. Cleanse the area with an alcohol wipe. Hold the alcohol wipe with two fingers on one side so that only one side of the alcohol wipe touches the area of the puncture site. Cleanse the area using a circular motion beginning with a narrow radius and moving outward so as not to cross over the already-cleansed area. Allow area to air dry. Do not palpate the vein after cleansing the skin.
  26. Remove the cover from the needle.

27. The vein should be fixed or held taut during the puncture. Place the left thumb about 1 inch below the point of entry and pull the skin gently in a downward motion (this stretches the skin and anchors or fixes the vein).
28. Hold the needle in line with the vein, with the bevel up and at a 15° angle with the skin, about 1/2-inch below the proposed point of entry to the vein.
29. Push the needle firmly and deliberately into the vein. When firmly in the vein, blood appears in the tubing of the needle assembly past the end of the needle. This blood flow into the tubing verifies that the needle has adequately penetrated the selected vein.
30. Quickly push the first blood tube onto the needle in the holder, puncturing the center of the stopper.
31. If no blood enters the tube and no bruise is forming, probe the vein until entry is indicated by blood flowing into the tube.
32. If no blood enters the tube and a bruise is forming, remove the needle immediately. Do not keep probing as this could cause severe bruising. Place a gauze pad over the puncture site and ask the participant to apply firm pressure to the puncture site for 3 minutes. *Remove the tourniquet.*
33. Ask the participant if a second attempt may be made. If he or she agrees, make a second attempt on the other arm with new sterile collection supplies and new tubes. A second attempt is allowed only after verbal consent from the participant. *No more than two attempts should be made.*
34. Release the tourniquet after the flow is established in the tube or if the participant becomes uncomfortable. The participant may open his or her fist once blood flow in the first tube is established.
35. When the first tube is filled to capacity, remove it from the holder and place the next tube in the holder.

For study events where a P100 tube is collected, please note the following:

The P100 tube contains a mechanical separator. When pushing the P100 tube onto the needle in the holder, insert it firmly yet carefully into the center of the stopper to minimize premature separation of the mechanical separator from the stopper (i.e., “pre-launch”). If the mechanical separator moves toward the bottom of the tube during blood collection, immediately remove and discard the pre-launched tube and redraw with a new backup P100 tube found in the auxiliary bag.

36. You may drape a clean piece of gauze over the needle to obstruct the study participant’s view.

37. *Gently* invert each tube 8–10 times immediately upon removing each tube (and while filling the next tube).
38. Repeat until all the desired tubes are filled.
39. When the last tube is filled, carefully withdraw the needle, covering the puncture site with a sterile gauze pad. Remove the needle in a smooth and quick motion. *NEVER* apply pressure to the gauze until the needle is clear of the puncture site and away from the arm. Applying pressure during the needle withdrawal causes the needle tip to scratch the skin under the gauze.
40. Have the participant hold the gauze pad with mild pressure and raise the arm in the air for 2 minutes without bending the arm. This procedure helps prevent the formation of a hematoma.
41. Immediately slide the needle safety guard forward to prevent an accidental needle stick. Place the entire used needle assembly in the sharps container. Discard the entire assembly. *DO NOT* reuse the needle holder for multiple blood draws.
42. Check the venipuncture site. If it is adequately clotted, remove the gauze and apply a Band-Aid. Instruct the participant to remove it in no less than 45 minutes if the bleeding has stopped. Also, suggest that he or she sit quietly for a few minutes. Observe the participant during this time for adverse effects. If bleeding continues, keep direct pressure on the site for 5 minutes or more.

### **1.3 Documenting Adult Blood Collection**

1. Record the collection status of each blood tube in FACE and wand the bar code label on each tube. If FACE is not available, record the collection status on the hard copy backup Adult Blood Data Collection Form.  
  
*If centrifuging at the home, cover the blood tubes with an amber bag immediately after wanding the tubes. This will protect them from exposure to light while preparing for centrifugation.*
2. Record the collection status of each blood tube and the time blood collection was completed on the Biospecimen Transmittal Form.
3. Immediately prepare the tubes for centrifugation or transport according to the location where centrifugation will be performed, following the procedures in Chapter 2 of this part and volume.
4. Record any comments pertaining to the blood specimen collection in FACE (up to a 250-character limit) or on the hard copy backup Adult Blood Data Collection Form. If using the backup form, ensure the form is complete.

5. If an incident occurs during the blood draw 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.

## 1.4 Clean-Up Procedures

1. After completing the blood collection procedures and preparing the blood tubes for transport, 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 in the biohazard waste bag.
  - c. If the blood specimens are the last biospecimens collected at the visit, remove the computer keyboard cover, clean the work area, and pack all collection supplies.
2. Close the sharps container. If this is the last time the sharps container will be used, permanently seal the container and discard it in the biohazard waste bag. If the sharps container will be used for subsequent visits, transport the closed container in the auxiliary bag.
3. 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.

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Part 4

Appendix 1-A

Blood Tubes by Kit Type



**Appendix 1-A.  
Blood Tubes by Kit Type**

<b>Adult Blood Collection Kit Type</b>	<b>Blood Tube ID</b>	<b>Blood Tube Description</b>
<b>P1 Mother</b>	LP10	3 mL Prescreened Lavender Top Tube
	LV10	6 mL Lavender Top Tube
	PP10	5 mL Plasma Preparation (PPT) White Top Tube
	SS10	8.5 mL Serum Separator (SST) Tiger Top Tube
	RD10	10 mL Plain Red Top Tube
	RD11	10 mL Plain Red Top Tube
<b>T1 Mother</b>	LP10	3 mL Prescreened Lavender Top Tube
	LV10	6 mL Lavender Top Tube
	PP10	5 mL Plasma Preparation (PPT) White Top Tube
	PN10	8.5 mL Plasma with Inhibitor (P100) White/Red Top Tube
	SS10	8.5 mL Serum Separator (SST) Tiger Top Tube
	RD10	10 mL Plain Red Top Tube
	RD11	10 mL Plain Red Top Tube
<b>T1 Father</b>	LP10	3 mL Prescreened Lavender Top Tube
	LV11	6 mL Lavender Top Tube
	RD12	10 mL Plain Red Top Tube
	AD10	8.5 mL ACD Yellow Top Tube
<b>T3 Mother</b>	LV10	6 mL Lavender Top Tube
	PP10	5 mL Plasma Preparation (PPT) White Top Tube
	PN10	8.5 mL Plasma with Inhibitor (P100) White/Red Top Tube
	SS10	8.5 mL Serum Separator (SST) Tiger Top Tube
	RD13	10 mL Plain Red Top Tube
	RD11	10 mL Plain Red Top Tube
	AD10	8.5 mL ACD Yellow Top Tube
	PX10	2.5 mL PAXgene Clear Top Tube
<b>Birth Mother</b>	LP10	3 mL Prescreened Lavender Top Tube
	RD14	10 mL Plain Red Top Tube
	RD15	10 mL Plain Red Top Tube
	RD16	10 mL Plain Red Top Tube

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Part 4

Appendix 1-B

Adult Blood Data Collection Form – P1 Mother  
and Field-by-Field Instructions



**Appendix 1-B.**  
**Adult Blood Data Collection Form–P1 Mother and Field-by-Field Instructions**

	<p>National Children's Study  <b>Adult Blood</b>  <b>Data Collection Form – P1 Mother</b></p>	<p>P1</p>
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(Only for use when FACE is not available)

<b>Part A: Administrative</b>		
<p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: center; font-size: small;">m m d d y y y y</p> <p>Data collector ID:  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Visit location:   <input type="checkbox"/> Home   <input type="checkbox"/> Clinic/Office</p>	<p>Time collection kit opened: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>   <input type="checkbox"/> a.m.   <input type="checkbox"/> p.m.</p> <p style="text-align: center; font-size: small;">h h m m</p> <div style="border: 1px solid black; padding: 5px; text-align: center; margin: 10px auto; width: 80%;">                 Place Adult Blood Collection–P1                  Mother or Adult BNC Saliva Collection                  DC Label Here             </div>	
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>		
<p>1) Do you have hemophilia or any bleeding disorder?      <input type="checkbox"/> Yes (Go to Part F)      <input type="checkbox"/> No  <i>¿Tiene hemofilia o algún problema de coagulación?</i>      <input type="checkbox"/> Refused      <input type="checkbox"/> Don't know</p>		
<p>2) Do you take any blood thinning medication, such as Coumadin or warfarin?  <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i></p> <p style="text-align: right;"> <input type="checkbox"/> Yes (Go to Part F)      <input type="checkbox"/> No  <input type="checkbox"/> Refused      <input type="checkbox"/> Don't know                 </p>		
<p>3) Have you had cancer chemotherapy within the past 4 weeks?  <i>¿Ha recibido algún tratamiento de quimioterapia para el cáncer en las últimas 4 semanas?</i></p> <p style="text-align: right;"> <input type="checkbox"/> Yes (Go to Part F)      <input type="checkbox"/> No  <input type="checkbox"/> Refused      <input type="checkbox"/> Don't know                 </p>		
<p>4) Have you had any problems with a blood draw in the past?  <i>¿Ha tenido algún problema en el pasado con una extracción de sangre?</i></p> <p style="text-align: right;"> <input type="checkbox"/> Yes      <input type="checkbox"/> No (Go to Q6)  <input type="checkbox"/> Refused (Go to Q6)      <input type="checkbox"/> Don't know (Go to Q6)                 </p>		

BDFPIM

**Subject Label**

Assignment ID,  
 Subject ID, Event Type





Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)	
<p>Because we are not able to draw your blood, we are requesting to collect a saliva sample. Several measures that are performed in blood can be measured in saliva. Are you able to provide a saliva sample?</p> <p><i>Debido a que no pudimos sacarle sangre, quisiéramos pedirle una muestra de saliva. Varios análisis que se llevan a cabo en la sangre se pueden hacer en la saliva. ¿Puede darnos una muestra de saliva?</i></p> <p style="text-align: center;"> <input type="checkbox"/> Yes                      <input type="checkbox"/> No (END)         </p> <p><b>BE SURE TO REVIEW SALIVA SAMPLE COLLECTION INSTRUCTIONS WITH THE PARTICIPANT</b></p>	
<input type="checkbox"/> Collected <input type="checkbox"/> Not collected	
<p><b>Reason not done or partial:</b> (Mark all that apply.)</p> <input type="checkbox"/> No time <input type="checkbox"/> Participant Ill/Emergency <input type="checkbox"/> Equipment failure	<input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Refuse
<p><b>Saliva Comments:</b></p> <hr/> <hr/> <hr/>	

**Data collector ID for field QC**

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**Date entered into CHITA:**

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

**ID of data collector who entered the form:**


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**ADULT BLOOD DATA COLLECTION FORM–P1 MOTHER:  
FIELD-BY-FIELD INSTRUCTIONS**

This form is only to be completed when the Field-Administrated Collection Environment (FACE) is not available at a P1 mother data collection visit. This form is to be completed by the biospecimen data collector performing the phlebotomy (i.e., blood 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 and accuracy 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 recorded on the form 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  
**Adult Blood**  
**Data Collection Form – P1 Mother**

P1

(Only for use when FACE is not available)

<b>Part A: Administrative</b>	
<p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> 2 <input type="text"/> 0 <input type="text"/> <input type="text"/></p> <p style="text-align: center; font-size: small;">m m d d y y y y</p> <p>Data collector ID:  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Visit location:   <input type="checkbox"/> Home   <input type="checkbox"/> Clinic/Office</p>	<p>Time collection kit opened: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>   <input type="checkbox"/> a.m.  <span style="font-size: small; margin-left: 10px;">h h m m   <input type="checkbox"/> p.m.</span></p> <div style="border: 1px solid black; padding: 10px; text-align: center; margin: 10px auto; width: 80%;"> <p>Place Adult Blood Collection—P1                      Mother or Adult BNC Saliva Collection                      DC Label Here</p> </div>
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>	
<p>1) Do you have hemophilia or any bleeding disorder?   <input type="checkbox"/> Yes (Go to Part F)   <input type="checkbox"/> No  <i>¿Tiene hemofilia o algún problema de coagulación?</i>   <input type="checkbox"/> Refused   <input type="checkbox"/> Don't know</p>	
<p>2) Do you take any blood thinning medication, such as Coumadin or warfarin?  <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i></p> <p style="text-align: right;"><input type="checkbox"/> Yes (Go to Part F)   <input type="checkbox"/> No  <input type="checkbox"/> Refused   <input type="checkbox"/> Don't know</p>	
<p>3) Have you had cancer chemotherapy within the past 4 weeks?  <i>¿Ha recibido algún tratamiento de quimioterapia para el cáncer en las últimas 4 semanas?</i></p> <p style="text-align: right;"><input type="checkbox"/> Yes (Go to Part F)   <input type="checkbox"/> No  <input type="checkbox"/> Refused   <input type="checkbox"/> Don't know</p>	
<p>4) Have you had any problems with a blood draw in the past?  <i>¿Ha tenido algún problema en el pasado con una extracción de sangre?</i></p> <p style="text-align: right;"><input type="checkbox"/> Yes   <input type="checkbox"/> No (Go to Q6)  <input type="checkbox"/> Refused (Go to Q6)   <input type="checkbox"/> Don't know (Go to Q6)</p>	

BDFPIM

**Subject Label**

Assignment ID,  
 Subject ID, Event Type


**Part A: Administrative Section**

- *Date*—Record the date that the blood draw is 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 study participant’s study visit.
- *Data collector ID*—Record the data collector ID of the phlebotomist who completes the form.
- *Visit location*—Mark the box corresponding to the location of the visit.
- *Time collection kit opened*—Record the time the Adult Blood 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 the kit is opened at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
- *Kit label*—Open the Adult Blood Collection Kit and place the DC label in the appropriate place on the data collection form. If the study participant refuses or is unable to provide a blood specimen but is willing to provide a saliva specimen, open the Adult Blood Not Collected (BNC) Saliva Collection Kit and place the DC label in the space provided on the front page of the form.

**Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)**

Questions 1–5 must be asked prior to each blood draw.

1. *Do you have hemophilia or any bleeding disorder?*
  - Mark the box that corresponds to the study participant’s response.
  - If the participant answers “Yes” or “Don’t know” or she refuses to answer, mark the corresponding box and go to Part F.
2. *Do you take any blood thinning medication, such as Coumadin or warfarin?*
  - Mark the box that corresponds to the study participant’s response.
  - If the participant answers “Yes” or “Don’t know” or she refuses to answer, mark the corresponding box and go to Part F.



National Children's Study  
**Adult Blood**  
**Data Collection Form – P1 Mother**

P1

(Only for use when FACE is not available)

<b>Part A: Administrative</b>	
<p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> 2 <input type="text"/> 0 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: center; font-size: small;">m m d d y y y y</p> <p>Data collector ID:  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Visit location:   <input type="checkbox"/> Home      <input type="checkbox"/> Clinic/Office</p>	<p>Time collection kit opened: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>    <input type="checkbox"/> a.m.  <span style="margin-left: 100px;">h h m m</span>                      <input type="checkbox"/> p.m.</p> <div style="border: 1px solid black; padding: 10px; text-align: center; margin: 10px auto; width: 80%;"> <p>Place Adult Blood Collection—P1                      Mother or Adult BNC Saliva Collection                      DC Label Here</p> </div>
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>	
<p>1) Do you have hemophilia or any bleeding disorder?  <i>¿Tiene hemofilia o algún problema de coagulación?</i></p> <p style="text-align: right;"> <input type="checkbox"/> Yes (Go to Part F)                      <input type="checkbox"/> No  <input type="checkbox"/> Refused    <input type="checkbox"/> Don't know                 </p>	
<p>2) Do you take any blood thinning medication, such as Coumadin or warfarin?  <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i></p> <p style="text-align: right;"> <input type="checkbox"/> Yes (Go to Part F)                      <input type="checkbox"/> No  <input type="checkbox"/> Refused    <input type="checkbox"/> Don't know                 </p>	
<p>3) Have you had cancer chemotherapy within the past 4 weeks?  <i>¿Ha recibido algún tratamiento de quimioterapia para el cáncer en las últimas 4 semanas?</i></p> <p style="text-align: right;"> <input type="checkbox"/> Yes (Go to Part F)                      <input type="checkbox"/> No  <input type="checkbox"/> Refused    <input type="checkbox"/> Don't know                 </p>	
<p>4) Have you had any problems with a blood draw in the past?  <i>¿Ha tenido algún problema en el pasado con una extracción de sangre?</i></p> <p style="text-align: right;"> <input type="checkbox"/> Yes    <input type="checkbox"/> No (Go to Q6)  <input type="checkbox"/> Refused (Go to Q6)                      <input type="checkbox"/> Don't know (Go to Q6)                 </p>	

BDFP1M

**Subject Label**

Assignment ID,  
 Subject ID, Event Type

3. *Have you had cancer chemotherapy within the past 4 weeks?*

- Mark the box that corresponds to the study participant's response.
- If the participant answers "Yes" or "Don't know" or she refuses to answer, mark the corresponding box and go to Part F.

4. *Have you had any problems with a blood draw in the past?*

- Mark the box that corresponds to the study participant's response.
- If the participant answers "No," "Refuse," or "Don't know," mark the corresponding box and go to question 6.

### **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.

5) What problems did you have with a blood draw in the past? (Mark all that apply.) <i>¿Qué problemas tuvo en el pasado con una extracción de sangre? (Mark all that apply.)</i>	
<input type="checkbox"/> Fainting / <i>Desmayos</i> <input type="checkbox"/> Light-headedness / <i>Mareos</i> <input type="checkbox"/> Hematoma / <i>Hematomas</i>	<input type="checkbox"/> Bruising / <i>Moretones</i> <input type="checkbox"/> Other—specify / <i>Otro—especifique:</i> _____ <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
6) When was the last time you had anything to eat or drink? <i>¿A qué hora comió o bebió algo por última vez?</i>	
<input type="text"/> : <input type="text"/> : <input type="text"/> : <input type="text"/> h h m m <input type="checkbox"/> a.m. <input type="checkbox"/> p.m. <input type="checkbox"/> Refused <input type="checkbox"/> Don't know	
<b>Part C: Blood Collection Tubes</b>	
<b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done	
<b>Reason for not done/partial:</b> (Mark one.) <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant Ill/Emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient	<input type="checkbox"/> Defective collection kit <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/Guardian refusal <input type="checkbox"/> Other—specify: _____
<b>LP10</b> 3mL Lavender Prescreened	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw <b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>SS10</b> Serum Separator tube 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw <b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>RD10</b> 10mL Red Top 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw <b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

5. What problems did you have with a blood draw in the past? (Mark all that apply)
- Read the first four choices to the study participant.
  - Mark the box that corresponds to the types of problems that the participant experienced during previous blood draws.
  - If the participant reports a problem that is not included in the list, mark the box that corresponds to “Other–specify” and briefly describe the problem in the space provided.
  - If the participant refuses to answer or does not remember specifically what type of problem she experienced in the past, mark the appropriate box and go to Part C.
6. *When was the last time you had anything to eat or drink?*
- Record the time the study participant reports last eating or drinking anything other than water. Be sure to fill in the spaces with zero when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the participant ate at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
  - If the participant answers “Don’t know” or she refuses to answer, mark the corresponding box.

**Part C: Blood Collection Tubes**

- *Collection status* (Mark one)—Mark the box corresponding to the status of the blood draw:
  - “Complete”—Mark this box to indicate that all blood tubes are filled to at least 3/4 the desired capacity. Desired capacity is defined as filled to the full line marked on the blood tube. This box should not be checked if there are any partially filled tubes.
  - “Partial complete”—Mark this box to indicate that at least one but not all of the blood tubes is filled to at least 3/4 of the desired capacity. When this box is marked, the phlebotomist must indicate the reason that the blood specimen collection is partially complete.
  - “Not done”—Mark this box to indicate that no blood tubes were collected. When this box is marked, the phlebotomist must indicate the reason that the blood specimen collection was not done.

5) What problems did you have with a blood draw in the past? (Mark all that apply.)  
*¿Qué problemas tuvo en el pasado con una extracción de sangre? (Mark all that apply.)*

Fainting / *Desmayos*  
 Light-headedness / *Mareos*  
 Hematoma / *Hematomas*

Bruising / *Moretones*  
 Other—specify / *Otro—especifique:* \_\_\_\_\_  
 Refused  
 Don't know

6) When was the last time you had anything to eat or drink?  
*¿A qué hora comió o bebió algo por última vez?*

:  :  :   
 h h m m       a.m.       p.m.  
 Refused       Don't know

**Part C: Blood Collection Tubes**

**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: \_\_\_\_\_

**LP10**  
3mL Lavender  
Prescreened

Full draw       Short draw       No draw

**Reason for short draw or no draw:** (Mark all that apply.)

Equipment failure       Bruising  
 Fainting       Vein collapsed during the procedure  
 Light-headedness       Other—specify: \_\_\_\_\_  
 Hematoma       Refused  
 No suitable vein

**SS10**  
Serum Separator  
tube 10

Full draw       Short draw       No draw

**Reason for short draw or no draw:** (Mark all that apply.)

Equipment failure       Bruising  
 Fainting       Vein collapsed during the procedure  
 Light-headedness       Other—specify: \_\_\_\_\_  
 Hematoma       Refused  
 No suitable vein

**RD10**  
10mL Red Top  
10

Full draw       Short draw       No draw

**Reason for short draw or no draw:** (Mark all that apply.)

Equipment failure       Bruising  
 Fainting       Vein collapsed during the procedure  
 Light-headedness       Other—specify: \_\_\_\_\_  
 Hematoma       Refused  
 No suitable vein



*Reason for not done/partial* (Mark one)—Mark the box that best describes why the blood draw was either not done or partially completed:

- “Participant refusal”—Mark this box to indicate that the study participant is unwilling to provide a blood specimen. When the participant refuses, refer to Part F of the form, which asks the participant to provide a saliva specimen. Do not mark this box to indicate that the participant refuses to provide a saliva specimen.
- “Participant Ill/Emergency”—Mark this box to indicate that the study participant had an emergency or illness that required termination of the visit prior to the collection of the blood specimens. Record a brief description of the nature of the emergency or illness in the Comments section of Part E.
- “No time”—Mark this box to indicate that the blood specimen was not collected because the visit was ended ahead of schedule. In the Comments section of Part E, record a brief description of the reason why the visit was ended.
- “Safety exclusion”—Mark this box to indicate that the study participant is ineligible to provide a blood specimen because she has a bleeding disorder, is taking blood thinning medication such as Coumadin or warfarin; or has had cancer chemotherapy during the past 4 weeks. When the participant is ineligible to provide a blood specimen, refer to Part F of the form, which asks the participant to provide a saliva specimen.
- “Physical limitations”—Mark this box to indicate that the study participant has a physical limitation that prevented her from providing blood. This type of limitation includes but is not limited to an infection or cellulites at the draw site or an inability to straighten one’s arm. Blood should not be drawn from an arm that contains a shunt or is in a cast. Record a brief description of the type of physical limitation in the Comments section of Part E. When the participant is not able to provide a blood specimen because of a physical limitation, refer to Part F of the form, which asks the participant to provide a saliva specimen.
- “Quantity not sufficient”—This box is marked in certain situations to indicate that not all of the blood tubes required for this visit were collected. It also is marked in certain situations when one or more of the blood tubes is filled to less than 3/4 the desired capacity. Desired capacity is defined as filled to the full line marked on the blood tube. Please see the instructions for selecting a reason for a “Short draw” or “No draw” in Part C to determine when this box is marked.
- “Defective collection kit”—Mark this box to indicate that the blood specimen was not collected because of a problem with the Adult Blood Collection Kit. This includes not having the appropriate supplies available in the home or clinic.

<p>5) What problems did you have with a blood draw in the past? (Mark all that apply.)  <i>¿Qué problemas tuvo en el pasado con una extracción de sangre? (Mark all that apply.)</i></p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><input type="checkbox"/> Fainting / <i>Desmayos</i></p> <p><input type="checkbox"/> Light-headedness / <i>Mareos</i></p> <p><input type="checkbox"/> Hematoma / <i>Hematomas</i></p> </div> <div style="width: 45%;"> <p><input type="checkbox"/> Bruising / <i>Moretones</i></p> <p><input type="checkbox"/> Other—specify / <i>Otro—especifique:</i> _____</p> <p><input type="checkbox"/> Refused</p> <p><input type="checkbox"/> Don't know</p> </div> </div>	
<p>6) When was the last time you had anything to eat or drink?  <i>¿A qué hora comió o bebió algo por última vez?</i></p> <div style="display: flex; justify-content: flex-end; align-items: center;"> <div style="margin-right: 20px;"> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> : <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> : <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> : <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>  <small>h h m m</small> </div> <div style="margin-right: 20px;"> <input type="checkbox"/> a.m.  <input type="checkbox"/> p.m.         </div> </div> <p><input type="checkbox"/> Refused    <input type="checkbox"/> Don't know</p>	
<b>Part C: Blood Collection Tubes</b>	
<p><b>Collection status:</b> (Mark one.)</p> <p><input type="checkbox"/> Complete</p> <p><input type="checkbox"/> Partial complete</p> <p><input type="checkbox"/> Not done</p> <p><b>Reason for not done/partial:</b> (Mark one.)</p> <p><input type="checkbox"/> Participant refusal</p> <p><input type="checkbox"/> Participant Ill/Emergency</p> <p><input type="checkbox"/> No time</p> <p><input type="checkbox"/> Safety exclusion</p> <p><input type="checkbox"/> Physical limitations</p> <p><input type="checkbox"/> Quantity not sufficient</p>	<p><input type="checkbox"/> Defective collection kit</p> <p><input type="checkbox"/> Language issue, Spanish</p> <p><input type="checkbox"/> Language issue, non-Spanish</p> <p><input type="checkbox"/> Cognitive disability</p> <p><input type="checkbox"/> Parent/Guardian refusal</p> <p><input type="checkbox"/> Other—specify: _____</p>
<p><b>LP10</b> 3mL Lavender Prescreened</p>	<p><input type="checkbox"/> Full draw                      <input type="checkbox"/> Short draw                      <input type="checkbox"/> No draw</p> <p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><input type="checkbox"/> Equipment failure</p> <p><input type="checkbox"/> Fainting</p> <p><input type="checkbox"/> Light-headedness</p> <p><input type="checkbox"/> Hematoma</p> <p><input type="checkbox"/> No suitable vein</p> </div> <div style="width: 45%;"> <p><input type="checkbox"/> Bruising</p> <p><input type="checkbox"/> Vein collapsed during the procedure</p> <p><input type="checkbox"/> Other—specify: _____</p> <p><input type="checkbox"/> Refused</p> </div> </div>
<p><b>SS10</b> Serum Separator tube 10</p>	<p><input type="checkbox"/> Full draw                      <input type="checkbox"/> Short draw                      <input type="checkbox"/> No draw</p> <p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><input type="checkbox"/> Equipment failure</p> <p><input type="checkbox"/> Fainting</p> <p><input type="checkbox"/> Light-headedness</p> <p><input type="checkbox"/> Hematoma</p> <p><input type="checkbox"/> No suitable vein</p> </div> <div style="width: 45%;"> <p><input type="checkbox"/> Bruising</p> <p><input type="checkbox"/> Vein collapsed during the procedure</p> <p><input type="checkbox"/> Other—specify: _____</p> <p><input type="checkbox"/> Refused</p> </div> </div>
<p><b>RD10</b> 10mL Red Top 10</p>	<p><input type="checkbox"/> Full draw                      <input type="checkbox"/> Short draw                      <input type="checkbox"/> No draw</p> <p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><input type="checkbox"/> Equipment failure</p> <p><input type="checkbox"/> Fainting</p> <p><input type="checkbox"/> Light-headedness</p> <p><input type="checkbox"/> Hematoma</p> <p><input type="checkbox"/> No suitable vein</p> </div> <div style="width: 45%;"> <p><input type="checkbox"/> Bruising</p> <p><input type="checkbox"/> Vein collapsed during the procedure</p> <p><input type="checkbox"/> Other—specify: _____</p> <p><input type="checkbox"/> Refused</p> </div> </div>

- “Language issue, Spanish”—Mark this box to indicate that the blood specimens were not collected because the phlebotomist does not speak Spanish well enough to communicate the necessary instructions to the study participant.
- “Language issue, non-Spanish”—Mark this box to indicate that the blood specimens were not collected because the phlebotomist is unable to communicate the necessary instructions to the study participant.
- “Cognitive disability”—Mark this box to indicate that the blood specimens were not collected because the study 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 study participant is younger than 18 years old and her parent or guardian refused to allow her to provide a blood specimen. When the parent or guardian refuses, refer to Part F of the form, which asks the participant to provide a saliva specimen. Do not mark this box to indicate that the parent or guardian refused to allow the participant to provide a saliva specimen.
- “Other—Specify”—Mark this box to indicate that the blood specimens were not collected for a reason other than those listed; specify the reason in the space provided.

*Collection of Tubes LP10–PP10*—Indicate the collection status of each blood tube and, if necessary, provide a reason why the blood tube collection is incomplete. Select the box that corresponds to the status of the blood collection for each tube listed in the left column. Different tubes will be collected for each study event type.

- “Full draw”—This box is marked to indicate that the corresponding blood tube was filled to at least 3/4 the desired capacity. Desired capacity is defined as filled to the full line marked on the blood tube. *Note that the lavender prescreened tube (LP10) is considered full when it is at least 2/3 of the desired capacity.*
- “Short draw”—This box is marked to indicate that the corresponding blood tube was filled to less than 3/4 of the desired capacity. When this box is marked, indicate the reason for the short draw.
- “No draw”—This box is marked to indicate that the blood tube was not collected. When this box is marked, indicate the reason that the blood tube was not drawn.



- *Reason for short draw or no draw*—Mark the box that best describes why the blood draw was either short or not done.
  - “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. This includes not having the appropriate supplies available in the home or clinic. Record a brief description of the problem in the Comments section of Part E. If the equipment fails before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part C by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part C by marking the box that corresponds to “Defective collection kit.”
  - “Fainting”—Mark this box to indicate that the study participant experienced a temporary loss of consciousness during the collection of the corresponding tube. Feeling faint or dizzy is not considered fainting. If the participant faints before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part C by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part C by marking the box that corresponds to “Quantity not sufficient.” An Incident Report Form also must be completed.
  - “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. If the participant becomes light-headed before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part C by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part C by marking the box that corresponds to “Quantity not sufficient.”
  - “Hematoma”—Mark this box to indicate that the study participant experienced a localized mass of blood, usually clotted, in the venipuncture space or surrounding tissue. If the participant experiences a hematoma before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part C by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part C by marking the box that corresponds to “Quantity not sufficient.” 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. Record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part C by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part C by marking the box that corresponds to “Physical limitations.”

<b>RD11</b> 10mL Red Top 11	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>LV10</b> Lavender Top 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>PP10</b> Plasma Preparation Tube 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

**Part D: Transport Temperatures**

Time placed in refrigerated chamber:   :    a.m.  
h h m m  p.m.

Refrigerated chamber temperature:   .  °C  Not able to measure

Status of refrigerated chamber cold threshold monitor:  Yes, in chamber  
 No, not in chamber

Status of refrigerated chamber warm threshold monitor:  Yes, in chamber/activated  
 No, not in chamber

Status of ambient chamber cold threshold monitor:  Yes, in chamber  
 No, not in chamber

**Part E: Blood Collection Comments**

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Subject Label**

Assignment ID,  
 Subject ID, Event Type

- “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. If the bruising occurs before all of the blood tubes are drawn, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part C by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part C by marking the box that corresponds to “Quantity not sufficient.”
- “Vein collapsed during the procedure”—Mark this box if the vein collapses during the blood draw. If this occurs before all of the tubes are drawn, be sure to complete the *Collection status* portion of Part C by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part C by marking the box that corresponds to “Quantity not sufficient.”
- “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.
- “Refused”—Mark this box to indicate that the study participant is unwilling to allow the completion of the blood draw procedure.

#### Part D: Transport Temperatures

- *Time placed in refrigerated chamber*—Record the time the tubes were placed in the refrigerated chamber of the transport cooler. 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 tubes are placed in the cooler at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
- *Refrigerated chamber temperature*—Record the temperature reading on the digital thermometer in the refrigerated chamber of the transport cooler at the time that the blood tubes are placed in the chamber. The temperature should be recorded to the first decimal point. Be sure to zero fill the space to the right of the decimal when necessary.
- *Status of refrigerated chamber cold threshold monitor*—Mark the box to indicate whether the cold threshold monitor is present in the refrigerated chamber of the transport cooler.
- *Status of refrigerated chamber warm threshold monitor*—Mark the box that corresponds to the status of the warm threshold monitor in the refrigerated chamber of the transport cooler. If the monitor is present, pull the tab to activate it and mark the box that corresponds to “Yes, in chamber/activated.” If the monitor is not present, mark the box that corresponds to “No, not in the chamber.”

<b>RD11</b> 10mL Red Top 11	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>LV10</b> Lavender Top 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>PP10</b> Plasma Preparation Tube 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

**Part D: Transport Temperatures**

Time placed in refrigerated chamber:   :    a.m.  
h h m m  p.m.

Refrigerated chamber temperature:   .  °C  Not able to measure

Status of refrigerated chamber cold threshold monitor:  Yes, in chamber  
 No, not in chamber

Status of refrigerated chamber warm threshold monitor:  Yes, in chamber/activated  
 No, not in chamber

Status of ambient chamber cold threshold monitor:  Yes, in chamber  
 No, not in chamber

**Part E: Blood Collection Comments**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Subject Label**

Assignment ID,  
Subject ID, Event Type

- *Status of ambient chamber cold threshold monitor*—Mark the box to indicate whether the cold threshold monitor is present in the ambient chamber of the transport cooler.

**Part E: Blood Collection Comments**

Additional comments may include reasons for partial draws or problems with the study participant's venous system. This space also should be used to record any problems with the pre-collection or post-collection processing, such as a problem with the thermometer or the threshold monitors.

<b>Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)</b>	
<p>Because we are not able to draw your blood, we are requesting to collect a saliva sample. Several measures that are performed in blood can be measured in saliva. Are you able to provide a saliva sample?</p> <p><i>Debido a que no pudimos sacarle sangre, quisiéramos pedirle una muestra de saliva. Varios análisis que se llevan a cabo en la sangre se pueden hacer en la saliva. ¿Puede darnos una muestra de saliva?</i></p> <p style="text-align: center;"> <input type="checkbox"/> Yes                      <input type="checkbox"/> No (END)         </p> <p><b>BE SURE TO REVIEW SALIVA SAMPLE COLLECTION INSTRUCTIONS WITH THE PARTICIPANT</b></p>	
<input type="checkbox"/> Collected <input type="checkbox"/> Not collected	
<p><b>Reason not done or partial:</b> (Mark all that apply.)</p> <p><input type="checkbox"/> No time</p> <p><input type="checkbox"/> Participant Ill/Emergency</p> <p><input type="checkbox"/> Equipment failure</p>	<p><input type="checkbox"/> Other—specify: _____</p> <p><input type="checkbox"/> Refuse</p>
<p><b>Saliva Comments:</b></p> <p>_____</p> <p>_____</p> <p>_____</p>	

<p><b>Data collector ID for field QC</b></p> <p style="text-align: center;"> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </p>
---

<p><b>Date entered into CHITA:</b> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: center;"> <small>m m d d y y y y</small> </p> <p><b>ID of data collector who entered the form:</b></p> <p style="text-align: center;"> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </p>
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**Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)**

This portion of the form should be completed only for those study participants who refuse or are unable to provide a blood specimen but are willing to provide a saliva specimen.

*Are you able to provide a saliva sample?*

- Mark the box that corresponds to the participant’s response.
- If the participant is able to provide a saliva specimen, be sure to review the specimen collection instructions provided in the kit insert with her.
- Mark the box that corresponds to the status of the saliva collection:
  - “Collected”—Mark this box to indicate that a complete specimen has been collected. The specimen is considered complete when the liquid in the clear container is level with where the flat part of the neck meets the cap. See Picture 2 in the kit insert.
  - “Not collected”—Mark this box to indicate that the participant agreed to provide a saliva specimen but was not able to do so. Please indicate the reason the specimen was not collected by marking the box that corresponds to the explanation that best describes why a complete specimen was not collected.

*Reason not done or partial (Mark all that apply)*

- “No time”—Mark this box to indicate that the saliva specimen was not collected because the visit was ended ahead of schedule.
- “Participant Ill/Emergency”—Mark this box to indicate that the participant had an emergency or illness that requires termination of the visit prior to the collection of the saliva specimen. In the Saliva Comments section of Part F, record a brief description of the nature of the emergency or illness.
- “Equipment failure”—Mark this box to indicate that the saliva was not collected because of a problem with the collection container. This includes not having the appropriate supplies available in the home or clinic.
- “Other—specify”—Mark this box to indicate that the saliva was not collected for a reason other than those listed. Specify the reason in the space provided.
- “Refuse”—Mark this box to indicate that the participant refused to provide a saliva specimen.

*Saliva Comments*—Additional comments may include reasons for not collecting a specimen or problems with the collection. This space also should be used to record problems with the pre-collection or post-collection processing.

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Part 4


Appendix 1-C

Adult Blood Data Collection Form – T1 Mother



Appendix 1-C.  
Adult Blood Data Collection Form – T1 Mother

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

	<p><b>National Children's Study</b> <b>Adult Blood</b> <b>Data Collection Form – T1 Mom</b></p>	<p>T1-1<sup>st</sup>, T1 Prior</p>
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(Only for use when FACE is not available)

<b>Part A: Administrative</b>		
<p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 20 <input type="text"/> <input type="text"/></p> <p style="font-size: small; margin-left: 20px;">m m d d y y y y</p> <p>Data Collector ID:</p> <p style="text-align: center;"><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office</p>	<p><b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done</p> <p><b>Reason for not done/partial:</b> (Mark one.)</p> <p><input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant III/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient <input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____</p>	
<p>Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p>	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> <p>Place Adult Blood Collection—T1 Mother or Adult BNC Saliva Collection DC Label Here</p> </div>	
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>		
<p>1) Do you have hemophilia or any bleeding disorder? <input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <i>¿Tiene hemofilia o algún problema de coagulación?</i> <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>		
<p>2) Do you take any blood thinning medication, such as Coumadin or warfarin? <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i></p> <p style="text-align: right;"><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>		

**Subject Label**

Assignment ID,  
Subject ID, Event Type

Public reporting burden for this collection of information is estimated to average 11 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 1-C.  
Adult Blood Data Collection Form – T1 Mother (continued)**

3) Have you had cancer chemotherapy within the past 4 weeks? <i>¿Ha recibido algún tratamiento de quimioterapia para el cáncer en las últimas 4 semanas?</i>	
<input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know	
4) Have you had any problems with a blood draw in the past? <i>¿Ha tenido algún problema en el pasado con una extracción de sangre?</i>	
<input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Part C) <input type="checkbox"/> Refused (Go to Part C) <input type="checkbox"/> Don't know (Go to Part C)	
5) What problems did you have with a blood draw in the past? (Mark all that apply.) <i>¿Qué problemas tuvo en el pasado con una extracción de sangre? (Mark all that apply.)</i>	
<input type="checkbox"/> Bruising / Moretones <input type="checkbox"/> Other—specify / Otro—especifique: _____ <input type="checkbox"/> Fainting / Desmayos <input type="checkbox"/> Refused <input type="checkbox"/> Light-headedness / Mareos <input type="checkbox"/> Don't know <input type="checkbox"/> Hematoma / Hematomas	
6) When was the last time you had anything to eat or drink? <i>¿A qué hora comió o bebió algo por última vez?</i>	
<input type="checkbox"/> <input type="checkbox"/> : <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> a.m. <input type="checkbox"/> <input type="checkbox"/> : <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> p.m. <input type="checkbox"/> Refused <input type="checkbox"/> Don't know	
<b>Part C: Blood Collection Tubes</b>	
<b>LP10</b> 3mL Lavender Prescreened	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>SS10</b> Serum Separator tube 10 SST	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>RD10</b> 10mL Red Top 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

**Appendix 1-C.  
Adult Blood Data Collection Form – T1 Mother (continued)**

<b>RD11</b> 10mL Red Top 11	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>LV10</b> Lavender Top 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>PP10</b> Plasma Preparation Tube 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>PN10</b> P100	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

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<p><b>Subject Label</b></p> <p>Assignment ID, Subject ID, Event Type</p>
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**Appendix 1-C.  
Adult Blood Data Collection Form – T1 Mother (continued)**

<b>Part D: Transport Temperatures</b>	
Time placed in refrigerated chamber	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
Refrigerated chamber temperature:	<input type="text"/> <input type="text"/> . <input type="text"/> °C <input type="checkbox"/> Not able to measure
Status of refrigerated chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
Status of refrigerated chamber warm threshold monitor	<input type="checkbox"/> Yes, in chamber/activated <input type="checkbox"/> No, not in chamber
Status of ambient chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
<b>Part E: Blood Collection Comments</b>	
<hr/> <hr/> <hr/>	
<b>Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)</b>	
Because we are not able to draw your blood, we are requesting to collect a saliva sample. Several measures that are performed in blood can be measured in saliva. Are you able to provide a saliva sample? <i>Debido a que no pudimos sacarle sangre, quisiéramos pedirle una muestra de saliva. Varios análisis que se llevan a cabo en la sangre se pueden hacer en la saliva. ¿Puede darnos una muestra de saliva?</i>	
<input type="checkbox"/> Yes <input type="checkbox"/> No (END)	
<b>BE SURE TO REVIEW SALIVA SAMPLE COLLECTION INSTRUCTIONS WITH THE PARTICIPANT</b>	
<input type="checkbox"/> Collected <input type="checkbox"/> Not collected	
<b>Reason not done or partial:</b> (Mark all that apply.) <input type="checkbox"/> No time <input type="checkbox"/> Participant III/emergency <input type="checkbox"/> Equipment failure	<input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Refuse

Appendix 1-C.  
Adult Blood Data Collection Form – T1 Mother (continued)

**Saliva Comments:**

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**Data Collector ID for field QC**

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**Date entered into CHITA:** //20  
m m d d y y y y

**ID of Data Collector who entered the form:**

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**Subject Label**

Assignment ID,  
Subject ID, Event Type

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Part 4

Appendix 1-D

Adult Blood Data Collection Form – T1 Mother:  
Field-by-Field Instructions




**Appendix 1-D.**  
**Adult Blood Data Collection Form – T1 Mother: Field-by-Field Instructions**

**ADULT BLOOD DATA COLLECTION FORM- T1 MOTHER:  
FIELD-BY-FIELD INSTRUCTIONS**

This form is only to be completed when the Field-Administrated Collection Environment (FACE) is not available at a T1 mother data collection visit. This form is to be completed by the biospecimen data collector performing the phlebotomy (blood 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 and accuracy should write her data collector ID in the space provided at the bottom of the last page.
- The data collector who enters the data recorded on the form in FACE will record the date of data entry and her data collector identification number (ID) in the space provided on the last page of the form.


**National Children's Study  
 Adult Blood  
 Data Collection Form – T1 Mom**

T1-1<sup>st</sup>, T1 Prior

(Only for use when FACE is not available)

<b>Part A: Administrative</b>	
Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> 2 <input type="text"/> 0 <input type="text"/> <input type="text"/> <small>m m d d y y y y</small>	<b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done
Data Collector ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<b>Reason for not done/partial:</b> (Mark one.) <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant III/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient <input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____
Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office	Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">                     Place Adult Blood Collection—T1                      Mother or Adult BNC Saliva Collection                      DC Label Here                 </div>	
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>	
1) Do you have hemophilia or any bleeding disorder? <input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <i>¿Tiene hemofilia o algún problema de coagulación?</i> <input type="checkbox"/> Refused <input type="checkbox"/> Don't know	
2) Do you take any blood thinning medication, such as Coumadin or warfarin? <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i>	
<input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know	

**Subject Label**

Assignment ID,  
 Subject ID, Event Type

Public reporting burden for this collection of information is estimated to average 11 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.



**Part A: Administrative Section**

- *Date*—Record the date that the blood draw is completed or attempted. The month, day, and the last 2 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 phlebotomist who completes the form.
- *Visit location*—Mark the box corresponding to the location of the visit.
- *Collection status (Mark one)*—Mark the box corresponding to the status of the blood draw:
  - “Complete”—Mark this box to indicate that all blood tubes are filled to at least 3/4 the desired capacity. Desired capacity is defined as filled to the full line marked on the blood tube. This box should not be checked if there are any partially filled tubes.
  - “Partial complete”—Mark this box to indicate that at least one, but not all of the blood tubes is filled to at least 3/4 of the desired capacity. When this box is marked, the phlebotomist must indicate the reason that the blood specimen collection is partially complete.
  - “Not done”—Mark this box to indicate that no blood tubes were collected. When this box is marked, the phlebotomist must indicate the reason that the blood specimen collection was not done.
- *Reason for not done/partial (Mark one)*—Mark the box that best describes why the blood draw was either not done or partially completed:
  - “Participant refusal”—Mark this box to indicate that the participant is unwilling to provide a blood specimen. When the participant refuses, refer to Part F of the form, which asks the participant to provide a saliva specimen. Do not mark this box to indicate that the participant refuses to provide a saliva specimen.
  - “Participant Ill/ emergency”—Mark this box to indicate that the participant had an emergency or illness that required termination of the visit prior to the collection of the blood specimens. Record a brief description of the nature of the emergency or illness in the Comments section of Part E.
  - “No time”—Mark this box to indicate that the blood specimen was not collected because the visit was ended ahead of schedule. Record a brief description of reason that the visit was ended in Comments section of Part E.



National Children's Study  
**Adult Blood**  
**Data Collection Form – T1 Mom**

T1-1<sup>st</sup>, T1 Prior

(Only for use when FACE is not available)

<b>Part A: Administrative</b>	
Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 2 0 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y Data Collector ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office	<b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done  <b>Reason for not done/partial:</b> (Mark one.) <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant III/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient <input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____
Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.  <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">                     Place Adult Blood Collection—T1                      Mother or Adult BNC Saliva Collection                      DC Label Here                 </div>	
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>	
1) Do you have hemophilia or any bleeding disorder? <input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <i>¿Tiene hemofilia o algún problema de coagulación?</i> <input type="checkbox"/> Refused <input type="checkbox"/> Don't know	
2) Do you take any blood thinning medication, such as Coumadin or warfarin? <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i> <input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know	

**Subject Label**

Assignment ID,  
Subject ID, Event Type

Public reporting burden for this collection of information is estimated to average 11 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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- “Safety exclusion”—Mark this box to indicate that the participant is ineligible to provide a blood specimen because she has a bleeding disorder, is taking blood thinning medication such as Coumadin or warfarin; or has had cancer chemotherapy during the past 4 weeks. When the participant is ineligible to provide a blood specimen, refer to Part F of the form, which asks the participant to provide a saliva specimen.
- “Physical limitations”—Mark this box to indicate that the participant has a physical limitation that prevented her from providing blood. This type of limitation includes but is not limited to an infection or cellulites at the draw site; or an inability to straighten one’s arm. Blood should not be drawn from an arm that contains a shunt or is in a cast. Record a brief description of the type of physical limitation in the Comments section of Part E. When the participant is not able to provide a blood specimen because of a physical limitation, refer to Part F of the form, which asks the participant to provide a saliva specimen.
- “Quantity not sufficient”—This box is marked in certain situations to indicate that not all of the blood tubes required for this visit were collected. It also is marked in certain situations when one or more of the blood tubes is filled to less than 3/4 the desired capacity. Desired capacity is defined as filled to the full line marked on the blood tube. Please see the instructions for selecting a reason for a “Short draw” or “No draw” in Part C to determine when this box is marked.
- “Defective collection kit”—Mark this box to indicate that the blood specimen was not collected because of a problem with the Adult Blood Collection Kit. This includes not having the appropriate supplies available in the home or clinic.
- “Slide broken”—This reason code does not apply to this specimen collection activity.
- “Language issue, Spanish”—Mark this box to indicate that the blood specimens were not collected because the phlebotomist 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 blood specimens were not collected because the phlebotomist is unable to communicate the necessary instructions to the participant.
- “Cognitive disability”—Mark this box to indicate that the blood specimens were not collected because the participant is cognitively or developmentally impaired and therefore unable to understand the specimen collection instructions.



National Children's Study  
**Adult Blood**  
**Data Collection Form – T1 Mom**

T1-1<sup>st</sup>, T1 Prior

(Only for use when FACE is not available)

<b>Part A: Administrative</b>	
Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 2 0 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y Data Collector ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office	<b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done  <b>Reason for not done/partial:</b> (Mark one.) <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant III/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient <input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____
Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.  <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">                     Place Adult Blood Collection—T1                      Mother or Adult BNC Saliva Collection                      DC Label Here                 </div>	
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>	
1) Do you have hemophilia or any bleeding disorder? <i>¿Tiene hemofilia o algún problema de coagulación?</i>	
<input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know	
2) Do you take any blood thinning medication, such as Coumadin or warfarin? <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i>	
<input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know	

**Subject Label**

Assignment ID,  
Subject ID, Event Type

Public reporting burden for this collection of information is estimated to average 11 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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- “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 blood specimen. When the parent or guardian refuses, refer to Part F of the form, which asks the participant to provide a saliva specimen. Do not mark this box to indicate that the parent or guardian refused to allow the participant to provide a saliva specimen.
- “Other—Specify”—Mark this box to indicate that the blood specimens were 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 Blood 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 the kit is opened at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
- *Kit Label*—Open the Adult Blood Collection Kit and place the DC label in the appropriate place on the data collection form. If the participant refuses or is unable to provide a blood specimen but is willing to provide a saliva specimen, open the Adult Blood Not Collected (BNC) Saliva Collection Kit and place the DC label in the space provided on the front page of the form.

## Part B: Blood Pre-Screening Questions

Questions 1 through 5 must be asked prior to each blood draw.

1. *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 and go to Part F.

2. *Do you take any blood thinning medication, 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 and go to Part F.

## 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) Have you had cancer chemotherapy within the past 4 weeks? <i>¿Ha recibido algún tratamiento de quimioterapia para el cáncer en las últimas 4 semanas?</i>	
<input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know	
4) Have you had any problems with a blood draw in the past? <i>¿Ha tenido algún problema en el pasado con una extracción de sangre?</i>	
<input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Part C) <input type="checkbox"/> Refused (Go to Part C) <input type="checkbox"/> Don't know (Go to Part C)	
5) What problems did you have with a blood draw in the past? (Mark all that apply.) <i>¿Qué problemas tuvo en el pasado con una extracción de sangre? (Mark all that apply.)</i>	
<input type="checkbox"/> Bruising / Moretones <input type="checkbox"/> Other—specify / Otro—especifique: _____ <input type="checkbox"/> Fainting / Desmayos <input type="checkbox"/> Refused <input type="checkbox"/> Light-headedness / Mareos <input type="checkbox"/> Don't know <input type="checkbox"/> Hematoma / Hematomas	
6) When was the last time you had anything to eat or drink? <i>¿A qué hora comió o bebió algo por última vez?</i>	
<input type="checkbox"/> <input type="checkbox"/> : <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m. <input type="checkbox"/> Refused <input type="checkbox"/> Don't know	
<b>Part C: Blood Collection Tubes</b>	
<b>LP10</b> 3mL Lavender Prescreened	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>SS10</b> Serum Separator tube 10 SST	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>RD10</b> 10mL Red Top 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

3. *Have you had cancer chemotherapy within the past 4 weeks?*
  - 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 and go to Part F.
4. *Have you had any problems with a blood draw in the past?*
  - Mark the box that corresponds to the participant’s response.
  - If the participant answers “No,” “Refuse,” or “Don’t know,” mark the corresponding box and go to Part C.
5. *What problems did you have with a blood draw in the past? (Mark all that apply)*
  - Read the first four choices to the participant.
  - Mark the box that corresponds to the types of problems that the participant experienced during previous blood draws.
  - If the participant reports a problem that is not included in the list mark that box that corresponds to “Other—specify” and briefly describe the problem in the space provided.
  - If the participant refuses to answer or does not remember specifically what type of problem she experienced in the past, mark the appropriate box and go to Part C.
6. *When was the last time you had anything to eat or drink?*
  - Record the time 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.”

**Adult Blood Collection Procedures**

<p>3) Have you had cancer chemotherapy within the past 4 weeks?  <i>¿Ha recibido algún tratamiento de quimioterapia para el cáncer en las últimas 4 semanas?</i></p> <p style="text-align: right;"> <input type="checkbox"/> Yes (Go to Part F)      <input type="checkbox"/> No  <input type="checkbox"/> Refused      <input type="checkbox"/> Don't know         </p>											
<p>4) Have you had any problems with a blood draw in the past?  <i>¿Ha tenido algún problema en el pasado con una extracción de sangre?</i></p> <p style="text-align: right;"> <input type="checkbox"/> Yes      <input type="checkbox"/> No (Go to Part C)  <input type="checkbox"/> Refused (Go to Part C)      <input type="checkbox"/> Don't know (Go to Part C)         </p>											
<p>5) What problems did you have with a blood draw in the past? (Mark all that apply.)  <i>¿Qué problemas tuvo en el pasado con una extracción de sangre? (Mark all that apply.)</i></p> <p style="text-align: right;"> <input type="checkbox"/> Bruising / Moretones  <input type="checkbox"/> Other—specify / Otro—especifique: _____  <input type="checkbox"/> Fainting / Desmayos      <input type="checkbox"/> Refused  <input type="checkbox"/> Light-headedness / Mareos      <input type="checkbox"/> Don't know  <input type="checkbox"/> Hematoma / Hematomas         </p>											
<p>6) When was the last time you had anything to eat or drink?  <i>¿A qué hora comió o bebió algo por última vez?</i></p> <p style="text-align: right;"> <input type="checkbox"/> <input type="checkbox"/> : <input type="checkbox"/> <input type="checkbox"/>      <input type="checkbox"/> a.m.  <input type="checkbox"/> p.m.  <input type="checkbox"/> Refused      <input type="checkbox"/> Don't know         </p>											
<b>Part C: Blood Collection Tubes</b>											
<p><b>LP10</b> 3mL Lavender Prescreened</p>	<p> <input type="checkbox"/> Full draw      <input type="checkbox"/> Short draw      <input type="checkbox"/> No draw         </p> <p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <table style="width: 100%;"> <tr> <td><input type="checkbox"/> Equipment failure</td> <td><input type="checkbox"/> Bruising</td> </tr> <tr> <td><input type="checkbox"/> Fainting</td> <td><input type="checkbox"/> Vein collapsed during the procedure</td> </tr> <tr> <td><input type="checkbox"/> Light-headedness</td> <td><input type="checkbox"/> Other—specify: _____</td> </tr> <tr> <td><input type="checkbox"/> Hematoma</td> <td><input type="checkbox"/> Refused</td> </tr> <tr> <td><input type="checkbox"/> No suitable vein</td> <td></td> </tr> </table>	<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising	<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure	<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____	<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused	<input type="checkbox"/> No suitable vein	
<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising										
<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure										
<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____										
<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused										
<input type="checkbox"/> No suitable vein											
<p><b>SS10</b> Serum Separator tube 10 SST</p>	<p> <input type="checkbox"/> Full draw      <input type="checkbox"/> Short draw      <input type="checkbox"/> No draw         </p> <p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <table style="width: 100%;"> <tr> <td><input type="checkbox"/> Equipment failure</td> <td><input type="checkbox"/> Bruising</td> </tr> <tr> <td><input type="checkbox"/> Fainting</td> <td><input type="checkbox"/> Vein collapsed during the procedure</td> </tr> <tr> <td><input type="checkbox"/> Light-headedness</td> <td><input type="checkbox"/> Other—specify: _____</td> </tr> <tr> <td><input type="checkbox"/> Hematoma</td> <td><input type="checkbox"/> Refused</td> </tr> <tr> <td><input type="checkbox"/> No suitable vein</td> <td></td> </tr> </table>	<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising	<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure	<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____	<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused	<input type="checkbox"/> No suitable vein	
<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising										
<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure										
<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____										
<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused										
<input type="checkbox"/> No suitable vein											
<p><b>RD10</b> 10mL Red Top 10</p>	<p> <input type="checkbox"/> Full draw      <input type="checkbox"/> Short draw      <input type="checkbox"/> No draw         </p> <p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <table style="width: 100%;"> <tr> <td><input type="checkbox"/> Equipment failure</td> <td><input type="checkbox"/> Bruising</td> </tr> <tr> <td><input type="checkbox"/> Fainting</td> <td><input type="checkbox"/> Vein collapsed during the procedure</td> </tr> <tr> <td><input type="checkbox"/> Light-headedness</td> <td><input type="checkbox"/> Other—specify: _____</td> </tr> <tr> <td><input type="checkbox"/> Hematoma</td> <td><input type="checkbox"/> Refused</td> </tr> <tr> <td><input type="checkbox"/> No suitable vein</td> <td></td> </tr> </table>	<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising	<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure	<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____	<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused	<input type="checkbox"/> No suitable vein	
<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising										
<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure										
<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____										
<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused										
<input type="checkbox"/> No suitable vein											

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## Part C: Blood Collection Tubes

Indicate the collection status of each blood tube and if necessary, provide a reason why the blood tube collection is incomplete.

Select the box that corresponds to the status of the blood collection for each tube listed in the left hand column. Different tubes will be collected for each study event type.

- “Full draw”—This box is marked to indicate that the corresponding blood tube was filled to at least 3/4 the desired capacity. Desired capacity is defined as filled to the full line marked on the blood tube. *Note the lavender prescreened tube (LP10) is considered full when it is at least 2/3 of the desired capacity.*
- “Short draw”—This box is marked to indicate that the corresponding blood tube was filled to less than 3/4 of the desired capacity. When this box is marked, indicate the reason for the short draw.
- “No draw”—This box is marked to indicate that the blood tube was not collected. When this box is marked, indicate the reason that the blood tube was not drawn.
- *Reason for short draw or no draw*—Mark the box that best describes why the blood draw was either short or not done.
  - “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. This includes not having the appropriate supplies available in the home or clinic. Record a brief description of the problem in Comments section of Part C. If the equipment fails before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Defective collection kit.”
  - “Fainting”—Mark this box to indicate that the participant experienced a temporary loss of consciousness during the collection of the corresponding tube. Feeling faint or dizzy is not considered fainting. If the participant faints before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.” An Incident Report Form also must be completed.

**Adult Blood Collection Procedures**

<b>RD11</b> 10mL Red Top 11	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>LV10</b> Lavender Top 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>PP10</b> Plasma Preparation Tube 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>PN10</b> P100	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

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<p><b>Subject Label</b></p> <p>Assignment ID, Subject ID, Event Type</p>
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- “Light-headedness”—Mark this box to indicate that the participant reported a temporary feeling of lightheadedness, feeling faint, or dizzy. This does not require the completion of an Incident Report Form. If the participant becomes light-headed before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the “Collection status” portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.”
- “Hematoma”—Mark this box to indicate that the participant experienced a localized mass of blood, usually clotted, in the venipuncture space or surrounding tissue. If the participant experiences a hematoma before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.” An Incident Report Form also must be completed.
- “No suitable vein”—Mark this box to indicate that the participant does not have a suitable vein to draw the blood specimen. Record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Physical limitation.”
- “Bruising”—Mark this box if the 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. If the bruising occurs before all of the blood tubes are drawn, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.”
- “Vein collapsed during the procedure”—Mark this box if the vein collapses during the blood draw. If this occurs before all of the tubes are drawn, be sure to complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.”
- “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.
- “Refused”—Mark this box to indicate that the participant is unwilling to allow the completion of the blood draw procedure.

<b>Part D: Transport Temperatures</b>	
Time placed in refrigerated chamber	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
Refrigerated chamber temperature:	<input type="text"/> <input type="text"/> . <input type="text"/> °C <input type="checkbox"/> Not able to measure
Status of refrigerated chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
Status of refrigerated chamber warm threshold monitor	<input type="checkbox"/> Yes, in chamber/activated <input type="checkbox"/> No, not in chamber
Status of ambient chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
<b>Part E: Blood Collection Comments</b>	
<hr/> <hr/> <hr/> <hr/> <hr/>	
<b>Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)</b>	
Because we are not able to draw your blood, we are requesting to collect a saliva sample. Several measures that are performed in blood can be measured in saliva. Are you able to provide a saliva sample? <i>Debido a que no pudimos sacarle sangre, quisiéramos pedirle una muestra de saliva. Varios análisis que se llevan a cabo en la sangre se pueden hacer en la saliva. ¿Puede darnos una muestra de saliva?</i>	
<input type="checkbox"/> Yes <input type="checkbox"/> No (END)	
<b>BE SURE TO REVIEW SALIVA SAMPLE COLLECTION INSTRUCTIONS WITH THE PARTICIPANT</b>	
<input type="checkbox"/> Collected <input type="checkbox"/> Not collected	
<b>Reason not done or partial:</b> (Mark all that apply.) <input type="checkbox"/> No time <input type="checkbox"/> Participant III/emergency <input type="checkbox"/> Equipment failure	<input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Refuse

## Part D: Transport Temperatures

- *Time placed in refrigerated chamber*—Record the time the tubes were placed into the refrigerated chamber of the transport cooler. 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 tubes are placed in the cooler at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
- *Refrigerated chamber temperature*—Record the temperature reading on the digital thermometer in the refrigerated chamber of the transport cooler at the time that the blood tubes are placed in the chamber. The temperature should be recorded to the first decimal point. Be sure to zero fill the space to the right of the decimal when necessary.
- *Status of refrigerated chamber cold threshold monitor*—Mark the box to indicate whether the cold threshold monitor is present in the refrigerated chamber of the transport cooler.
- *Status of the refrigerated chamber warm threshold monitor*—Mark the box that corresponds to the status of the warm threshold monitor in the refrigerated chamber of the transport cooler. If the monitor is present, pull the tab to activate it and mark the box that corresponds to “Yes, in chamber/activated.” If the monitor is not present, mark the box that corresponds to “No, not in the chamber.”
- *Status of the ambient chamber cold threshold monitor*—Mark the box to indicate whether the cold threshold monitor is present in the ambient chamber of the transport cooler.

## Part E: Blood Collection Comments

Additional comments may include reasons for partial draws or problems with the participant’s venous system. This space also should be used to record any problems with the pre-collection or post-collection processing, such as a problem with the thermometer or the threshold monitors.

<b>Part D: Transport Temperatures</b>	
Time placed in refrigerated chamber	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <span style="margin-left: 20px;"><input type="checkbox"/> a.m.</span> <span style="margin-left: 20px;"><input type="checkbox"/> p.m.</span>
Refrigerated chamber temperature:	<input type="text"/> <input type="text"/> . <input type="text"/> °C <span style="margin-left: 20px;"><input type="checkbox"/> Not able to measure</span>
Status of refrigerated chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
Status of refrigerated chamber warm threshold monitor	<input type="checkbox"/> Yes, in chamber/activated <input type="checkbox"/> No, not in chamber
Status of ambient chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
<b>Part E: Blood Collection Comments</b>	
<div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div>	
<b>Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)</b>	
Because we are not able to draw your blood, we are requesting to collect a saliva sample. Several measures that are performed in blood can be measured in saliva. Are you able to provide a saliva sample? <i>Debido a que no pudimos sacarle sangre, quisiéramos pedirle una muestra de saliva. Varios análisis que se llevan a cabo en la sangre se pueden hacer en la saliva. ¿Puede darnos una muestra de saliva?</i>	
<input type="checkbox"/> Yes <span style="margin-left: 100px;"><input type="checkbox"/> No (END)</span>	
<b>BE SURE TO REVIEW SALIVA SAMPLE COLLECTION INSTRUCTIONS WITH THE PARTICIPANT</b>	
<input type="checkbox"/> Collected <span style="margin-left: 100px;"><input type="checkbox"/> Not collected</span>	
<b>Reason not done or partial:</b> (Mark all that apply.) <input type="checkbox"/> No time <input type="checkbox"/> Participant III/emergency <input type="checkbox"/> Equipment failure	<input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Refuse

**Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)**

This portion of the form should be completed only for those participants who refuse or are unable to provide a blood specimen but are willing to provide a saliva specimen.

*Are you able to provide a saliva sample?*

- Mark the box that corresponds to the participant's response.
- If the participant is able to provide a saliva specimen, be sure to review the specimen collection instructions provided in the kit insert with her.
- Mark the box that corresponds to the status of the saliva collection:
  - “Collected”—Mark this box to indicate that a complete specimen has been collected. The specimen is considered complete when the liquid in the clear container is level with where the flat part of the neck meets the cap. See picture number 2 in the kit insert.
  - “Not collected”—Mark this box to indicate that the participant agreed to provide a saliva specimen but was not able to do so. Please indicate the reason the specimen was not collected by marking the box that corresponds to the explanation that best describes why a complete specimen was not collected.

*Reason not done or partial (Mark all that apply)*

- “No time”—Mark this box to indicate that the saliva specimen was not collected because the visit was ended ahead of schedule.
- “Participant Ill/ emergency”—Mark this box to indicate that the participant had an emergency or illness that requires termination of the visit prior to the collection of the saliva specimen. Record a brief description of the nature of the emergency or illness in the Saliva Comments section of Part F.
- “Equipment failure”—Mark this box to indicate that the saliva was not collected because of a problem with the collection container. This includes not having the appropriate supplies available in the home or clinic.
- “Other—specify”—Mark this box to indicate that the saliva was not collected for a reason other than those listed. Specify the reason in the space provided.
- “Refuse”—Mark this box to indicate that the participant refused to provide a saliva specimen.



- *Saliva comments*—Additional comments may include reasons for not collecting a specimen or problems with the collection. This space should also be used to record problems with the pre-collection or post-collection processing.

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Part 4

Appendix 1-E

Adult Blood Data Collection Form – T1 Father



Appendix 1-E.  
Adult Blood Data Collection Form – T1 Father

	<p><b>National Children's Study</b> <b>Adult Blood</b> <b>Data Collection Form – T1 Father</b></p>	T1-Father
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(Only for use when FACE is not available)

<b>Part A: Administrative</b>	
<p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> 2 <input type="text"/> 0 <input type="text"/> <input type="text"/></p> <p style="font-size: small; margin-left: 20px;">m m d d y y y y</p> <p>Data collector ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office</p>	<p>Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p> <p style="text-align: center; font-size: small;">h h m m</p> <div style="border: 1px solid black; padding: 5px; text-align: center; margin: 10px auto; width: 80%;">                 Place Adult Blood Collection—T1 Father or Adult BNC Saliva Collection DC Label Here             </div>
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>	
<p>1) Do you have hemophilia or any bleeding disorder? <i>¿Tiene hemofilia o algún problema de coagulación?</i></p>	<p><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>
<p>2) Do you take any blood thinning medication, such as Coumadin or warfarin? <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i></p>	<p><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>
<p>3) Have you had cancer chemotherapy within the past 4 weeks? <i>¿Ha recibido algún tratamiento de quimioterapia para el cáncer en las últimas 4 semanas?</i></p>	<p><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>
<p>4) Have you had any problems with a blood draw in the past? <i>¿Ha tenido algún problema en el pasado con una extracción de sangre?</i></p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Q6) <input type="checkbox"/> Refused (Go to Q6) <input type="checkbox"/> Don't know (Go to Q6)</p>
<p>5) What problems did you have with a blood draw in the past? (Mark all that apply.) <i>¿Qué problemas tuvo en el pasado con una extracción de sangre? (Mark all that apply.)</i></p>	<p><input type="checkbox"/> Bruising / Moretones <input type="checkbox"/> Other—specify / Otro—especifique: _____ <input type="checkbox"/> Fainting / Desmayos <input type="checkbox"/> Refused <input type="checkbox"/> Light-headedness / Mareos <input type="checkbox"/> Don't know <input type="checkbox"/> Hematoma / Hematomas</p>
<p>6) When was the last time you had anything to eat or drink? <i>¿A qué hora comió o bebió algo por última vez?</i></p>	<p><input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p> <p style="font-size: small; margin-left: 20px;">h h m m</p> <p><input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>

**Subject Label**

Assignment ID,  
Subject ID, Event Type

BDFT1D01.00DU

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**Appendix 1-E.  
Adult Blood Data Collection Form – T1 Father (continued)**

<b>Part C: Blood Collection Tubes</b>	
<b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done	
<b>Reason for not done/partial:</b> (Mark one.) <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient	
<input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____	
<b>LP10</b> 3mL Lavender Prescreened	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>RD12</b> 10mL Red Top 12	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>LV11</b> Lavender Top 11	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>AD 10</b> ACD Tube	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

**Appendix 1-E.  
Adult Blood Data Collection Form – T1 Father (continued)**

<b>Part D: Transport Temperatures</b>	
Time placed in refrigerated chamber: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> a.m.
<small>h h m m</small>	<input type="checkbox"/> p.m.
Refrigerated chamber temperature: <input type="text"/> <input type="text"/> . <input type="text"/> °C	<input type="checkbox"/> Not able to measure
Status of refrigerated chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
Status of refrigerated chamber warm threshold monitor	<input type="checkbox"/> Yes, in chamber/activated <input type="checkbox"/> No, not in chamber
Status of ambient chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
<b>Part E: Blood Collection Comments</b>	
<hr/> <hr/>	
<b>Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)</b>	
Because we are not able to draw your blood, we are requesting to collect a saliva sample. Several measures that are performed in blood can be measured in saliva. Are you able to provide a saliva sample? <i>Debido a que no pudimos sacarle sangre, quisiéramos pedirle una muestra de saliva. Varios análisis que se llevan a cabo en la sangre se pueden hacer en la saliva. ¿Puede darnos una muestra de saliva?</i>	
<input type="checkbox"/> Yes <input type="checkbox"/> No (END)	
<b>BE SURE TO REVIEW SALIVA SAMPLE COLLECTION INSTRUCTIONS WITH THE PARTICIPANT</b>	
<input type="checkbox"/> Collected <input type="checkbox"/> Not collected	
<b>Reason not done or partial:</b> (Mark all that apply.) <input type="checkbox"/> No time <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> Equipment failure	<input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Refuse
<b>Saliva Comments:</b>	
<hr/> <hr/> <hr/>	

**Subject Label**

Assignment ID,  
Subject ID, Event Type



Part 4

Appendix 1-F

Adult Blood Data Collection Form – T1 Father:  
Field-by-Field Instructions




**Appendix 1-F.**  
**Adult Blood Data Collection Form- T1 Father: Field-by-Field Instructions**

**ADULT BLOOD DATA COLLECTION FORM- T1 FATHER:  
FIELD-BY-FIELD INSTRUCTIONS**

This form is only to be completed when the Field-Administrated Collection Environment (FACE) is not available at a T1 father data collection visit. This form is to be completed by the biospecimen data collector performing the phlebotomy (blood 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 and accuracy should write her data collector ID in the space provided at the bottom of the last page.
- The data collector who enters the data recorded on the form in FACE will record the date of data entry and her data collector identification number (ID) in the space provided on the last page of the form.



**National Children's Study**  
**Adult Blood**  
**Data Collection Form – T1 Father**

T1-Father

(Only for use when FACE is not available)

<b>Part A: Administrative</b>	
<p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 2 0 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="font-size: small; margin-left: 20px;">m m d d y y y y</p> <p>Data collector ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office</p>	<p>Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m.  <input type="checkbox"/> p.m.</p> <p style="text-align: center; border: 1px solid black; padding: 5px;">Place Adult Blood Collection—T1 Father or Adult BNC Saliva Collection DC Label Here</p>
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>	
<p>1) Do you have hemophilia or any bleeding disorder?  <i>¿Tiene hemofilia o algún problema de coagulación?</i></p>	<p><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No  <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>
<p>2) Do you take any blood thinning medication, such as Coumadin or warfarin?  <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i></p>	<p><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No  <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>
<p>3) Have you had cancer chemotherapy within the past 4 weeks?  <i>¿Ha recibido algún tratamiento de quimioterapia para el cáncer en las últimas 4 semanas?</i></p>	<p><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No  <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>
<p>4) Have you had any problems with a blood draw in the past?  <i>¿Ha tenido algún problema en el pasado con una extracción de sangre?</i></p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Q6)  <input type="checkbox"/> Refused (Go to Q6) <input type="checkbox"/> Don't know (Go to Q6)</p>
<p>5) What problems did you have with a blood draw in the past? (Mark all that apply.)  <i>¿Qué problemas tuvo en el pasado con una extracción de sangre? (Mark all that apply.)</i></p>	<p><input type="checkbox"/> Bruising / Moretones  <input type="checkbox"/> Other—specify / Otro—especifique: _____  <input type="checkbox"/> Refused  <input type="checkbox"/> Don't know</p>
<p>6) When was the last time you had anything to eat or drink?  <i>¿A qué hora comió o bebió algo por última vez?</i></p>	<p><input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m.  <input type="checkbox"/> p.m.</p> <p><input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>

**Subject Label**

Assignment ID,  
Subject ID, Event Type

BDFT1D01.00DU

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**Part A: Administrative Section**

- *Date*—Record the date that the blood draw is completed or attempted. The month, day, and the last 2 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 phlebotomist who completes the form.
- *Visit location*—Mark the box corresponding to the location of the visit.
- *Time collection kit opened*—Record the time the Adult Blood 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 the kit is opened at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
- *Kit Label*—Open the Adult Blood Collection Kit and place the DC label in the appropriate place on the data collection form. If the participant refuses or is unable to provide a blood specimen but is willing to provide a saliva specimen, open the Adult Blood Not Collected (BNC) Saliva Collection Kit and place the DC label in the space provided on the front page of the form.

**Part B: Blood Pre-Screening Questions**

Questions 1 through 5 must be asked prior to each blood draw.

1. *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 he refuses to answer, mark the corresponding box and go to Part F.
2. *Do you take any blood thinning medication, 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 he refuses to answer, mark the corresponding box and go to Part F.
3. *Have you had cancer chemotherapy within the past 4 weeks?*
  - Mark the box that corresponds to the participant’s response.
  - If the participant answers “Yes” or “Don’t know,” or he refuses to answer, mark the corresponding box and go to Part F.



**National Children's Study**  
**Adult Blood**  
**Data Collection Form – T1 Father**

T1-Father

(Only for use when FACE is not available)

<b>Part A: Administrative</b>	
<p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 2 0 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="font-size: small; margin-left: 20px;">m m d d y y y y</p> <p>Data collector ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office</p>	<p>Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p> <p style="text-align: center; font-size: small;">h h m m</p> <div style="border: 1px solid black; padding: 5px; text-align: center; margin: 10px auto; width: 80%;"> <p>Place Adult Blood Collection—T1                      Father or Adult BNC Saliva Collection                      DC Label Here</p> </div>
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>	
<p>1) Do you have hemophilia or any bleeding disorder?  <i>¿Tiene hemofilia o algún problema de coagulación?</i></p>	<p><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No  <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>
<p>2) Do you take any blood thinning medication, such as Coumadin or warfarin?  <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i></p>	<p><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No  <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>
<p>3) Have you had cancer chemotherapy within the past 4 weeks?  <i>¿Ha recibido algún tratamiento de quimioterapia para el cáncer en las últimas 4 semanas?</i></p>	<p><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No  <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>
<p>4) Have you had any problems with a blood draw in the past?  <i>¿Ha tenido algún problema en el pasado con una extracción de sangre?</i></p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Q6)  <input type="checkbox"/> Refused (Go to Q6) <input type="checkbox"/> Don't know (Go to Q6)</p>
<p>5) What problems did you have with a blood draw in the past? (Mark all that apply.)  <i>¿Qué problemas tuvo en el pasado con una extracción de sangre? (Mark all that apply.)</i></p> <p><input type="checkbox"/> Fainting / <i>Desmayos</i>  <input type="checkbox"/> Light-headedness / <i>Mareos</i>  <input type="checkbox"/> Hematoma / <i>Hematomas</i></p>	<p><input type="checkbox"/> Bruising / <i>Moretones</i>  <input type="checkbox"/> Other—specify / <i>Otro—especifique:</i> _____  <input type="checkbox"/> Refused  <input type="checkbox"/> Don't know</p>
<p>6) When was the last time you had anything to eat or drink?  <i>¿A qué hora comió o bebió algo por última vez?</i></p>	<p><input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p> <p style="font-size: small; text-align: center;">h h m m</p> <p><input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>

**Subject Label**

Assignment ID,  
 Subject ID, Event Type

BDFT1D01.00DU

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4. *Have you had any problems with a blood draw in the past?*
- Mark the box that corresponds to the participant's response.
  - If the participant answers "No," "Refuse," or "Don't know," mark the corresponding box and go to question 6.
5. *What problems did you have with a blood draw in the past? (Mark all that apply)*
- Read the first four choices to the participant.
  - Mark the box that corresponds to the types of problems that the participant experienced during previous blood draws.
  - If the participant reports a problem that is not included in the list mark that box that corresponds to "Other—specify" and briefly describe the problem in the space provided.
  - If the participant refuses to answer or does not remember specifically what type of problem he experienced in the past, mark the appropriate box and go to Part C.
6. *When was the last time you had anything to eat or drink?*
- Record the time 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 participant ate at 2:05 p.m., record "02:05" and mark the box corresponding to "p.m."
  - If the participant answers "Don't know," or he refuses to answer, 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.

<b>Part C: Blood Collection Tubes</b>	
<p><b>Collection status:</b> (Mark one.)</p> <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done	
<p><b>Reason for not done/partial:</b> (Mark one.)</p> <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient	<input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____
<p><b>LP10</b> 3mL Lavender Prescreened</p>	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<p><b>RD12</b> 10mL Red Top 12</p>	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<p><b>LV11</b> Lavender Top 11</p>	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<p><b>AD 10</b> ACD Tube</p>	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

**Part C: Blood Collection Tubes**

- *Collection status* (Mark one)—Mark the box corresponding to the status of the blood draw:
  - “Complete”—Mark this box to indicate that all blood tubes are filled to at least 3/4 the desired capacity. Desired capacity is defined as filled to the full line marked on the blood tube. This box should not be checked if there are any partially filled tubes.
  - “Partial complete”—Mark this box to indicate that at least one, but not all of the blood tubes is filled to at least 3/4 of the desired capacity. When this box is marked, the phlebotomist must indicate the reason that the blood specimen collection is partially complete.
  - “Not done”—Mark this box to indicate that no blood tubes were collected. When this box is marked, the phlebotomist must indicate the reason that the blood specimen collection was not done.
  
- *Reason for not done/partial* (Mark one)—Mark the box that best describes why the blood draw was either not done or partially completed:
  - “Participant refusal”—Mark this box to indicate that the participant is unwilling to provide a blood specimen. When the participant refuses, refer to Part F of the form, which asks the participant to provide a saliva specimen. Do not mark this box to indicate that the participant refuses to provide a saliva specimen.
  - “Participant ill/ emergency”—Mark this box to indicate that the participant had an emergency or illness that required termination of the visit prior to the collection of the blood specimens. Record a brief description of the nature of the emergency or illness in the Comments section of Part E.
  - “No time”—Mark this box to indicate that the blood specimen was not collected because the visit was ended ahead of schedule. Record a brief description of reason that the visit was ended in Comments section of Part E.
  - “Safety exclusion”—Mark this box to indicate that the participant is ineligible to provide a blood specimen because he has a bleeding disorder, is taking blood thinning medication such as Coumadin or warfarin; or has had cancer chemotherapy during the past 4 weeks. When the participant is ineligible to provide a blood specimen, refer to Part F of the form, which asks the participant to provide a saliva specimen.

<b>Part C: Blood Collection Tubes</b>	
<b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done	
<b>Reason for not done/partial:</b> (Mark one.) <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient	
<input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____	
<b>LP10</b> 3mL Lavender Prescreened	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>RD12</b> 10mL Red Top 12	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>LV11</b> Lavender Top 11	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>AD 10</b> ACD Tube	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

- “Physical limitations”—Mark this box to indicate that the participant has a physical limitation that prevented him from providing blood. This type of limitation includes but is not limited to an infection or cellulites at the draw site; or an inability to straighten one’s arm. Blood should not be drawn from an arm that contains a shunt or is in a cast. Record a brief description of the type of physical limitation in the Comments section of Part E. When the participant is not able to provide a blood specimen because of a physical limitation, refer to Part F of the form, which asks the participant to provide a saliva specimen.
- “Quantity not sufficient”—This box is marked in certain situations to indicate that not all of the blood tubes required for this visit were collected. It also is marked in certain situations when one or more of the blood tubes is filled to less than 3/4 the desired capacity. Desired capacity is defined as filled to the full line marked on the blood tube. Please see the instructions for selecting a reason for a “Short draw” or “No draw” in Part C to determine when this box is marked.
- “Defective collection kit”—Mark this box to indicate that the blood specimen was not collected because of a problem with the Adult Blood Collection Kit. This includes not having the appropriate supplies available in the home or clinic.
- “Slide broken”—This reason code does not apply to this specimen collection activity.
- “Language issue, Spanish”—Mark this box to indicate that the blood specimens were not collected because the phlebotomist 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 blood specimens were not collected because the phlebotomist is unable to communicate the necessary instructions to the participant.
- “Cognitive disability”—Mark this box to indicate that the blood 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 his parent or guardian refused to allow him to provide a blood specimen. When the parent or guardian refuses, refer to Part F of the form, which asks the participant to provide a saliva specimen. Do not mark this box to indicate that the parent or guardian refused to allow the participant to provide a saliva specimen.
- “Other—Specify”—Mark this box to indicate that the blood specimens were not collected for a reason other than those listed; specify the reason in the space provided.

<b>Part C: Blood Collection Tubes</b>	
<b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done	
<b>Reason for not done/partial:</b> (Mark one.) <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient	
<input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____	
<b>LP10</b> 3mL Lavender Prescreened	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>RD12</b> 10mL Red Top 12	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>LV11</b> Lavender Top 11	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>AD 10</b> ACD Tube	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

Indicate the collection status of each blood tube and if necessary, provide a reason why the blood tube collection is incomplete.

Select the box that corresponds to the status of the blood collection for each tube listed in the left hand column. Different tubes will be collected for each study event type.

- “Full draw”—This box is marked to indicate that the corresponding blood tube was filled to at least 3/4 the desired capacity. Desired capacity is defined as filled to the full line marked on the blood tube. *Note the lavender prescreened tube (LP10) is considered full when it is at least 2/3 of the desired capacity.*
- “Short draw”—This box is marked to indicate that the corresponding blood tube was filled to less than 3/4 of the desired capacity. When this box is marked, indicate the reason for the short draw.
- “No draw”—This box is marked to indicate that the blood tube was not collected. When this box is marked, indicate the reason that the blood tube was not drawn.
- *Reason for short draw or no draw*—Mark the box that best describes why the blood draw was either short or not done.
  - “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. This includes not having the appropriate supplies available in the home or clinic. Record a brief description of the problem in Comments section of Part E. If the equipment fails before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Defective collection kit.”
  - “Fainting”—Mark this box to indicate that the participant experienced a temporary loss of consciousness during the collection of the corresponding tube. Feeling faint or dizzy is not considered fainting. If the participant faints before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.” An Incident Report Form also must be completed.

<b>Part C: Blood Collection Tubes</b>	
<p><b>Collection status:</b> (Mark one.)</p> <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done	
<p><b>Reason for not done/partial:</b> (Mark one.)</p> <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient	<input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____
<p><b>LP10</b> 3mL Lavender Prescreened</p>	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<p><b>RD12</b> 10mL Red Top 12</p>	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<p><b>LV11</b> Lavender Top 11</p>	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<p><b>AD 10</b> ACD Tube</p>	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

- “Light-headedness”—Mark this box to indicate that the participant reported a temporary feeling of lightheadedness, feeling faint, or dizzy. This does not require the completion of an Incident Report Form. If the participant becomes light-headed before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the “Collection status” portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.”
- “Hematoma”—Mark this box to indicate that the participant experienced a localized mass of blood, usually clotted, in the venipuncture space or surrounding tissue. If the participant experiences a hematoma before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.” An Incident Report Form also must be completed.
- “No suitable vein”—Mark this box to indicate that the participant does not have a suitable vein to draw the blood specimen. Record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Physical limitation.”
- “Bruising”—Mark this box if the 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. If the bruising occurs before all of the blood tubes are drawn, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.”
- “Vein collapsed during the procedure”—Mark this box if the vein collapses during the blood draw. If this occurs before all of the tubes are drawn, be sure to complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.”
- “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.
- “Refused”—Mark this box to indicate that the participant is unwilling to allow the completion of the blood draw procedure.

<b>Part D: Transport Temperatures</b>	
Time placed in refrigerated chamber: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <span style="margin-left: 100px;"><small>h h m m</small></span>	<input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
Refrigerated chamber temperature: <input type="text"/> <input type="text"/> . <input type="text"/> °C	<input type="checkbox"/> Not able to measure
Status of refrigerated chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
Status of refrigerated chamber warm threshold monitor	<input type="checkbox"/> Yes, in chamber/activated <input type="checkbox"/> No, not in chamber
Status of ambient chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
<b>Part E: Blood Collection Comments</b>	
<div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px;"></div>	
<b>Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)</b>	
<p>Because we are not able to draw your blood, we are requesting to collect a saliva sample. Several measures that are performed in blood can be measured in saliva. Are you able to provide a saliva sample?</p> <p><i>Debido a que no pudimos sacarle sangre, quisiéramos pedirle una muestra de saliva. Varios análisis que se llevan a cabo en la sangre se pueden hacer en la saliva. ¿Puede darnos una muestra de saliva?</i></p> <p style="text-align: center;"><input type="checkbox"/> Yes <span style="margin-left: 100px;"><input type="checkbox"/> No (END)</span></p> <p><b>BE SURE TO REVIEW SALIVA SAMPLE COLLECTION INSTRUCTIONS WITH THE PARTICIPANT</b></p> <p style="text-align: center;"><input type="checkbox"/> Collected <span style="margin-left: 100px;"><input type="checkbox"/> Not collected</span></p>	
<p><b>Reason not done or partial:</b> (Mark all that apply.)</p> <p><input type="checkbox"/> No time</p> <p><input type="checkbox"/> Participant ill/emergency</p> <p><input type="checkbox"/> Equipment failure</p>	<p><input type="checkbox"/> Other—specify: _____</p> <p><input type="checkbox"/> Refuse</p>
<p><b>Saliva Comments:</b></p> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px;"></div>	

**Subject Label**

Assignment ID,  
Subject ID, Event Type

**Part D: Transport Temperatures**

- *Time placed in refrigerated chamber*—Record the time the tubes were placed into the refrigerated chamber of the transport cooler. 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 tubes are placed in the cooler at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
- *Refrigerated chamber temperature*—Record the temperature reading on the digital thermometer in the refrigerated chamber of the transport cooler at the time that the blood tubes are placed in the chamber. The temperature should be recorded to the first decimal point. Be sure to zero fill the space to the right of the decimal when necessary.
- *Status of refrigerated chamber cold threshold monitor*—Mark the box to indicate whether the cold threshold monitor is present in the refrigerated chamber of the transport cooler.
- *Status of the refrigerated chamber warm threshold monitor*—Mark the box that corresponds to the status of the warm threshold monitor in the refrigerated chamber of the transport cooler. If the monitor is present, pull the tab to activate it and mark the box that corresponds to “Yes, in chamber/activated.” If the monitor is not present, mark the box that corresponds to “No, not in the chamber.”
- *Status of the ambient chamber cold threshold monitor*—Mark the box to indicate whether the cold threshold monitor is present in the ambient chamber of the transport cooler.

**Part E: Blood Collection Comments**

Additional comments may include reasons for partial draws or problems with the participant’s venous system. This space also should be used to record any problems with the pre-collection or post-collection processing, such as a problem with the thermometer or the threshold monitors.

<b>Part D: Transport Temperatures</b>	
Time placed in refrigerated chamber: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <span style="margin-left: 40px;">h h m m</span>	<input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
Refrigerated chamber temperature: <input type="text"/> <input type="text"/> . <input type="text"/> °C	<input type="checkbox"/> Not able to measure
Status of refrigerated chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
Status of refrigerated chamber warm threshold monitor	<input type="checkbox"/> Yes, in chamber/activated <input type="checkbox"/> No, not in chamber
Status of ambient chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
<b>Part E: Blood Collection Comments</b>	
<div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px;"></div>	
<b>Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)</b>	
<p>Because we are not able to draw your blood, we are requesting to collect a saliva sample. Several measures that are performed in blood can be measured in saliva. Are you able to provide a saliva sample?</p> <p><i>Debido a que no pudimos sacarle sangre, quisiéramos pedirle una muestra de saliva. Varios análisis que se llevan a cabo en la sangre se pueden hacer en la saliva. ¿Puede darnos una muestra de saliva?</i></p> <p style="text-align: center;"><input type="checkbox"/> Yes <span style="margin-left: 100px;"><input type="checkbox"/> No (END)</span></p> <p><b>BE SURE TO REVIEW SALIVA SAMPLE COLLECTION INSTRUCTIONS WITH THE PARTICIPANT</b></p> <p style="text-align: center;"><input type="checkbox"/> Collected <span style="margin-left: 50px;"><input type="checkbox"/> Not collected</span></p>	
<p><b>Reason not done or partial:</b> (Mark all that apply.)</p> <p><input type="checkbox"/> No time</p> <p><input type="checkbox"/> Participant ill/emergency</p> <p><input type="checkbox"/> Equipment failure</p>	<p><input type="checkbox"/> Other—specify: _____</p> <p><input type="checkbox"/> Refuse</p>
<p><b>Saliva Comments:</b></p> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px;"></div>	

**Subject Label**

Assignment ID,  
Subject ID, Event Type

**Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)**

This portion of the form should be completed only for those participants who refuse or are unable to provide a blood specimen but are willing to provide a saliva specimen.

*Are you able to provide a saliva sample?*

- Mark the box that corresponds to the participant’s response.
- If the participant is able to provide a saliva specimen, be sure to review the specimen collection instructions provided in the kit insert with him.
- Mark the box that corresponds to the status of the saliva collection:
  - “Collected”—Mark this box to indicate that a complete specimen has been collected. The specimen is considered complete when the liquid in the clear container is level with where the flat part of the neck meets the cap. See picture number 2 in the kit insert.
  - “Not collected”—Mark this box to indicate that the participant agreed to provide a saliva specimen but was not able to do so. Please indicate the reason the specimen was not collected by marking the box that corresponds to the explanation that best describes why a complete specimen was not collected.

*Reason not done or partial (Mark all that apply)*

- “No time”—Mark this box to indicate that the saliva specimen was not collected because the visit was ended ahead of schedule.
- “Participant Ill/ emergency”—Mark this box to indicate that the participant had an emergency or illness that requires termination of the visit prior to the collection of the saliva specimen. Record a brief description of the nature of the emergency or illness in the Saliva Comments section of Part F.
- “Equipment failure”—Mark this box to indicate that the saliva was not collected because of a problem with the collection container. This includes not having the appropriate supplies available in the home or clinic.
- “Other—specify”—Mark this box to indicate that the saliva was not collected for a reason other than those listed. Specify the reason in the space provided.
- “Refuse”—Mark this box to indicate that the participant refused to provide a saliva specimen

*Saliva comments*—Additional comments may include reasons for not collecting a specimen or problems with the collection. This space should also be used to record problems with the pre-collection or post-collection processing.




Part 4

Appendix 1-G

Adult Blood Data Collection Form – T3 Mother



Appendix 1-G.  
Adult Blood Data Collection Form – T3 Mother

	<p><b>National Children's Study</b> <b>Adult Blood</b> <b>Data Collection Form – T3 Mother</b></p>	<p>T3-1<sup>st</sup>, T3 Prior</p>
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(Only for use when FACE is not available)

<b>Part A: Administrative</b>	
Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 2 <input type="text"/> 0 <input type="text"/> <input type="text"/> <small>m m d d y y y y</small>	Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <small>h h m m</small> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
Data collector ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">                     Place Adult Blood Collection—T3-Mother or Adult BNC Saliva Collection DC Label Here                 </div>
Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office	
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>	
1) Do you have hemophilia or any bleeding disorder? <i>¿Tiene hemofilia o algún problema de coagulación?</i>	<input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
2) Do you take any blood thinning medication, such as Coumadin or warfarin? <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i>	<input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
3) Have you had cancer chemotherapy within the past 4 weeks? <i>¿Ha recibido algún tratamiento de quimioterapia para el cáncer en las últimas 4 semanas?</i>	<input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
4) Have you had any problems with a blood draw in the past? <i>¿Ha tenido algún problema en el pasado con una extracción de sangre?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Q6) <input type="checkbox"/> Refused (Go to Q6) <input type="checkbox"/> Don't know (Go to Q6)
5) What problems did you have with a blood draw in the past? (Mark all that apply.) <i>¿Qué problemas tuvo en el pasado con una extracción de sangre? (Marque todo lo que corresponda.)</i>	<input type="checkbox"/> Fainting / Desmayos <input type="checkbox"/> Light-headedness / Mareos <input type="checkbox"/> Hematoma / Hematomas
6) When was the last time you ate or drank anything other than plain water? Do not include coffee or tea without sweetener or milk. <i>¿A qué hora comió o bebió algo por última vez además de agua?</i> No incluya café o té sin edulcorante o sin leche.	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <small>h h m m</small> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.  <input type="checkbox"/> Refused <input type="checkbox"/> Don't know

**Subject Label**

Assignment ID,  
Subject ID, Event Type

BDDFT301.00DU

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**Appendix 1-G.  
Adult Blood Data Collection Form – T3 Mother (continued)**

<b>For Data Collector Use only:</b>	
7) Is this a fasting blood sample? (If the answer to Question 6 is less than 8 hours ago the answer is No.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
8) Have you had coffee or tea with sweetener or milk in the last 8 hours? <i>¿Ha tomado café o té con leche, o endulzado con un edulcorante en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
9) Have you had alcohol such as beer wine or liquor in the last 8 hours? <i>¿Ha tomado alcohol, tal como cerveza, vino o licor en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
10) Have you chewed gum, used breath mints, lozenges or cough drops, or other cough or cold remedies since in the last 8 hours? <i>¿Ha masticado chicle, usado mentas para el aliento, pastillas de chupar para la garganta o caramelos para la tos, u otro remedio para la tos o para el resfriado en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
11) Have you used antacid, laxatives, or anti-diarrheal medications in the last 8 hours? <i>¿Ha tomado antiácidos, laxantes o purgantes o antidiarreicos en las últimas 8 horas</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
12) Have you taken a dietary supplement such as vitamins or minerals in the last 8 hours? <i>¿Ha tomado suplementos alimenticios como vitaminas o minerales en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
13) Are you a diabetic? This includes gestational diabetes. <i>¿Es usted diabética? Incluya la diabetes gestacional o diabetes del embarazo.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Part C) <input type="checkbox"/> Refused (Go to Part C) <input type="checkbox"/> Don't know (Go to Part C)
14) Have you taken any insulin in the last 8 hours? <i>¿Ha tomado insulina en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
<b>Part C: Blood Collection Tubes</b>	
<b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done  <b>Reason for not done/partial:</b> (Mark one.) <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient	<input type="checkbox"/> Defective collection kit <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____

**Appendix 1- G.  
Adult Blood Data Collection Form – T3 Mother (continued)**

<b>SS10</b> Serum Separator Tube	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>RD11</b> 10mL Red Top 11	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>RD13</b> 10mL Red Top 13	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>LV10</b> 6 mL Lavender Top 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

<p><b>Subject Label</b></p> <p>Assignment ID, Subject ID, Event Type</p>
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**Appendix 1- G.  
Adult Blood Data Collection Form – T3 Mother (continued)**

<p align="center"><b>PP10</b> Plasma Preparation Tube</p>	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw									
	<p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <table border="0"> <tr> <td><input type="checkbox"/> Equipment failure</td> <td><input type="checkbox"/> Bruising</td> </tr> <tr> <td><input type="checkbox"/> Fainting</td> <td><input type="checkbox"/> Vein collapsed during the procedure</td> </tr> <tr> <td><input type="checkbox"/> Light-headedness</td> <td><input type="checkbox"/> Other—specify: _____</td> </tr> <tr> <td><input type="checkbox"/> Hematoma</td> <td><input type="checkbox"/> Refused</td> </tr> <tr> <td><input type="checkbox"/> No suitable vein</td> <td></td> </tr> </table>	<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising	<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure	<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____	<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused	<input type="checkbox"/> No suitable vein
<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising									
<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure									
<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____									
<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused									
<input type="checkbox"/> No suitable vein										
<p align="center"><b>AD 10</b> ACD Tube</p>	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw									
	<p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <table border="0"> <tr> <td><input type="checkbox"/> Equipment failure</td> <td><input type="checkbox"/> Bruising</td> </tr> <tr> <td><input type="checkbox"/> Fainting</td> <td><input type="checkbox"/> Vein collapsed during the procedure</td> </tr> <tr> <td><input type="checkbox"/> Light-headedness</td> <td><input type="checkbox"/> Other—specify: _____</td> </tr> <tr> <td><input type="checkbox"/> Hematoma</td> <td><input type="checkbox"/> Refused</td> </tr> <tr> <td><input type="checkbox"/> No suitable vein</td> <td></td> </tr> </table>	<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising	<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure	<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____	<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused	<input type="checkbox"/> No suitable vein
<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising									
<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure									
<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____									
<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused									
<input type="checkbox"/> No suitable vein										
<p align="center"><b>PN 10</b> P100 Tube</p>	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw									
	<p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <table border="0"> <tr> <td><input type="checkbox"/> Equipment failure</td> <td><input type="checkbox"/> Bruising</td> </tr> <tr> <td><input type="checkbox"/> Fainting</td> <td><input type="checkbox"/> Vein collapsed during the procedure</td> </tr> <tr> <td><input type="checkbox"/> Light-headedness</td> <td><input type="checkbox"/> Other—specify: _____</td> </tr> <tr> <td><input type="checkbox"/> Hematoma</td> <td><input type="checkbox"/> Refused</td> </tr> <tr> <td><input type="checkbox"/> No suitable vein</td> <td></td> </tr> </table>	<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising	<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure	<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____	<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused	<input type="checkbox"/> No suitable vein
<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising									
<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure									
<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____									
<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused									
<input type="checkbox"/> No suitable vein										
<p align="center"><b>PX 10</b> PaxGene Tube</p>	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw									
	<p><b>Reason for short draw or no draw:</b> (Mark all that apply.)</p> <table border="0"> <tr> <td><input type="checkbox"/> Equipment failure</td> <td><input type="checkbox"/> Bruising</td> </tr> <tr> <td><input type="checkbox"/> Fainting</td> <td><input type="checkbox"/> Vein collapsed during the procedure</td> </tr> <tr> <td><input type="checkbox"/> Light-headedness</td> <td><input type="checkbox"/> Other—specify: _____</td> </tr> <tr> <td><input type="checkbox"/> Hematoma</td> <td><input type="checkbox"/> Refused</td> </tr> <tr> <td><input type="checkbox"/> No suitable vein</td> <td></td> </tr> </table>	<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising	<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure	<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____	<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused	<input type="checkbox"/> No suitable vein
<input type="checkbox"/> Equipment failure	<input type="checkbox"/> Bruising									
<input type="checkbox"/> Fainting	<input type="checkbox"/> Vein collapsed during the procedure									
<input type="checkbox"/> Light-headedness	<input type="checkbox"/> Other—specify: _____									
<input type="checkbox"/> Hematoma	<input type="checkbox"/> Refused									
<input type="checkbox"/> No suitable vein										

**Appendix 1- G.  
Adult Blood Data Collection Form – T3 Mother (continued)**

<b>Part D: Transport Temperatures</b>	
Time placed in refrigerated chamber: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="checkbox"/> a.m.
<small>h h m m</small>	<input type="checkbox"/> p.m.
Refrigerated chamber temperature: <input type="text"/> <input type="text"/> . <input type="text"/> °C	<input type="checkbox"/> Not able to measure
Status of refrigerated chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
Status of refrigerated chamber warm threshold monitor	<input type="checkbox"/> Yes, in chamber/activated <input type="checkbox"/> No, not in chamber
Status of ambient chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
<b>Part E: Blood Collection Comments</b>	
<hr/> <hr/>	
<b>Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)</b>	
<p>Because we are not able to draw your blood, we are requesting to collect a saliva sample. Several measures that are performed in blood can be measured in saliva. Are you able to provide a saliva sample?</p> <p><i>Debido a que no pudimos sacarle sangre, quisiéramos pedirle una muestra de saliva. Varios análisis que se llevan a cabo en la sangre se pueden hacer en la saliva. ¿Puede darnos una muestra de saliva?</i></p> <p align="center"><input type="checkbox"/> Yes                      <input type="checkbox"/> No (END)</p>	
<b>BE SURE TO REVIEW SALIVA SAMPLE COLLECTION INSTRUCTIONS WITH THE PARTICIPANT</b>	
<input type="checkbox"/> Collected <input type="checkbox"/> Not collected	
<b>Reason not done or partial:</b> (Mark all that apply.) <input type="checkbox"/> No time <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> Equipment failure	<input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Refused
<b>Saliva Comments:</b>	
<hr/> <hr/>	

<p><b>Subject Label</b></p> <p>Assignment ID, Subject ID, Event Type</p>
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**Appendix 1- G.**  
**Adult Blood Data Collection Form – T3 Mother (continued)**

**Data collector ID for field QC**

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**Date entered into FACE:** //20  
m m d d y y y y

**ID of Data collector who entered the form:**

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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For Reference Only

Part 4

Appendix 1-H

Adult Blood Data Collection Form – T3 Mother:  
Field-by-Field Instructions




**Appendix 1-H.**  
**Adult Blood Data Collection Form- T3 Mother: Field-by-Field Instructions**

**ADULT BLOOD DATA COLLECTION FORM- T3 MOTHER:  
FIELD-BY-FIELD INSTRUCTIONS**

This form is only to be completed when the Field-Administrated Collection Environment (FACE) is not available at a T3 mother data collection visit. This form is to be completed by the biospecimen data collector performing the phlebotomy (blood 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 and accuracy should write her data collector ID in the space provided at the bottom of the last page.
- The data collector who enters the data recorded on the form in FACE will record the date of data entry and her data collector identification number (ID) in the space provided on the last page of the form.



**National Children's Study**  
**Adult Blood**  
**Data Collection Form – T3 Mother**

T3-1<sup>st</sup>, T3 Prior

(Only for use when FACE is not available)

<b>Part A: Administrative</b>	
<p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> 2 <input type="text"/> 0 <input type="text"/> <input type="text"/></p> <p style="font-size: small; margin-left: 20px;">m m d d y y y y</p> <p>Data collector ID:  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office</p>	<p>Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m.  <input type="checkbox"/> p.m.</p> <p style="text-align: center; border: 1px solid black; padding: 5px; margin: 10px 0;">Place Adult Blood Collection—T3-Mother or Adult BNC Saliva Collection DC Label Here</p>
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>	
<p>1) Do you have hemophilia or any bleeding disorder?  <i>¿Tiene hemofilia o algún problema de coagulación?</i></p>	<p><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No  <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>
<p>2) Do you take any blood thinning medication, such as Coumadin or warfarin?  <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i></p>	<p><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No  <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>
<p>3) Have you had cancer chemotherapy within the past 4 weeks?  <i>¿Ha recibido algún tratamiento de quimioterapia para el cáncer en las últimas 4 semanas?</i></p>	<p><input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No  <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>
<p>4) Have you had any problems with a blood draw in the past?  <i>¿Ha tenido algún problema en el pasado con una extracción de sangre?</i></p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Q6)  <input type="checkbox"/> Refused (Go to Q6) <input type="checkbox"/> Don't know (Go to Q6)</p>
<p>5) What problems did you have with a blood draw in the past? (Mark all that apply.)  <i>¿Qué problemas tuvo en el pasado con una extracción de sangre? (Marque todo lo que corresponda.)</i></p>	<p><input type="checkbox"/> Fainting / Desmayos  <input type="checkbox"/> Light-headedness / Mareos  <input type="checkbox"/> Hematoma / Hematomas</p>
<p>6) When was the last time you ate or drank anything other than plain water?                      Do not include coffee or tea without sweetener or milk.  <i>¿A qué hora comió o bebió algo por última vez además de agua?</i>                      No incluya café o té sin edulcorante o sin leche.</p>	<p><input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m.  <input type="checkbox"/> p.m.</p> <p><input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>

**Subject Label**

Assignment ID,  
Subject ID, Event Type

BDDFT301.00DU

1

**Part A: Administrative Section**

- *Date*—Record the date that the blood draw is completed or attempted. The month, day, and the last 2 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 phlebotomist who completes the form.
- *Visit location*—Mark the box corresponding to the location of the visit.
- *Time collection kit opened*—Record the time the Adult Blood 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 the kit is opened at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
- *Kit Label*—Open the Adult Blood Collection Kit and place the DC label in the appropriate place on the data collection form. If the participant refuses or is unable to provide a blood specimen but is willing to provide a saliva specimen, open the Adult Blood Not Collected (BNC) Saliva Collection Kit and place the DC label in the space provided on the front page of the form.

**Part B: Blood Pre-Screening Questions**


Questions 1 through 5 must be asked prior to each blood draw.

1. *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 and go to Part F.

2. *Do you take any blood thinning medication, 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 and go to Part F.


**National Children's Study  
Adult Blood  
Data Collection Form – T3 Mother**
T3-1<sup>st</sup>, T3 Prior

(Only for use when FACE is not available)

<b>Part A: Administrative</b>	
Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> 2 <input type="text"/> 0 <input type="text"/> <input type="text"/> <small>m m d d y y y y</small>	Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <small>h h m m</small> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
Data collector ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">                         Place Adult Blood Collection—T3-Mother or Adult BNC Saliva Collection DC Label Here                     </div>
Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office	
<b>Part B: Blood Pre-Screening Questions (Ask these questions at all visits when blood is drawn.)</b>	
1) Do you have hemophilia or any bleeding disorder? <i>¿Tiene hemofilia o algún problema de coagulación?</i>	<input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
2) Do you take any blood thinning medication, such as Coumadin or warfarin? <i>¿Toma algún medicamento anticoagulante como Coumadin o warfarina?</i>	<input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
3) Have you had cancer chemotherapy within the past 4 weeks? <i>¿Ha recibido algún tratamiento de quimioterapia para el cáncer en las últimas 4 semanas?</i>	<input type="checkbox"/> Yes (Go to Part F) <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
4) Have you had any problems with a blood draw in the past? <i>¿Ha tenido algún problema en el pasado con una extracción de sangre?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Q6) <input type="checkbox"/> Refused (Go to Q6) <input type="checkbox"/> Don't know (Go to Q6)
5) What problems did you have with a blood draw in the past? (Mark all that apply.) <i>¿Qué problemas tuvo en el pasado con una extracción de sangre? (Marque todo lo que corresponda.)</i>	<input type="checkbox"/> Fainting / Desmayos <input type="checkbox"/> Light-headedness / Mareos <input type="checkbox"/> Hematoma / Hematomas
6) When was the last time you ate or drank anything other than plain water? Do not include coffee or tea without sweetener or milk. <i>¿A qué hora comió o bebió algo por última vez además de agua?</i> No incluya café o té sin edulcorante o sin leche.	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <small>h h m m</small> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.  <input type="checkbox"/> Refused <input type="checkbox"/> Don't know

**Subject Label**

Assignment ID,  
Subject ID, Event Type

BDDFT301.00DU

1

3. *Have you had cancer chemotherapy within the past 4 weeks?*
  - 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 and go to Part F.
4. *Have you had any problems with a blood draw in the past?*
  - Mark the box that corresponds to the participant's response.
  - If the participant answers "No," "Refuse," or "Don't know," mark the corresponding box and go to question 6.
5. *What problems did you have with a blood draw in the past? (Mark all that apply)*
  - Read the first four choices to the participant.
  - Mark the box that corresponds to the types of problems that the participant experienced during previous blood draws.
  - If the participant reports a problem that is not included in the list mark that box that corresponds to "Other—specify" and briefly describe the problem in the space provided.
  - If the participant refuses to answer or does not remember specifically what type of problem she experienced in the past, mark the appropriate box and go to Part C.
6. *When was the last time you ate or drank anything other than plain water? Do not include coffee or tea without sweetener or milk.*
  - Record the time 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 participant last ate 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.

<b>For Data Collector Use only:</b>	
7) Is this a fasting blood sample? (If the answer to Question 6 is less than 8 hours ago the answer is No.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
8) Have you had coffee or tea with sweetener or milk in the last 8 hours? <i>¿Ha tomado café o té con leche, o endulzado con un edulcorante en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
9) Have you had alcohol such as beer wine or liquor in the last 8 hours? <i>¿Ha tomado alcohol, tal como cerveza, vino o licor en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
10) Have you chewed gum, used breath mints, lozenges or cough drops, or other cough or cold remedies since in the last 8 hours? <i>¿Ha masticado chicle, usado mentas para el aliento, pastillas de chupar para la garganta o caramelos para la tos, u otro remedio para la tos o para el resfriado en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
11) Have you used antacid, laxatives, or anti-diarrheal medications in the last 8 hours? <i>¿Ha tomado antiácidos, laxantes o purgantes o antidiarreicos en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
12) Have you taken a dietary supplement such as vitamins or minerals in the last 8 hours? <i>¿Ha tomado suplementos alimenticios como vitaminas o minerales en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
13) Are you a diabetic? This includes gestational diabetes. <i>¿Es usted diabética? Incluya la diabetes gestacional o diabetes del embarazo.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Part C) <input type="checkbox"/> Refused (Go to Part C) <input type="checkbox"/> Don't know (Go to Part C)
14) Have you taken any insulin in the last 8 hours? <i>¿Ha tomado insulina en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
<b>Part C: Blood Collection Tubes</b>	
<b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done	
<b>Reason for not done/partial:</b> (Mark one.) <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient	<input type="checkbox"/> Defective collection kit <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____

7. *Is this a fasting blood sample? (For Data Collector Use Only)*

- This question is for the Data Collector's use only. Do not ask the study participant this question.
- If the study participant's response to Question 6 indicates that she has not consumed anything other than water, coffee, or tea without sweetener or milk within the past 8 hours, mark "Yes".
- If the study participant's response to Question 6 indicates that she has consumed anything other than water, or has consumed coffee or tea with sweetener or milk, within the past 8 hours, mark "No".

8. *Have you had coffee or tea with sweetener or milk in the last 8 hours?*

- Mark the box that corresponds to the participant's response.
- "Sweetener" includes sugar, honey, and flavored creamers. If the study participant consumed an artificial sweetener in coffee, tea, or a diet soda, mark "No".

9. *Have you had alcohol such as beer, wine, or liquor in the last 8 hours?*

- Mark the box that corresponds to the participant's response.

10. *Have you chewed gum, used breath mints, lozenges or cough drops, or other cough or cold remedies since in the last 8 hours?*

- Mark the box that corresponds to the participant's response.

11. *Have you used antacid, laxatives, or anti-diarrheal medications in the last 8 hours?*

- Mark the box that corresponds to the participant's response.

12. *Have you taken a dietary supplement such as vitamins or minerals in the last 8 hours?*

- Mark the box that corresponds to the participant's response.

13. *Are you a diabetic?*

- Mark the box that corresponds to the participant's response.
- If the study participant has gestational diabetes, mark "Yes".
- If the participant answers "No," "Refuse," or "Don't know," mark the corresponding box and go to Part C.

<b>For Data Collector Use only:</b>	
7) Is this a fasting blood sample? (If the answer to Question 6 is less than 8 hours ago the answer is No.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
8) Have you had coffee or tea with sweetener or milk in the last 8 hours? <i>¿Ha tomado café o té con leche, o endulzado con un edulcorante en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
9) Have you had alcohol such as beer wine or liquor in the last 8 hours? <i>¿Ha tomado alcohol, tal como cerveza, vino o licor en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
10) Have you chewed gum, used breath mints, lozenges or cough drops, or other cough or cold remedies since in the last 8 hours? <i>¿Ha masticado chicle, usado mentas para el aliento, pastillas de chupar para la garganta o caramelos para la tos, u otro remedio para la tos o para el resfriado en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
11) Have you used antacid, laxatives, or anti-diarrheal medications in the last 8 hours? <i>¿Ha tomado antiácidos, laxantes o purgantes o antidiarreicos en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
12) Have you taken a dietary supplement such as vitamins or minerals in the last 8 hours? <i>¿Ha tomado suplementos alimenticios como vitaminas o minerales en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
13) Are you a diabetic? This includes gestational diabetes. <i>¿Es usted diabética? Incluye la diabetes gestacional o diabetes del embarazo.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Part C) <input type="checkbox"/> Refused (Go to Part C) <input type="checkbox"/> Don't know (Go to Part C)
14) Have you taken any insulin in the last 8 hours? <i>¿Ha tomado insulina en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
<b>Part C: Blood Collection Tubes</b>	
<b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done	
<b>Reason for not done/partial:</b> (Mark one.) <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient	<input type="checkbox"/> Defective collection kit <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____

14. *Have you taken any insulin in the last 8 hours?*

- Mark the box that corresponds to the participant’s response.

**Part C: Blood Collection Tubes**

- *Collection status* (Mark one)—Mark the box corresponding to the status of the blood draw:
  - “Complete”—Mark this box to indicate that all blood tubes are filled to at least 3/4 the desired capacity. Desired capacity is defined as filled to the full line marked on the blood tube. This box should not be checked if there are any partially filled tubes.
  - “Partial complete”—Mark this box to indicate that at least one, but not all of the blood tubes is filled to at least 3/4 of the desired capacity. When this box is marked, the phlebotomist must indicate the reason that the blood specimen collection is partially complete.
  - “Not done”—Mark this box to indicate that no blood tubes were collected. When this box is marked, the phlebotomist must indicate the reason that the blood specimen collection was not done.
- *Reason for not done/partial* (Mark one)—Mark the box that best describes why the blood draw was either not done or partially completed:
  - “Participant refusal”—Mark this box to indicate that the participant is unwilling to provide a blood specimen. When the participant refuses, refer to Part F of the form, which asks the participant to provide a saliva specimen. Do not mark this box to indicate that the participant refuses to provide a saliva specimen.
  - “Participant Ill/ emergency”—Mark this box to indicate that the participant had an emergency or illness that required termination of the visit prior to the collection of the blood specimens. Record a brief description of the nature of the emergency or illness in the Comments section of Part E.
  - “No time”—Mark this box to indicate that the blood specimen was not collected because the visit was ended ahead of schedule. Record a brief description of reason that the visit was ended in Comments section of Part E.

For Data Collector Use only:	
7) Is this a fasting blood sample? (If the answer to Question 6 is less than 8 hours ago the answer is No.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
8) Have you had coffee or tea with sweetener or milk in the last 8 hours? <i>¿Ha tomado café o té con leche, o endulzado con un edulcorante en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
9) Have you had alcohol such as beer wine or liquor in the last 8 hours? <i>¿Ha tomado alcohol, tal como cerveza, vino o licor en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
10) Have you chewed gum, used breath mints, lozenges or cough drops, or other cough or cold remedies since in the last 8 hours? <i>¿Ha masticado chicle, usado mentas para el aliento, pastillas de chupar para la garganta o caramelos para la tos, u otro remedio para la tos o para el resfriado en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
11) Have you used antacid, laxatives, or anti-diarrheal medications in the last 8 hours? <i>¿Ha tomado antiácidos, laxantes o purgantes o antidiarreicos en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
12) Have you taken a dietary supplement such as vitamins or minerals in the last 8 hours? <i>¿Ha tomado suplementos alimenticios como vitaminas o minerales en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
13) Are you a diabetic? This includes gestational diabetes. <i>¿Es usted diabética? Incluye la diabetes gestacional o diabetes del embarazo.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Part C) <input type="checkbox"/> Refused (Go to Part C) <input type="checkbox"/> Don't know (Go to Part C)
14) Have you taken any insulin in the last 8 hours? <i>¿Ha tomado insulina en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
Part C: Blood Collection Tubes	
<b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done	
<b>Reason for not done/partial:</b> (Mark one.) <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient	<input type="checkbox"/> Defective collection kit <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____

- “Safety exclusion”—Mark this box to indicate that the participant is ineligible to provide a blood specimen because she has a bleeding disorder, is taking blood thinning medication such as Coumadin or warfarin; or has had cancer chemotherapy during the past 4 weeks. When the participant is ineligible to provide a blood specimen, refer to Part F of the form, which asks the participant to provide a saliva specimen.
- “Physical limitations”—Mark this box to indicate that the participant has a physical limitation that prevented her from providing blood. This type of limitation includes but is not limited to an infection or cellulites at the draw site; or an inability to straighten one’s arm. Blood should not be drawn from an arm that contains a shunt or is in a cast. Record a brief description of the type of physical limitation in the Comments section of Part E. When the participant is not able to provide a blood specimen because of a physical limitation, refer to Part F of the form, which asks the participant to provide a saliva specimen.
- “Quantity not sufficient”—This box is marked in certain situations to indicate that not all of the blood tubes required for this visit were collected. It also is marked in certain situations when one or more of the blood tubes is filled to less than 3/4 the desired capacity. Desired capacity is defined as filled to the full line marked on the blood tube. Please see the instructions for selecting a reason for a “Short draw” or “No draw” in Part C to determine when this box is marked.
- “Defective collection kit”—Mark this box to indicate that the blood specimen was not collected because of a problem with the Adult Blood Collection Kit. This includes not having the appropriate supplies available in the home or clinic.
- “Slide broken”—This reason code does not apply to this specimen collection activity.
- “Language issue, Spanish”—Mark this box to indicate that the blood specimens were not collected because the phlebotomist 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 blood specimens were not collected because the phlebotomist is unable to communicate the necessary instructions to the participant.
- “Cognitive disability”—Mark this box to indicate that the blood specimens were not collected because the participant is cognitively or developmentally impaired and therefore unable to understand the specimen collection instructions.

<b>For Data Collector Use only:</b>	
7) Is this a fasting blood sample? (If the answer to Question 6 is less than 8 hours ago the answer is No.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
8) Have you had coffee or tea with sweetener or milk in the last 8 hours? <i>¿Ha tomado café o té con leche, o endulzado con un edulcorante en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
9) Have you had alcohol such as beer wine or liquor in the last 8 hours? <i>¿Ha tomado alcohol, tal como cerveza, vino o licor en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
10) Have you chewed gum, used breath mints, lozenges or cough drops, or other cough or cold remedies since in the last 8 hours? <i>¿Ha masticado chicle, usado mentas para el aliento, pastillas de chupar para la garganta o caramelos para la tos, u otro remedio para la tos o para el resfriado en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
11) Have you used antacid, laxatives, or anti-diarrheal medications in the last 8 hours? <i>¿Ha tomado antiácidos, laxantes o purgantes o antidiarreicos en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
12) Have you taken a dietary supplement such as vitamins or minerals in the last 8 hours? <i>¿Ha tomado suplementos alimenticios como vitaminas o minerales en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
13) Are you a diabetic? This includes gestational diabetes. <i>¿Es usted diabética? Incluya la diabetes gestacional o diabetes del embarazo.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No (Go to Part C) <input type="checkbox"/> Refused (Go to Part C) <input type="checkbox"/> Don't know (Go to Part C)
14) Have you taken any insulin in the last 8 hours? <i>¿Ha tomado insulina en las últimas 8 horas?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't know
<b>Part C: Blood Collection Tubes</b>	
<b>Collection status:</b> (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial complete <input type="checkbox"/> Not done	
<b>Reason for not done/partial:</b> (Mark one.) <input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient	<input type="checkbox"/> Defective collection kit <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other—specify: _____

- “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 blood specimen. When the parent or guardian refuses, refer to Part F of the form, which asks the participant to provide a saliva specimen. Do not mark this box to indicate that the parent or guardian refused to allow the participant to provide a saliva specimen.
  
- “Other—Specify”—Mark this box to indicate that the blood specimens were not collected for a reason other than those listed; specify the reason in the space provided.

<b>SS10</b> Serum Separator Tube	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>RD11</b> 10mL Red Top 11	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>RD13</b> 10mL Red Top 13	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein
<b>LV10</b> 6 mL Lavender Top 10	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw
	<b>Reason for short draw or no draw:</b> (Mark all that apply.) <input type="checkbox"/> Equipment failure <input type="checkbox"/> Bruising <input type="checkbox"/> Fainting <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Light-headedness <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Hematoma <input type="checkbox"/> Refused <input type="checkbox"/> No suitable vein

**Subject Label**  
 Assignment ID,  
 Subject ID, Event Type

Indicate the collection status of each blood tube and if necessary, provide a reason why the blood tube collection is incomplete.

- Mark the box that corresponds to the status of the blood collection for each tube listed in the left hand column. Different tubes will be collected for each study event type.
  - “Full draw”—This box is marked to indicate that the corresponding blood tube was filled to at least 3/4 the desired capacity. Desired capacity is defined as filled to the full line marked on the blood tube.
  - “Short draw”—This box is marked to indicate that the corresponding blood tube was filled to less than 3/4 of the desired capacity. When this box is marked, indicate the reason for the short draw.
  - “No draw”—This box is marked to indicate that the blood tube was not collected. When this box is marked, indicate the reason that the blood tube was not drawn.
- *Reason for short draw or no draw*—Mark the box that best describes why the blood draw was either short or not done.
  - “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. This includes not having the appropriate supplies available in the home or clinic. Record a brief description of the problem in Comments section of Part E. If the equipment fails before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Defective collection kit.”
  - “Fainting”—Mark this box to indicate that the participant experienced a temporary loss of consciousness during the collection of the corresponding tube. Feeling faint or dizzy is not considered fainting. If the participant faints before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.” An Incident Report Form also must be completed.

<b>PP10</b> Plasma Preparation Tube	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw	
	<b>Reason for short draw or no draw:</b> <input type="checkbox"/> Equipment failure <input type="checkbox"/> Fainting <input type="checkbox"/> Light-headedness <input type="checkbox"/> Hematoma <input type="checkbox"/> No suitable vein	(Mark all that apply.) <input type="checkbox"/> Bruising <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Refused
<b>AD 10</b> ACD Tube	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw	
	<b>Reason for short draw or no draw:</b> <input type="checkbox"/> Equipment failure <input type="checkbox"/> Fainting <input type="checkbox"/> Light-headedness <input type="checkbox"/> Hematoma <input type="checkbox"/> No suitable vein	(Mark all that apply.) <input type="checkbox"/> Bruising <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Refused
<b>PN 10</b> P100 Tube	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw	
	<b>Reason for short draw or no draw:</b> <input type="checkbox"/> Equipment failure <input type="checkbox"/> Fainting <input type="checkbox"/> Light-headedness <input type="checkbox"/> Hematoma <input type="checkbox"/> No suitable vein	(Mark all that apply.) <input type="checkbox"/> Bruising <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Refused
<b>PX 10</b> PaxGene Tube	<input type="checkbox"/> Full draw <input type="checkbox"/> Short draw <input type="checkbox"/> No draw	
	<input type="checkbox"/> Equipment failure <input type="checkbox"/> Fainting <input type="checkbox"/> Light-headedness <input type="checkbox"/> Hematoma <input type="checkbox"/> No suitable vein	(Mark all that apply.) <input type="checkbox"/> Bruising <input type="checkbox"/> Vein collapsed during the procedure <input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Refused

- “Light-headedness”—Mark this box to indicate that the participant reported a temporary feeling of lightheadedness, feeling faint, or dizzy. This does not require the completion of an Incident Report Form. If the participant becomes light-headed before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the “Collection status” portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.”
- “Hematoma”—Mark this box to indicate that the participant experienced a localized mass of blood, usually clotted, in the venipuncture space or surrounding tissue. If the participant experiences a hematoma before all of the tubes can be collected, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.” An Incident Report Form also must be completed.
- “No suitable vein”—Mark this box to indicate that the participant does not have a suitable vein to draw the blood specimen. Record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Physical limitation.”
- “Bruising”—Mark this box if the 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. If the bruising occurs before all of the blood tubes are drawn, record the information required for the affected tube in Part C. Complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.”
- “Vein collapsed during the procedure”—Mark this box if the vein collapses during the blood draw. If this occurs before all of the tubes are drawn, be sure to complete the *Collection status* portion of Part A by marking the box that corresponds to “Partial complete” and the *Reason for not done/partial* section of Part A by marking the box that corresponds to “Quantity not sufficient.”
- “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.
- “Refused”—Mark this box to indicate that the participant is unwilling to allow the completion of the blood draw procedure.

<b>Part D: Transport Temperatures</b>	
Time placed in refrigerated chamber: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <span style="margin-left: 100px;"><small>h h m m</small></span>	<input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
Refrigerated chamber temperature: <input type="text"/> <input type="text"/> . <input type="text"/> °C	<input type="checkbox"/> Not able to measure
Status of refrigerated chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
Status of refrigerated chamber warm threshold monitor	<input type="checkbox"/> Yes, in chamber/activated <input type="checkbox"/> No, not in chamber
Status of ambient chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
<b>Part E: Blood Collection Comments</b>	
<hr/> <hr/> <hr/>	
<b>Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)</b>	
<p>Because we are not able to draw your blood, we are requesting to collect a saliva sample. Several measures that are performed in blood can be measured in saliva. Are you able to provide a saliva sample?</p> <p><i>Debido a que no pudimos sacarle sangre, quisiéramos pedirle una muestra de saliva. Varios análisis que se llevan a cabo en la sangre se pueden hacer en la saliva. ¿Puede darnos una muestra de saliva?</i></p> <p style="text-align: center;"><input type="checkbox"/> Yes                      <input type="checkbox"/> No (END)</p> <p><b>BE SURE TO REVIEW SALIVA SAMPLE COLLECTION INSTRUCTIONS WITH THE PARTICIPANT</b></p> <p style="text-align: center;"><input type="checkbox"/> Collected                      <input type="checkbox"/> Not collected</p>	
<p><b>Reason not done or partial:</b> (Mark all that apply.)</p> <p><input type="checkbox"/> No time</p> <p><input type="checkbox"/> Participant ill/emergency</p> <p><input type="checkbox"/> Equipment failure</p>	<p><input type="checkbox"/> Other—specify: _____</p> <p><input type="checkbox"/> Refused</p>
<p><b>Saliva Comments:</b></p> <hr/> <hr/> <hr/>	

**Subject Label**

Assignment ID,  
Subject ID, Event Type

**Part D: Transport Temperatures**

- *Time placed in refrigerated chamber*—Record the time the tubes were placed into the refrigerated chamber of the transport cooler. 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 tubes are placed in the cooler at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
- *Refrigerated chamber temperature*—Record the temperature reading on the digital thermometer in the refrigerated chamber of the transport cooler at the time that the blood tubes are placed in the chamber. The temperature should be recorded to the first decimal point. Be sure to zero fill the space to the right of the decimal when necessary.
- *Status of refrigerated chamber cold threshold monitor*—Mark the box to indicate whether the cold threshold monitor is present in the refrigerated chamber of the transport cooler.
- *Status of the refrigerated chamber warm threshold monitor*—Mark the box that corresponds to the status of the warm threshold monitor in the refrigerated chamber of the transport cooler. If the monitor is present, pull the tab to activate it and mark the box that corresponds to “Yes, in chamber/activated.” If the monitor is not present, mark the box that corresponds to “No, not in the chamber.”
- *Status of the ambient chamber cold threshold monitor*—Mark the box to indicate whether the cold threshold monitor is present in the ambient chamber of the transport cooler.

**Part E: Blood Collection Comments**

Additional comments may include reasons for partial draws or problems with the participant’s venous system. This space also should be used to record any problems with the pre-collection or post-collection processing, such as a problem with the thermometer or the threshold monitors.

<b>Part D: Transport Temperatures</b>	
Time placed in refrigerated chamber: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <small style="margin-left: 100px;">h h m m</small>	<input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
Refrigerated chamber temperature: <input type="text"/> <input type="text"/> . <input type="text"/> °C	<input type="checkbox"/> Not able to measure
Status of refrigerated chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
Status of refrigerated chamber warm threshold monitor	<input type="checkbox"/> Yes, in chamber/activated <input type="checkbox"/> No, not in chamber
Status of ambient chamber cold threshold monitor	<input type="checkbox"/> Yes, in chamber <input type="checkbox"/> No, not in chamber
<b>Part E: Blood Collection Comments</b>	
_____ _____ _____	
<b>Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)</b>	
Because we are not able to draw your blood, we are requesting to collect a saliva sample. Several measures that are performed in blood can be measured in saliva. Are you able to provide a saliva sample?  <i>Debido a que no pudimos sacarle sangre, quisiéramos pedirle una muestra de saliva. Varios análisis que se llevan a cabo en la sangre se pueden hacer en la saliva. ¿Puede darnos una muestra de saliva?</i>	
<input type="checkbox"/> Yes <input type="checkbox"/> No (END)	
<b>BE SURE TO REVIEW SALIVA SAMPLE COLLECTION INSTRUCTIONS WITH THE PARTICIPANT</b>	
<input type="checkbox"/> Collected <input type="checkbox"/> Not collected	
<b>Reason not done or partial:</b> (Mark all that apply.) <input type="checkbox"/> No time <input type="checkbox"/> Participant ill/emergency <input type="checkbox"/> Equipment failure	<input type="checkbox"/> Other—specify: _____ <input type="checkbox"/> Refused
<b>Saliva Comments:</b> _____ _____ _____	

<p><b>Subject Label</b></p> <p>Assignment ID, Subject ID, Event Type</p>
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**Part F: Saliva BNC Collection (Only use if blood collection is refused or not possible.)**

This portion of the form should be completed only for those participants who refuse or are unable to provide a blood specimen but are willing to provide a saliva specimen.

*Are you able to provide a saliva sample?*

- Mark the box that corresponds to the participant’s response.
- If the participant is able to provide a saliva specimen, be sure to review the specimen collection instructions provided in the kit insert with her.
- Mark the box that corresponds to the status of the saliva collection:
  - “Collected”—Mark this box to indicate that a complete specimen has been collected. The specimen is considered complete when the liquid in the clear container is level with where the flat part of the neck meets the cap. See picture number 2 in the kit insert.
  - “Not collected”—Mark this box to indicate that the participant agreed to provide a saliva specimen but was not able to do so. Please indicate the reason the specimen was not collected by marking the box that corresponds to the explanation that best describes why a complete specimen was not collected.

*Reason not done or partial (Mark all that apply)*

- “No time”—Mark this box to indicate that the saliva specimen was not collected because the visit was ended ahead of schedule.
- “Participant ill/ emergency”—Mark this box to indicate that the participant had an emergency or illness that requires termination of the visit prior to the collection of the saliva specimen. Record a brief description of the nature of the emergency or illness in the Saliva Comments section of Part F.
- “Equipment failure”—Mark this box to indicate that the saliva was not collected because of a problem with the collection container. This includes not having the appropriate supplies available in the home or clinic.
- “Other—specify”—Mark this box to indicate that the saliva was not collected for a reason other than those listed. Specify the reason in the space provided.
- “Refuse”—Mark this box to indicate that the participant refused to provide a saliva specimen.
- *Saliva comments*—Additional comments may include reasons for not collecting a specimen or problems with the collection. This space should also be used to record problems with the pre-collection or post-collection processing.



# Adult Blood Transport, Processing, and Storage Procedures

## 2.1 Overview

After collection, blood specimens require transport to the Study Center Specimen Shipping and Processing Center (SPSC), processing (i.e., centrifugation), and receipt and storage before shipping to the NCS repository. This chapter presents the procedures for transport, processing, and storage of adult blood specimens in the context of three different scenarios, based on the location where centrifugation will be performed. Specific procedures for each scenario should be followed according to the appropriate section in this chapter. This chapter also describes the NCS centrifugation requirements and information concerning storage units for specimen storage at the SPSC.

## 2.2 Centrifugation Requirements

All study events where adult blood specimens are collected require centrifugation of specific blood tubes. The type of blood tube used for collection and the potential analytes that will be measured in each tube determine whether a particular blood tube should be shipped to the repository as whole blood (i.e., non-centrifuged), or whether serum or plasma must be separated from blood cells (i.e., centrifugation) prior to shipping. Table 2-1 displays centrifugation specifications by event type and blood tube type.

### 2.2.1 Centrifugation Time Requirement

To reduce variability in blood specimen handling and to preserve the integrity of a wide variety of blood analytes, the National Children’s Study (NCS) has established the following requirement: *Separation of serum or plasma from cells (centrifugation) must be completed within 2 hours of blood collection.*

Table 2-1. Blood centrifugation specifications by study event and blood tube type

Study Event	Blood Tube Type and ID	Non-centrifuged Tubes	Centrifuge for 15 min @ 3500 RPM
P1 Mother (6 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV10)	X	
	10 mL red top (RD10)		X
	10 mL red top (RD11)		X
	5 mL PPT white top (PP10)		X
	8.5 mL SST tiger top (SS10)		X
T1 Mother (7 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV10)	X	
	8.5 mL P100 white/red top (PN10)	X	
	10 mL red top (RD10)		X
	10 mL red top (RD11)		X
	5 mL PPT white top (PP10)		X
T1 Father (4 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV11)	X	
	ACD (AD10)	X	
	10 mL red top (RD12)		X
T3 Mother (8 tubes)	6 mL lavender (LV10)	X	
	ACD (AD10)	X	
	PAXgene (PX10)	X	
	8.5 mL P100 white/red top (PN10)	X	
	10 mL red top (RD11)		X
	10 mL red top (RD13)		X
	5 mL PPT white top (PP10)		X
8.5 mL SST tiger top (SS10)		X	
Birth Mother (4 tubes)	3 mL lavender (LP10)	X	
	10 mL red top (RD14)		X
	10 mL red top (RD15)		X
	10 mL red top (RD16)		X

This requirement applies to the centrifugation of all adult blood specimens with the exception of blood tubes collected from the mother at the birth event. These blood tubes must be centrifuged *within 24 hours* of collection. The 2-hour time requirement does not apply to blood tubes collected at the birth because of the logistical complexity of the birth visit and the difficulty in implementing a standard time requirement. Furthermore, the separation of plasma or serum from cells is not as time-sensitive or critical due to the specific analytes of interest for this study event.

### 2.2.2 Location of Centrifugation

In order to successfully meet the 2-hour time requirement from blood collection to completion of centrifugation, biospecimen data collectors must plan where centrifugation will be performed

prior to initiating a data collection visit. Considerations include the distance between the blood collection location (e.g., home or clinic) and the Specimen Processing and Shipping Center (SPSC), potential travel conditions (e.g., traffic and weather), and the schedule of data collection assignments.

It is optimal for centrifugation procedures to be performed at the Specimen Processing and Shipping Center (SPSC). However, to meet the 2-hour time requirement, Study Centers may perform centrifugation at the location where blood specimens are collected (e.g., at the participant's home, Study Center clinic) or other predetermined approved location (e.g., a satellite location).

### **2.2.3 Centrifugation Conditions**

To reduce variability in centrifugation conditions, the same portable centrifuge model (Hettich Helmer EBA 20) will be used to centrifuge all blood specimens whether centrifugation is performed at the SPSC, at the Study Center clinic, at the participant's home, or at a satellite location.

The recommended temperature range for centrifugation is 15° C to 25° C. To document the temperature at which centrifugation is performed, each portable centrifuge will have a small thermometer affixed to the outside lid. Staff performing centrifugation procedures will record the centrifuge temperature at the time of centrifugation. It is recommended that centrifuges are not left in extreme hot or cold temperature conditions (e.g., in a car) before centrifugation.

The adult blood transport, centrifugation, and storage procedures that follow are presented in the context of three different scenarios, depending on the location where centrifugation procedures will be performed. Study Centers should follow the specific procedures as appropriate according to the centrifugation scenario that will be implemented for each study event.

## **2.3 Storage Units**

After blood specimens are receipted in Biological and Environmental Sample Tracking system (BEST) and centrifugation data are recorded, the system will designate a specific storage unit

## Adult Blood Transport, Processing, and Storage Procedures

assignment for each blood tube based on the blood tube identification number (ID). For blood specimens, a storage unit is defined as a sealable plastic pressure bag. Storage units containing specimens will be maintained in one of three conditions, depending on the blood tube type—refrigerated, frozen, or ambient temperature. Table 2-2 lists the different storage units and the types of specimens that will be stored in each.

Table 2-2. Biospecimen storage units (P1 mother, T1 mother, T1 father, T3 mother study events)

Storage Unit Name	Storage Unit Type	Designated Storage Unit Contents	Max Specimens per Storage Unit	Storage Condition	Shipping Frequency
Refrigerated Blood	Small Pressure Bag	Blood tubes	12	Refrigerated	Daily
Refrigerated Cord Blood	Small Pressure Bag	Cord blood collection bag	1	Refrigerated	Daily
Refrigerated Placenta Fresh	Large Pressure Bag	Placenta and umbilical cord specimen	1	Refrigerated	Daily
Frozen Mixed	Small Pressure Bag	(P1 Mother) <ul style="list-style-type: none"> <li>• 1 Urine collection container</li> <li>• 2 Vaginal swab vials</li> <li>• 1 3 mL lavender blood tube</li> </ul> (T1 Mother) <ul style="list-style-type: none"> <li>• 1 Urine collection container</li> <li>• 2 Vaginal swab vials</li> <li>• 1 3 mL lavender blood tube</li> </ul> (T3 Mother) <ul style="list-style-type: none"> <li>• 1 Urine collection container</li> <li>• 2 Vaginal swab vials</li> <li>• 1 PaxGene blood tube</li> </ul> (T1 Father) <ul style="list-style-type: none"> <li>• 1 Urine collection container</li> <li>• 1 3 mL lavender blood tube</li> </ul>	4	Frozen	Weekly
Frozen Meconium/Blood	Small Pressure Bag	(Birth) <ul style="list-style-type: none"> <li>• 30 mL meconium vials</li> <li>• 3 mL lavender blood tubes</li> </ul>	4 (2 meconium and 2 blood tubes)	Frozen	Weekly
Frozen Blood Cards	Ziplock Bag	Protein Saver infant blood spot cards	20	Frozen	Weekly
Frozen Breast Milk/Formula	Small Pressure Bag	<ul style="list-style-type: none"> <li>• Breast milk collection container</li> <li>• Infant formula collection vial</li> </ul>	4 (2 breast milk and 2 formula)	Frozen	Weekly
Frozen Urine	Small Pressure Bag	Pregnancy Urine collection containers	2	Frozen	Weekly

Table 2-2. Biospecimen storage units (P1 mother, T1 mother, T1 father, T3 mother study events) (continued)

<b>Storage Unit Name</b>	<b>Storage Unit Type</b>	<b>Designated Storage Unit Contents</b>	<b>Max Specimens per Storage Unit</b>	<b>Storage Condition</b>	<b>Shipping Frequency</b>
Frozen 2-Day Saliva	Small Pressure Bag	2-day saliva vials	18 (6 bags x 3 vials each)	Frozen	Weekly
Ambient Blood	Small Pressure Bag	ACD Blood tube	1	Ambient	Daily
Ambient Placenta Fixed	Large Pressure Bag	Placenta and umbilical cord specimen in formalin	1	Ambient	Daily
Ambient Blood Cards	Multi-barrier Pouch	FTA® Mini infant blood spot cards	10	Ambient	Monthly
Ambient Slides	1-Gallon Ziplock Bag	Vaginal slides	50	Ambient	Monthly
Ambient Hair	1-Gallon Ziplock Bag	Hair specimens	50	Ambient	Monthly
Ambient Nails	1-Gallon Ziplock Bag	Toenail specimens	50	Ambient	Monthly
Ambient BNC Saliva	Small Pressure Bag	BNC saliva collection containers	3	Ambient	Monthly

Note: FTA = Flinders Technology Associates

Each storage unit must be visibly labeled on the outside with a bar code label to allow for the identification and electronic tracking of the storage unit in BEST. Before storage units are available for use, they must be prepared and created in the system according to the instructions in the BEST User’s Guide. Preparation of storage units entails labeling each type of bag with a preprinted bar code label and creating the storage unit in BEST. It is recommended that the receipt technician or other SPSC staff prepare storage units in advance of receipting specimens to streamline the receipt and storage process.

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## 2.4 Scenario 1: Centrifugation at the SPSC

### 2.4.1 Transport of Blood Specimens to the SPSC

After collection, adult blood specimens will be transported in the biospecimen transport cooler to the SPSC, where they will be centrifuged and stored until being shipped daily to the repository. Depending on the type of tube, blood specimens will either be transported at refrigerated or ambient temperature. Refrigerated tubes will be transported in a plastic clamshell within an amber colored bag to protect them from light, because some potential blood analytes may degrade if exposed to light. Ambient tubes will be transported in a Styrofoam tube holder within the insulated transport bag. Table 2-3 lists the appropriate transport temperature for each blood tube by study event type, when centrifugation is performed at the SPSC.

Table 2-3. Blood tube transport temperature by study event and tube type for centrifugation at the SPSC

Study Event	Blood Tube Type	Refrigerated	Ambient
P1 Mother (6 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV10)	X	
	10 mL red top (RD10)	X	
	10 mL red top (RD11)	X	
	5 mL PPT white top (PP10)		X
	8.5 mL SST red top (SS10)		X
T1 Mother (7 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV10)	X	
	10 mL red top (RD10)	X	
	10 mL red top (RD11)	X	
	8.5 mL P100 white/red top (PN10)	X	
	5 mL PPT white top (PP10)		X
	8.5 mL SST red top (SS10)		X
T1 Father (4 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV11)	X	
	10 mL red top (RD12)	X	
	ACD (AD10)		X
T3 Mother (8 tubes)	6 mL lavender (LV10)	X	
	PaxGene (PX10)	X	
	10 mL red top (RD11)	X	
	10 mL red top (RD13)	X	
	8.5 mL P100 white/red top (PN10)	X	
	5 mL PPT white top (PP10)		X
	8.5 mL SST red top (SS10)		X
	ACD (AD10)		X
Birth Mother (4 tubes)	3 mL lavender (LP10)	X	
	10 mL red top (RD14)	X	N/A
	10 mL red top (RD15)	X	
	10 mL red top (RD16)	X	

To ensure that the appropriate temperature conditions are maintained during transport of blood specimens, the temperature of the refrigerated chamber will be recorded at the time tubes are placed in the cooler and threshold temperature monitors will be used to indicate if the temperature goes beyond the acceptable range (i.e., threshold) during transport. The refrigerated chamber temperature and threshold temperature monitors will be checked upon arrival at the SPSC. Procedures for placement of temperature threshold monitors are provided in the following sections.

The following equipment and supplies are required to transport adult blood specimens to the SPSC for centrifugation:

- Disposable laboratory coat
- Gloves
- One plastic clamshell from Adult Blood Collection Kit
- One amber transport bag from Adult Blood Collection Kit
- Blood Tube Reference Card
- Hand sanitizer
- Biospecimen transport cooler with insulated transport bag.

The *refrigerated chamber* of the cooler should contain the following:

- Four -1° C cold packs
- Digital thermometer, affixed to chamber wall
- One upper threshold (20° C) temperature monitor.

The *insulated transport bag* should contain the following:

- Styrofoam 5-tube holder
- Two lower threshold (0° C) temperature monitors
- Computer tablet with bar code scanner
- Computer keyboard cover.

The following forms are required to transport adult blood specimens to the SPSC for centrifugation:

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

Temperature 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 temperature data (see Appendices 1-B through 1-F for forms and field-by-field instructions for each study event). Once the system becomes available, data must be entered in the system from the backup form.

#### **2.4.1.1 Procedures for Preparing Blood Tubes for Transport to the SPSC**

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

The following procedures should be done immediately after collecting the blood tubes and wand them into FACE to preserve the integrity of blood specimens and prevent potential loss of analytes.

1. Place the blood tubes in the refrigerated clamshell or the ambient tube holder according to Table 2-3. Refer to the Blood Tube Reference Card found in the blood collection kit as needed.
2. Locate a lower (0° C) threshold temperature monitor and place it inside the refrigerated 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 in the refrigerated chamber until just before it is affixed to the clamshell and activated. Remove the adhesive and affix it the outside of the refrigerated clamshell (see Exhibit 2-1 for proper placement). Activate the monitor by pulling the tab.

Exhibit 2-1. Placement of threshold temperature monitors in the refrigerated clamshell



4. Immediately place the refrigerated clamshell inside an amber bag to minimize exposure of the blood tubes to light, and seal the bag.
5. Position the amber bag securely and upright within the refrigerated chamber of the transport cooler as shown in Exhibit 2-2.

Exhibit 2-2. Proper packing of the refrigerated chamber



6. Read the temperature of the refrigerated chamber of the transport cooler using the digital thermometer located inside the chamber and record the temperature in FACE. Document the status of the threshold monitors in FACE. If FACE is not available, record the temperature and monitor status on the hard copy backup Adult Blood Data Collection Form.
7. When applicable for the event type, locate a lower (0° C) threshold temperature monitor and place it inside the ambient tube holder. This monitor will be used to determine if the temperature of the tube holder falls below 0° C during transport.
8. Immediately close the lid of the tube holder to minimize exposure of the blood tubes to light.
9. Place the ambient tube holder upright in the insulated transport bag and attach the bag securely to the cooler.

10. Document the status of the threshold monitor in FACE. If FACE is not available, record the monitor status on the hard copy backup Adult Blood Data Collection Form.
11. Complete the Biospecimen Transmittal Form and place it in the zippered document pouch inside the cooler lid, if this is the last biospecimen type collected at the visit, along with any unused labels.
12. Confirm the cooler is properly closed for transport.

## **2.4.2 Receipt, Centrifugation, and Storage of Blood Specimens at the SPSC**

The following equipment and supplies are required at the SPSC to receipt, centrifuge, and store adult blood specimens:

- Laboratory coat
- Gloves
- Centrifuge(s) with thermometer affixed to outside lid
- Balance tubes
- Tube sleeves
- Small pressure bags, prelabeled
- Styrofoam 2-tube shipper with absorbent strip (ACD tubes only)
- Computer with bar code scanner.

The following form is required to receipt adult blood specimens at the SPSC:

- Completed Biospecimen Transmittal Form.

Receipt, centrifugation, and storage data will be documented in BEST. If BEST is not available, the appropriate hard copy backup Blood Receipt Form must be used to document receipt, centrifugation, and storage data (see Appendices 2-A through 2-F for forms and field-by-field instructions for each study event). In this case, because a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store each tube. Once BEST

becomes available, data must be entered into the system from the back-up form, including updating the storage unit information in BEST.

### 2.4.2.1 Procedures

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

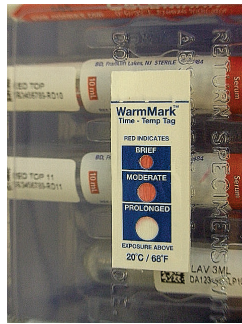
The following provides basic procedures for the receipt, centrifugation, and storage of adult blood specimens at the SPSC. Refer to the BEST User's Guide for more detailed instructions on how to use BEST when implementing these procedures. Please note that if an extra ("EX") bar code label was used at the time of collection or if the transmittal ("TM") form label will be used to receipt specimens, it will be necessary to perform contingent or stepwise receipt procedures as outlined in the BEST User's Guide.

1. Put on a lab coat and gloves.
2. Log into BEST.
3. If you have not already done so, wand the subject bar code label on the Biospecimen Transmittal Form by using the bar code scanner. Once you have accessed and confirmed the correct assignment, record the appropriate visit parameters in BEST, such as the collection date and centrifugation location.
4. Read the temperature of the refrigerated chamber of the transport cooler using the digital thermometer located inside the chamber and record the temperature (in Celsius) in BEST.
5. Retrieve the amber bag containing the refrigerated clamshell from the refrigerated chamber of the cooler.
6. Open the amber bag and remove the refrigerated clamshell. Check the upper threshold (20° C) temperature monitor on the outside of the clamshell to determine if the temperature of the clamshell went above 20° C during transport (see Exhibits 2-3 and 2-4).

Exhibit 2-3. Untriggered upper threshold temperature monitor



Exhibit 2-4. Triggered upper threshold temperature monitor



7. Check the lower threshold (0° C) temperature monitor inside both the refrigerated clamshell and the ambient tube holder to determine if the temperature went below 0° C during transport. As shown in Exhibit 2-5, a lower threshold temperature monitor that has been triggered will display a purple color (left and right monitors), whereas an untriggered monitor will remain clear (middle monitor).

Exhibit 2-5. Lower threshold temperature monitor



8. Record the threshold temperature monitor data in BEST using the “Add Event” feature.
9. Refer to Table 2-4 to determine which blood tubes require centrifugation, depending on the type of study event.

Table 2-4. Blood centrifugation specifications by study event and blood tube type

Study Event	Blood Tube Type and ID	Non-centrifuged Tubes	Centrifuge for 15 min @ 3500 RPM
P1 Mother (6 tubes)	3 mL lavender (LP10) 6 mL lavender (LV10) 10 mL red top (RD10) 10 mL red top (RD11) 5 mL PPT white top (PP10) 8.5 mL SST red top (SS10)	X X	X X X X
T1 Mother (7 tubes)	3 mL lavender (LP10) 6 mL lavender (LV10) 8.5 mL P100 white/red top (PN10) 10 mL red top (RD10) 10 mL red top (RD11) 5 mL PPT white top (PP10) 8.5 mL SST red top (SS10)	X X X	X X X X
T1 Father (4 tubes)	3 mL lavender (LP10) 6 mL lavender (LV11) ACD (AD10) 10 mL red top (RD12)	X X X	X
T3 Mother (8 tubes)	6 mL lavender (LV10) ACD (AD10) PAXgene (PX10) 8.5 mL P100 white/red top (PN10) 10 mL red top (RD11) 10 mL red top (RD13) 5 mL PPT white top (PP10) 8.5 mL SST red top (SS10)	X X X X	X X X X
Birth Mother (4 tubes)	3 mL lavender (LP10) 10 mL red top (RD14) 10 mL red top (RD15) 10 mL red top (RD16)	X	X X X

10. Prepare for centrifugation:

- a. Open the amber bag containing the refrigerated clamshell. Remove only the tubes to be centrifuged (see Table 2-4). Place the clamshell back in the amber bag and in the refrigerated chamber of the cooler or in the refrigerator.
- b. Open the ambient tube holder and remove only the tubes to be centrifuged (see Table 2-4).
- c. Before initiating centrifugation, verify that the red top tubes and SS10 tube are sufficiently clotted. If a blood tube has clotted, a large clump of cells will be visible and will adhere to the wall of the tube upon gentle inversion of the tube. It may take up to 45–60 minutes for a tube to clot completely. If a tube has not clotted within 60 minutes of the blood draw, this must be documented appropriately. An Incident Report Form must be completed and the biospecimen supervisor must be notified so that the appropriate follow-up measures can be taken. In this situation, the blood tubes should not be

- centrifuged, but a comment should be recorded in BEST and the tubes should be shipped to the repository for special handling.
- d. Wand the bar code labels on the tubes to receipt the tubes. This action automatically records the centrifugation start time.
  - e. Insert the tubes in the centrifuge and balance the tubes appropriately with balance tubes.
  - f. Close the lid securely and centrifuge for 15 minutes at 3500 RPM.
11. During centrifugation and as time allows, follow these steps to receipt and store the following types of blood tubes, as applicable for the event type. None of these blood tubes require centrifugation and can be receipted and stored without any further processing.
12. *6 mL Lavender Tubes (LV10) and P100 Tubes (PN10)*—LV10 and PN10 tubes are not centrifuged and will be stored refrigerated in a pressure bag together with all other refrigerated blood tubes from the same study visit. After centrifugation is complete, the centrifuged tubes from the same study visit will be added to this pressure bag. The pressure bag used to store the specimens in the refrigerator then will be used to ship the specimens to the repository.
- a. Retrieve the refrigerated clamshell and remove the LV10 tube and PN10 tube from the clamshell.
  - b. Wand the bar code label on the tube in BEST to receipt the tubes. This action automatically records the storage time.
  - c. BEST will assign a specific storage unit (i.e., refrigerated pressure bag) to store each tube, given that there are available storage units that have been pre-labeled and created in BEST. If no storage unit is available, follow the instructions in the BEST User's Guide to create a new storage unit. Retrieve the pressure bag designated by BEST.
  - d. Place the tubes in a tube sleeve.
  - e. Place the tube sleeve in the assigned pressure bag and place the pressure bag in the refrigerator until centrifugation is complete. Do not seal the pressure bag until the centrifuged tubes are added and the shipment is prepared. This is important because temperature threshold monitors will need to be placed inside the pressure bag before shipping. For shipping procedures for refrigerated specimens, see Chapter 2 of Part 5 in this volume.
13. *3 mL Lavender Tubes (LP10) and PAXgene Tubes (PX10)*—LP10 and PX10 tubes are not centrifuged and will be stored frozen in a pressure bag together with frozen urine and frozen vaginal swab specimens from the same study visit. The pressure bag

used to store the specimens in the freezer then will be used to ship the specimens to the repository.

- a. Retrieve the refrigerated clamshell and remove the LP10 tube from the clamshell.
  - b. Wand the bar code label on the tube in BEST to receipt the tube. This action automatically records the storage time.
  - c. BEST will assign a specific storage unit (i.e., frozen pressure bag) to store the 3 mL lavender blood tube, given that there are available storage units that have been prelabeled and created in BEST. If no storage unit is available, follow the instructions in the BEST User's Guide to create a new storage unit. Retrieve the pressure bag designated by BEST.
  - d. Place the tube in the tube sleeve.
  - e. Place the tube sleeve in the assigned pressure bag. Do not seal the pressure bag until the shipment is prepared.
  - f. Store the pressure bag *on its side* in the freezer storage bin. Confirm the master storage unit location (i.e., upper or lower freezer compartment) in BEST. If the location is not accurate, update the storage location information.
  - g. The pressure bag should be stored on its side until the 3 mL lavender tube is frozen to reduce the possibility of tube breakage. Once the 3 mL lavender tube is frozen, the pressure bag may be placed in an upright position and should be kept frozen until the shipment to the repository is prepared. For shipping procedures for frozen specimens, see Chapter 3 of Part 5 in this volume.
14. *ACD Tubes (AD10)*—AD10 tubes are not centrifuged and will be stored ambient in a pressure bag. The pressure bag used to store the specimen then will be used to ship the specimen to the repository.
- a. Retrieve the ambient tube holder and remove the AD10 tube.
  - b. Wand the bar code label on the tube in BEST to receipt the tube. This action automatically records the storage time.
  - c. BEST will assign a specific storage unit (i.e., ambient pressure bag) to store the ACD blood tube, given that there are available storage units that have been prelabeled and created in BEST. If no storage unit is available, follow the instructions in the BEST User's Guide to create a new storage unit. Retrieve the pressure bag designated by BEST.
  - d. Place the tube in a Styrofoam 2-tube shipper and close the lid.

- e. Place the 2-tube shipper in the assigned pressure bag along with an absorbent strip. Do not seal the pressure bag until the shipment is prepared.
  - f. Keep the pressure bag at ambient temperature until the shipment to the repository is prepared. For shipping procedures for ambient blood tube specimens, see Chapter 3 of Part 5 in this volume.
15. During centrifugation and as time allows, the biospecimen receipt and storage procedures in Part 3 of this volume may be performed to receipt and store the other biospecimen types collected at the study visit. *As soon as centrifugation is complete, however, blood tubes must be removed from the centrifuge and stored immediately at the appropriate temperatures.* If centrifugation is complete before the non-blood biospecimens can be receipted and stored, perform Step 16 before continuing with receipt and storage procedures for non-blood biospecimens.
16. When centrifugation is complete, do the following:
- a. When the centrifuge stops, open the lid and remove each tube carefully.
  - b. Select all the tubes from this spin (identified as Spin B in BEST) by checking the box next to each tube ID, and click “⊕” next to any selected tube to open the Results window. This action automatically records the centrifugation end time for all the selected tubes. Record the result as “Complete.”
  - c. Read the centrifuge temperature using the thermometer on the outside lid and enter the temperature in the Results window. This will record the temperature for all selected tubes.
  - d. Inspect each tube for hemolysis. Enter the status of the tubes in the Item Modifier field as “OK.” If one or more of the tubes is hemolyzed, after exiting the Result window, click “⊕” next to the hemolyzed tube to update the status for that tube.
  - e. Click “Save” to save the data entered in the Results window.
  - f. Wand the bar code label on each tube to obtain the storage unit assignment. This automatically records the storage time. BEST will assign a specific storage unit (i.e., refrigerated pressure bag) to store each blood tube, given that there are available storage units that have been prelabeled and created in BEST. If no storage unit is available, follow the instructions in the BEST User’s Guide to create a new storage unit. Retrieve the pressure bag designated by BEST.
  - g. Place the tubes in the tube sleeve.
  - h. Immediately place the tube sleeve inside the amber bag, seal the amber bag, and place it in the assigned pressure bag. Do not seal the pressure bag until the shipment to the repository is prepared. This is important because temperature

threshold monitors will need to be placed inside the pressure bag before shipping.

- i. Store the pressure bag in an upright position in the refrigerator storage bin until the shipment to the repository is prepared. For shipping procedures for refrigerated specimens, see Chapter 2 of Part 5 in this volume.

If the hard copy backup Blood Receipt Form was used to document receipt, centrifugation, and storage of adult blood specimens, the required data must be entered by the biospecimen receipt technician once BEST is available. This includes entering information concerning the storage unit and storage location.

## 2.5 Scenario 2: Centrifugation at a Satellite Location

### 2.5.1 Transport of Blood Specimens to a Satellite Location

After collection, adult blood specimens will be transported in the biospecimen transport cooler to a satellite location, where they will be centrifuged. Depending on the type of tube, blood specimens will be transported either at refrigerated or ambient temperature. Refrigerated tubes will be transported in a plastic clamshell within an amber colored bag to protect them from light, because some potential blood analytes may degrade if exposed to light. Ambient tubes will be transported in a Styrofoam tube holder within the insulated transport bag. After centrifugation at the satellite location, all centrifuged blood tubes will be transported at refrigerated temperature to the SPSC, where they will be stored until being shipped daily to the NCS repository.

To ensure that the appropriate temperature conditions are maintained during transport of blood specimens, the temperature of the refrigerated chamber will be recorded at the time tubes are placed in the cooler at the collection location and threshold temperature monitors will be used to indicate if the temperature went beyond the acceptable range (i.e., threshold) during transport. The refrigerated chamber temperature and threshold temperature monitors will be checked upon arrival at the SPSC (not at the satellite location). Procedures for placement of temperature threshold monitors are provided in this section.

Table 2-5 lists the appropriate transport temperature for each blood tube by study event, when blood specimens are centrifuged at a satellite location. These transport conditions apply only to transport from the point of collection to the satellite location, prior to centrifugation.

The following equipment and supplies are required to transport adult blood specimens to a satellite location for centrifugation:

- Disposable laboratory coat
- Gloves
- One plastic clamshell from Adult Blood Collection Kit
- One amber transport bag from Adult Blood Collection Kit
- Blood Tube Reference Card

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

Table 2-5. Pre-centrifugation blood tube transport temperature by study event and tube type for centrifugation at a satellite location

Study Event	Blood Tube Type	Refrigerated	Ambient
P1 Mother (6 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV10)	X	
	10 mL red top (RD10)	X	
	10 mL red top (RD11)	X	
	5 mL PPT white top (PP10)		X
	8.5 mL SST red top (SS10)		X
T1 Mother (7 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV10)	X	
	10 mL red top (RD10)	X	
	10 mL red top (RD11)	X	
	8.5 mL P100 white/red top (PN10)	X	
	5 mL PPT white top (PP10)		X
8.5 mL SST red top (SS10)		X	
T1 Father (4 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV11)	X	
	10 mL red top (RD12)	X	
	ACD (AD10)		X
T3 Mother (8 tubes)	6 mL lavender (LV10)	X	
	PAXgene (PX10)	X	
	10 mL red top (RD11)	X	
	10 mL red top (RD13)	X	
	8.5 mL P100 white/red top (PN10)	X	
	5 mL PPT white top (PP10)		X
	8.5 mL SST red top (SS10)		X
ACD (AD10)		X	
Birth Mother (4 tubes)	3 mL lavender (LP10)	X	
	10 mL red top (RD14)	X	
	10 mL red top (RD15)	X	
	10 mL red top (RD16)	X	

The *refrigerated chamber* of the cooler should contain the following:

- Four -1° C cold packs
- Digital thermometer, affixed to chamber wall
- One upper threshold (20° C) temperature monitor.

The *insulated transport bag* should contain the following:

- Styrofoam 5-tube holder; and
- Two lower threshold (0° C) temperature monitors.

The following form is required to transport adult blood specimens to a satellite location for centrifugation:

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

Temperature 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 temperature data (see Appendices 1-B through 1-F for forms and field-by-field instructions for each study event). Once the system becomes available, data must be entered in the system from the backup form.

### **2.5.1.1 Preparing Blood Tubes for Transport to a Satellite Location**

The following procedures should be done *immediately after* collecting the blood tubes and wand them in to FACE to preserve the integrity of blood specimens and prevent potential loss of analytes:

1. Place the blood tubes in the refrigerated clamshell or the ambient tube holder according to Table 2-5. Refer to the Blood Tube Reference Card found in the blood collection kit as needed.
2. Locate a lower (0° C) threshold temperature monitor and place it inside the refrigerated 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 in the refrigerated chamber until just before it is affixed to the clamshell and activated. Remove the adhesive and affix it the outside of the refrigerated clamshell (see Exhibit 2-6 for proper placement). Activate the monitor by pulling the tab.

Exhibit 2-6. Placement of threshold temperature monitors in the refrigerated clamshell



4. Immediately place the refrigerated clamshell inside an amber bag to minimize exposure of the blood tubes to light, and seal the bag.
5. Position the amber bag securely and upright within the refrigerated chamber of the transport cooler as shown in Exhibit 2-7.

Exhibit 2-7. Proper packing of the refrigerated chamber



6. Read the temperature of the refrigerated chamber of the transport cooler using the digital thermometer located inside the chamber, and record the temperature in FACE. Document the status of the threshold monitors in FACE.
7. When applicable for the event type, locate a lower (0° C) threshold temperature monitor and place it inside the ambient tube holder. This monitor will be used to determine if the temperature of the tube holder falls below 0° C during transport.
8. Immediately close the lid of the tube holder to minimize exposure of the blood tubes to light.

9. Place the ambient tube holder upright in the insulated transport bag and attach the bag securely to the transport cooler.
10. Document the status of the threshold monitor in FACE.
11. If this is the last biospecimen type collected at the visit, complete the Biospecimen Transmittal Form and place it in the zippered document pouch inside the cooler lid along with any unused labels.
12. Confirm the cooler is properly closed for transport.

## 2.5.2 Centrifugation of Blood Specimens at a Satellite Location

The following equipment and supplies are required at a satellite location to centrifuge adult blood specimens:

- Disposable laboratory coat
- Gloves
- Centrifuge with thermometer affixed to outside lid
- Balance tubes
- Bleach wipes
- Hand sanitizer
- Biohazard waste bag.

The following form is required to centrifuge adult blood specimens at a satellite location:

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

### 2.5.2.1 Centrifugation Procedures

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

1. Put on a lab coat and gloves.

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2. Identify a suitable flat surface to perform the centrifugation.
3. Place a chux pad on the flat surface and place the centrifuge on the chux pad. Make sure the centrifuge is level.
4. Plug the centrifuge into an electrical outlet. Remove the transport protective sponge from around the rotor.
5. Refer to Table 2-6 to determine which blood tubes require centrifugation, depending on the type of study event.

Table 2-6. Blood centrifugation specifications by study event and blood tube type

Study Event	Blood Tube Type and ID	Non-centrifuged Tubes	Centrifuge for 15 min @ 3500 RPM
P1 Mother (6 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV10)	X	
	10 mL red top (RD10)		X
	10 mL red top (RD11)		X
	5 mL PPT white top (PP10)		X
	8.5 mL SST red top (SS10)		X
T1 Mother (7 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV10)	X	
	8.5 mL P100 white/red top (PN10)	X	
	10 mL red top (RD10)		X
	10 mL red top (RD11)		X
	5 mL PPT white top (PP10)		X
	8.5 mL SST red top (SS10)		X
T1 Father (4 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV11)	X	
	ACD (AD10)	X	
	10 mL red top (RD12)		X
T3 Mother (8 tubes)	6 mL lavender (LV10)	X	
	ACD (AD10)	X	
	PAXgene (PX10)	X	
	8.5 mL P100 white/red top (PN10)	X	
	10 mL red top (RD11)		X
	10 mL red top (RD13)		X
	5 mL PPT white top (PP10)		X
	8.5 mL SST red top (SS10)		X
Birth Mother (4 tubes)	3 mL lavender (LP10)	X	
	10 mL red top (RD14)		X
	10 mL red top (RD15)		X
	10 mL red top (RD16)		X

6. Prepare for centrifugation:
  - a. Open the ambient tube holder and remove the tubes to be centrifuged (see Table 2-6).

- b. Before initiating centrifugation, verify that the red top tubes and SS10 tube are sufficiently clotted. If a blood tube has clotted, a large clump of cells will be visible and will adhere to the wall of the tube upon gentle inversion of the tube. It may take up to 45–60 minutes for a tube to clot completely. If a tube has not clotted within 60 minutes of the blood draw, this should be documented appropriately. An Incident Report Form should be completed and the biospecimen supervisor should be notified so that the appropriate follow-up measures can be taken. In this situation, the blood tubes should not be centrifuged and should be transported to the SPSC. These tubes will be shipped to the Repository for special handling.
7. *Perform centrifugation:*
  - a. Insert the tubes in the centrifuge and balance the tubes appropriately with balance tubes.
  - b. Close the lid securely and centrifuge for 15 minutes at 3500 RPM.
8. After starting the centrifuge, read the centrifuge temperature on the centrifuge lid and record the temperature and centrifugation start time in Part C of the Biospecimen Transmittal Form.
9. When centrifugation is complete, do the following:
  - a. When the centrifuge stops, open the lid and carefully remove each tube.
  - b. Remove the amber bag from the refrigerated chamber and immediately place the centrifuged tubes in the refrigerated clamshell. If necessary for the event type, use a second refrigerated clamshell.
  - c. Place the clamshell inside the amber bag. If there are two clamshells, place each clamshell inside a separate amber bag. Place the bags in an upright position in the refrigerated chamber of the cooler.

### 2.5.2.2 Clean-Up Procedures

1. After completing the centrifugation procedures, unplug the centrifuge.
2. Clean the outside of the centrifuge with a bleach wipe. Any spills on the inside should be cleaned appropriately.
3. Insert the transport protective sponge around the rotor so that it fits snugly between the rotor and the chamber.
4. Discard the chux and any additional items in the biohazard waste bag.

5. After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer.

If a blood tube breaks during centrifugation at a satellite location, close the centrifuge lid securely, unplug the centrifuge, and place the entire unit in an empty biohazard waste bag. Tie the biohazard waste bag closed and do not open the bag or attempt to remove the broken blood tube from the centrifuge until it has been transported safely to the SPSC. If a balance tube breaks during centrifugation, remove the blood tubes and place them in the refrigerated clamshell inside an amber bag. Place the bag in the refrigerated chamber of the transport cooler. Do not attempt to remove the broken balance tube from the centrifuge until it has been transported safely to the SPSC.

If an incident occurs while performing centrifugation in the field, a brief description of the incident should be recorded on the Biospecimen Transmittal Form, including a notation of which tubes were broken if applicable. An Incident Report Form must be completed and the incident reported to the biospecimen supervisor. Refer to Part 9 of Volume 9 for documentation of safety incidents.

### **2.5.3 Transport of Blood Specimens to the SPSC After Centrifugation**

After centrifugation, adult blood specimens will be transported in the biospecimen transport cooler from the satellite location to the SPSC, where they will be stored until being shipped daily to the repository. All centrifuged blood specimens will be transported to the SPSC at a refrigerated temperature. Refrigerated tubes will be transported in a plastic clamshell within an amber colored bag to protect them from light, because some potential blood analytes may degrade if exposed to light. If an ACD tube was collected at the visit (T1 father and T3 mother only), this tube will be transported in a Styrofoam tube holder within the insulated transport bag.

1. Ensure that all centrifuged blood tubes are in the refrigerated chamber of the transport cooler as shown in Exhibit 2-8.

Exhibit 2-8. Proper packing of the refrigerated chamber



2. Ensure that Part C of the appropriate Biospecimen Transmittal Form is completed and place the form in the zippered document pouch inside the lid of the refrigerated chamber.
3. Confirm the cooler is properly closed for transport.

#### 2.5.4 Receipt and Storage of Blood Specimens at the SPSC

The following equipment and supplies are required at the SPSC to receipt and store adult blood specimens:

- Laboratory coat
- Gloves
- Tube sleeve
- Small pressure bags, prelabeled
- Styrofoam 2-tube shipper with absorbent strip (ACD tubes only)
- Computer with bar code scanner.

The following form is required to receipt adult blood specimens at the SPSC:

- Completed Biospecimen Transmittal Form.

Receipt and storage data will be documented in BEST. If BEST is not available, the appropriate hard copy backup Blood Receipt Form must be used to document receipt and storage data (see

Appendices 2-A through 2-F for forms and field-by-field instructions for each study event). In this case, because a storage unit assignment cannot be made by BEST, available pre-labeled storage units should be selected to store each tube. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST.

### 2.5.4.1 Procedures

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

The following provides basic procedures for the receipt and storage of adult blood specimens. Refer to the BEST User's Guide for more detailed instructions on how to use BEST when implementing these procedures. Please note that if an extra ("EX") bar code label was used at the time of collection or if the transmittal ("TM") form label will be used to receipt specimens, it will be necessary to perform contingent or stepwise receipt procedures as outlined in the BEST User's Guide.

1. Put on a lab coat and gloves.
2. Log into BEST.
3. If you have not already done so, wand the subject bar code label on the Biospecimen Transmittal Form using the bar code scanner. Once you have accessed and confirmed the correct assignment, record the appropriate visit parameters in BEST, such as the collection date and centrifugation location.
4. Read the temperature of the refrigerated chamber of the transport cooler using the digital thermometer located inside the chamber and record the temperature (in Celsius) in BEST.
5. Retrieve the amber bags containing the refrigerated clamshells from the refrigerated chamber of the cooler.
6. Check the upper (20° C) threshold temperature monitor on the refrigerated clamshell to determine if the temperature went above 20° C during transport (see Exhibits 2-9 and 2-10). Only one refrigerated clamshell will contain the threshold monitors.

Exhibit 2-9. Untriggered upper threshold temperature monitor



Exhibit 2-10. Triggered upper threshold temperature monitor



7. Check the lower (0° C) threshold temperature monitor in the refrigerated clamshell to determine if the temperature went below 0° C during transport. As shown in Exhibit 2-11, a lower threshold temperature monitor that has been triggered will display a bright purple color (left and right monitors), whereas an untriggered monitor will remain clear (middle monitor).

Exhibit 2-11. Lower threshold temperature monitor



8. Record the threshold temperature monitor data in BEST using the “Add Event” feature.
9. Follow these steps to receipt and store the following types of blood tubes as applicable for the event type.

*All Centrifuged Tubes (RD10, RD11, PP10, SS10), uncentrifuged P100 Tubes (PN10), and uncentrifuged 6 mL Lavender Tubes (LV10)*—All centrifuged blood tubes, P100 tubes, and 6 mL lavender tubes collected at one study visit will be stored together in one refrigerated pressure bag. The pressure bag used to store the specimens in the refrigerator then will be used to ship the specimens to the repository.

- a. Retrieve the refrigerated clamshells from the transport cooler.
- b. One at a time, remove each tube (except the LP10 tube) from the refrigerated clamshells and wand the bar code label on each tube in BEST to receipt each tube.
- c. Select all the tubes from this spin (identified as Spin B in BEST), then click “⊕” next to any selected tube to open the Results window. This action automatically records the centrifugation end time for all the selected tubes. Record the result as “Complete.”
- d. Enter the centrifugation start time from the Biospecimen Transmittal Form. This action automatically records the centrifugation start time for all the selected tubes.
- e. Enter the centrifuge temperature from the Biospecimen Transmittal Form. This action automatically records the centrifugation temperature for all the selected tubes.
- f. Inspect each tube for hemolysis. Enter the status of the tubes in the Item Modifier field as “OK.” If one or more of the tubes is hemolyzed, click “⊕” next to the hemolyzed tube after exiting the Result window to update the status for that tube.
- g. Click “Save” to save the data entered in the Results window.
- h. Wand the bar code label on each tube to obtain the storage unit assignment. This automatically records the storage time. BEST will assign a specific storage unit (i.e., refrigerated pressure bag) to store each blood tube, given that there are available storage units that have been prelabeled and created in BEST. If no storage unit is available, follow the instructions in the BEST User’s Guide to create a new storage unit. Retrieve the pressure bag designated by BEST.
- i. Place all the tubes in one tube sleeve.
- j. Immediately place the tube sleeve in an amber bag and seal the bag. Place the amber bag in the assigned pressure bag. Do not seal the pressure bag until the time the shipment is prepared. This is important because temperature threshold monitors will need to be placed inside the pressure bag before shipping. The pressure bag should be kept refrigerated until the shipment to the repository is

prepared. For shipping procedures for refrigerated specimens, see Chapter 2 of Part 5 in this volume.

*3 mL Lavender Tubes (LP10) and PAXgene Tubes (PX10)*—LP10 and PX10 tubes are not centrifuged and will be stored frozen in a pressure bag together with frozen urine and frozen vaginal swab specimens from one study visit. The pressure bag used to store the specimens in the freezer then will be used to ship the specimens to the repository.

- a. Retrieve the refrigerated clamshell and remove the LP10 tube from the clamshell.
- b. Wand the bar code label on the tube in BEST to receipt the tube. This action automatically records the storage time.
- c. BEST will assign a specific storage unit (i.e., frozen pressure bag) to store the 3 mL lavender blood tube, given that there are available storage units that have been prelabeled and created in BEST. If no storage unit is available, follow the instructions in the BEST User's Guide to create a new storage unit. Retrieve the pressure bag designated by BEST.
- d. Place the tube in the tube sleeve.
- e. Place the tube sleeve in the assigned pressure bag. Do not seal the pressure bag until the shipment is prepared.
- f. Store the pressure bag *on its side* in the freezer storage bin. Confirm the master storage unit location (i.e., upper or lower freezer compartment) in BEST. If the location is not accurate, update the storage location information.
- g. The pressure bag should be stored on its side until the 3 mL lavender tube is frozen to reduce the possibility of tube breakage. Once the 3 mL lavender tube is frozen, the pressure bag may be placed in an upright position and should be kept frozen until the shipment to the repository is prepared. For shipping procedures for frozen specimens, see Chapter 3 of Part 5 in this volume.

*ACD Tubes (AD10)*—AD10 tubes are not centrifuged and will be stored ambient in a pressure bag. The pressure bag used to store the specimen then will be used to ship the specimen to the repository.

- a. Retrieve the ambient tube holder and remove the AD10 tube.
- b. Wand the bar code label on the tube in BEST to receipt the tube. This action automatically records the storage time.
- c. BEST will assign a specific storage unit (i.e., ambient pressure bag) to store the ACD blood tube, given that there are available storage units that have been prelabeled and created in BEST. If no storage unit is available, follow the

- instructions in the BEST User's Guide to create a new storage unit. Retrieve the pressure bag designated by BEST.
- d. Place the tube in a Styrofoam 2-tube shipper and close the lid.
  - e. Place the 2-tube shipper in the assigned pressure bag along with an absorbent strip. Do not seal the pressure bag until the shipment is prepared.
  - f. Keep the pressure bag at ambient temperature until the shipment to the repository is prepared. For shipping procedures for ambient blood tube specimens, see Chapter 3 of Part 5 in this volume.
10. After completing the receipt and storage procedures for blood specimens, complete the biospecimen receipt and storage procedures in Part 3 of this volume to receipt and store the other biospecimen types collected at the study visit.

## 2.6 Scenario 3: Centrifugation at the Home

### 2.6.1 Centrifugation of Blood Specimens at a Participant's Home

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

The following equipment and supplies are required to perform centrifugation at the home:

- Disposable laboratory coat
- Gloves
- Centrifuge with thermometer affixed to outside lid
- Balance tubes
- Chux pad
- Bleach wipes
- Hand sanitizer
- Biohazard waste bag.

The following form is required to perform centrifugation at the home:

- Completed Biospecimen Transmittal Form (see volume Appendices VIII-B through VIII-K for forms and field-by-field instructions for each study event).

It is recommended that the data collector sets up the centrifuge prior to the blood draw so that tubes may be spun immediately after collection. It also is recommended that the data collector place the blood tubes inside an amber bag immediately after wandng the tubes into FACE. This will protect them from exposure to light while preparing for centrifugation.

#### 2.6.1.1 Procedures

1. Put on a lab coat and gloves.
2. Identify a suitable flat surface to perform the centrifugation.

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3. Place a chux pad on the flat surface and place the centrifuge on the chux pad. Make sure the centrifuge is level.
4. Plug the centrifuge into an electrical outlet, being careful not to overload the electrical outlet. Ask for permission from the participant before unplugging any household appliances. Remove the transport protective sponge from around the rotor.
5. Refer to Table 2-7 to determine which blood tubes require centrifugation, depending on the type of study event.

*Note:* It will be necessary to wait at least 30 minutes for the SS10 and the red top tubes to clot before initiating centrifugation. It may take up to 45–60 minutes for a tube to clot completely. Proceed to Step 6 to place tubes at the appropriate temperatures until centrifugation can be initiated.

Table 2-7. Blood centrifugation specifications by study event and blood tube type

Study Event	Blood Tube Type and ID	Non-centrifuged Tubes	Centrifuge for 15 min @ 3500 RPM
P1 Mother (6 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV10)	X	
	10 mL red top (RD10)		X
	10 mL red top (RD11)		X
	5 mL PPT white top (PP10)		X
	8.5 mL SST red top (SS10)		X
T1 Mother (7 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV10)	X	
	8.5 mL P100 white/red top (PN10)	X	
	10 mL red top (RD10)		X
	10 mL red top (RD11)		X
	5 mL PPT white top (PP10)		X
8.5 mL SST red top (SS10)		X	
T1 Father (4 tubes)	3 mL lavender (LP10)	X	
	6 mL lavender (LV11)	X	
	ACD (AD10)	X	
	10 mL red top (RD12)		X
T3 Mother (8 tubes)	6 mL lavender (LV10)	X	
	ACD (AD10)	X	
	PAXgene (PX10)	X	
	8.5 mL P100 white/red top (PN10)	X	
	10 mL red top (RD11)		X
	10 mL red top (RD13)		X
	5 mL PPT white top (PP10)		X
8.5 mL SST red top (SS10)		X	
Birth Mother (4 tubes)	3 mL lavender (LP10)	X	
	10 mL red top (RD14)		X
	10 mL red top (RD15)		X
	10 mL red top (RD16)		X

6. Place the following types of blood tubes in the refrigerated clamshell. These tubes will not be centrifuged:
  - Lavender top tubes (LP10, LV10)
  - P100 tube (PN10).
7. Place the following types of blood tubes in the refrigerated clamshell. These tubes must be kept cold while clotting:
  - Red top tubes (RD10, RD11).
8. Immediately place the refrigerated clamshell inside an amber bag to minimize exposure of the blood tubes to light.
9. Position the amber bag securely in the refrigerated chamber within the transport cooler. It is recommended that the red top tubes be placed in an upright position while clotting.
10. The PP10 and SS10 tubes should be kept at ambient temperature before centrifugation. Place these tubes in the ambient tube holder until centrifugation is initiated. It will be necessary to wait at least 30 minutes for the SS10 tube to clot before initiating centrifugation. It may take up to 45–60 minutes for a tube to clot completely. It is recommended that the tubes be placed in an upright position while clotting.
11. Proceed with other biospecimen collection activities until the red top tubes and the SS10 tube have been given at least 30 minutes to clot.
12. After the red top tubes and the SS10 tube have been given 30 minutes to clot, prepare for centrifugation:
  - a. Remove the tubes to be centrifuged from the refrigerated clamshell (see Table 2-7). Place the clamshell back inside the amber bag and place the bag in the refrigerated chamber of the cooler.
  - b. Before initiating centrifugation, verify that the red top tubes and SS10 tube are sufficiently clotted. If a blood tube has clotted, a large clump of cells will be visible and will adhere to the wall of the tube upon gentle inversion of the tube. It may take up to 45–60 minutes for a tube to clot completely. If a tube has not clotted within 60 minutes of the blood draw, this should be documented appropriately. An Incident Report Form should be completed and the biospecimen supervisor should be notified so that the appropriate follow up measures can be taken. In this situation, the blood tubes should not be centrifuged and should be transported to the SPSC. These tubes will be shipped to the repository for special handling.

13. *Perform Centrifugation:*
  - a. Insert the tubes in the centrifuge and balance the tube/s appropriately with balance tubes.
  - b. Close the lid securely and centrifuge for 15 minutes at 3500 RPM.
  - c. After starting the centrifuge, read the centrifuge temperature on the centrifuge lid and record the temperature and centrifugation start time in Part C of the Biospecimen Transmittal Form.
14. Proceed with other biospecimen collection activities until centrifugation is complete.
15. When centrifugation is complete, do the following:
  - a. When the centrifuge stops, open the lid and carefully remove each tube.
  - b. Remove the amber bag from the refrigerated chamber and place the centrifuged tubes in the refrigerated clamshell. If necessary, use a second refrigerated clamshell.
16. Locate a lower (0° C) threshold temperature monitor and place it inside the refrigerated clamshell. This monitor will be used to determine if the temperature of the clamshell falls below 0° C during transport. If two clamshells are needed, it is only necessary to place threshold monitors in one clamshell.
17. Locate the upper (20° C) threshold temperature monitor in the refrigerated chamber. The monitor should remain in the refrigerated chamber until just before it is affixed to the clamshell and activated. Remove the adhesive and affix it the outside of the refrigerated clamshell (see Exhibit 2-12 for proper placement). Activate the monitor by pulling the tab.

Exhibit 2-12. Placement of threshold temperature monitors in the refrigerated clamshell



18. Immediately place the refrigerated clamshells inside an amber bag to minimize exposure of the blood tubes to light, and seal the bag.
19. Position the amber bag securely and upright within the refrigerated chamber of the transport cooler.

20. Read the temperature of the refrigerated chamber of the transport cooler using the digital thermometer located inside the chamber, and record the temperature in FACE. Document the status of the threshold monitors in FACE.
21. If this is the last biospecimen type collected at the visit, complete the Biospecimen Transmittal Form and place it in the zippered document pouch inside the cooler lid along with any unused labels.
22. Confirm the cooler is properly closed for transport.

### **2.6.1.2 Clean-Up Procedures**

1. After completing the centrifugation procedures, unplug the centrifuge. If any household appliances were unplugged, be sure to plug them back in.
2. Clean the outside of the centrifuge with a bleach wipe. Any spills on the inside should be cleaned appropriately. More extensive cleaning should be performed at the SPSC.
3. Insert the transport protective sponge around the rotor so that it fits snugly between the rotor and the chamber.
4. Discard the chux and any additional items in the biohazard waste bag.
5. After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer.

If a blood tube breaks during centrifugation at a participant's home, close the centrifuge lid securely, unplug the centrifuge, and place the entire unit in an empty biohazard waste bag. Tie the biohazard waste bag closed and do not open the bag or attempt to remove the broken blood tube from the centrifuge until it has been transported safely to the SPSC. If a balance tube breaks during centrifugation, remove the blood tubes and place them in the refrigerated clamshell inside an amber bag. Place the bag in the refrigerated chamber of the transport cooler. Do not attempt to remove the broken balance tube from the centrifuge until it has been transported safely to the SPSC.

If an incident occurs while performing centrifugation in the field, a brief description of the incident should be recorded on the Biospecimen Transmittal Form, including a notation of which tubes were broken if applicable. An Incident Report Form must be completed and the incident reported to the biospecimen supervisor. Refer to Part 9 of Volume I for documentation of safety incidents.

## 2.6.2 Transport of Blood Specimens to the SPSC After Centrifugation

After centrifugation, adult blood specimens will be transported in the biospecimen transport cooler from the participant's home to the SPSC, where they will be stored until being shipped daily to the NCS repository. All centrifuged blood specimens will be transported to the SPSC at a refrigerated temperature. Refrigerated tubes will be transported in a plastic clamshell within an amber colored bag to protect them from light, because some potential blood analytes may degrade if exposed to light. If an ACD tube was collected at the visit (T1 father and T3 mother only), this tube will be transported in a Styrofoam tube holder within the insulated transport bag.

1. Ensure that all centrifuged and non-centrifuged blood tubes (except the ACD tube if collected) are in the refrigerated chamber of the transport cooler. For some visits, two clamshells will be needed to transport the refrigerated tubes. The only tube that will be transported ambient in the insulated transport bag is the ACD tube, if it was collected.
2. Ensure that Part C of the appropriate Biospecimen Transmittal Form is completed and place the form in the zippered document pouch inside the lid of the refrigerated chamber.
3. Confirm the cooler is properly closed for transport.

## 2.6.3 Receipt and Storage Procedures at the SPSC

The following equipment and supplies are required at the SPSC to receipt and store adult blood specimens:

- Laboratory coat
- Gloves
- Tube sleeve
- Small pressure bags, pre-labeled
- Styrofoam 2-tube shipper with absorbent strip (ACD tubes only)
- Computer with bar code scanner.

The following form is required to receipt adult blood specimens at the SPSC:

- Completed Biospecimen Transmittal Form

Receipt and storage data will be documented in BEST. If BEST is not available, then the appropriate hard copy backup Blood Receipt Form must be used to document receipt and storage data (see Appendices 2-A through 2-F for forms and field-by-field instructions for each study event). In this case, because a storage unit assignment cannot be made by BEST, available prelabeled storage units should be selected to store each tube. Once BEST becomes available, data must be entered in the system from the backup form, including updating the storage unit information in BEST.

### **2.6.3.1 Procedures**

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

The following provides basic procedures for the receipt and storage of adult blood specimens. Refer to the BEST User's Guide for more detailed instructions on how to use BEST when implementing these procedures. Please note that if an extra ("EX") bar code label was used at the time of collection or if the transmittal ("TM") form label will be used to receipt specimens, it will be necessary to perform contingent or stepwise receipt procedures as outlined in the BEST User's Guide.

1. Put on a lab coat and gloves.
2. Log into BEST.
3. If you have not already done so, wand the subject bar code label on the Biospecimen Transmittal Form by using the bar code scanner. Record the appropriate visit parameters in BEST, such as centrifugation location and data collector ID.
4. Read the temperature of the refrigerated chamber of the transport cooler using the digital thermometer located inside the chamber and record the temperature (in Celsius) in BEST.
5. Retrieve the amber bags containing the refrigerated clamshells from the refrigerated chamber of the cooler.

6. Check the upper (20° C) threshold temperature monitor on the refrigerated clamshell to determine if the temperature went above 20° C during transport (see Exhibits 2-13 and 2-14). Only one refrigerated clamshell will contain the threshold monitors.

Exhibit 2-13. Untriggered upper threshold temperature monitor



Exhibit 2-14. Triggered upper threshold temperature monitor



7. Check the lower (0° C) threshold temperature monitor in the refrigerated clamshell to determine if the temperature went below 0° C during transport. As shown in Exhibit 2-15, a lower threshold temperature monitor that has been triggered will display a bright purple color (left and right monitors), whereas an untriggered monitor will remain clear (middle monitor).

Exhibit 2-15. Lower threshold temperature monitor



8. Record the threshold temperature monitor data in BEST using the “Add Event” feature.
9. Follow these steps to receipt and store the following types of blood tubes as applicable for the event type.

*All Centrifuged Tubes (RD10, RD11, PP10, SS10), uncentrifuged P100 Tubes (PN10), and 6 mL Lavender Tubes (LV10)*—All centrifuged blood tubes, P100 tubes, and 6 mL lavender tubes collected from the same study participant at one study visit will be stored together in one refrigerated pressure bag. The pressure bag used to store the specimens in the refrigerator then will be used to ship the specimens daily to the NCS repository.

- a. Retrieve the refrigerated clamshells from the transport cooler.
- b. Remove each tube (except the LP10 tube) one at a time from the refrigerated clamshell/s and wand the bar code label on each tube in BEST to receipt each tube and to document the storage time.
- c. Select all the tubes from this spin (identified as Spin B in BEST), then click “⊕” next to any selected tube to open the Results window. This action automatically records the centrifugation end time for all the selected tubes. Record the result as “Complete.”
- d. Enter the centrifugation start time from the Biospecimen Transmittal Form. This action automatically records the centrifugation start time for all the selected tubes.
- e. Enter the centrifuge temperature from the Biospecimen Transmittal Form. This action automatically records the centrifugation temperature for all the selected tubes.
- f. Inspect each tube for hemolysis. Enter the status of the tubes in the Item Modifier field as “OK.” If one or more of the tubes is hemolyzed, click “⊕” next to the hemolyzed tube after exiting the Result window to update the status for that tube.
- g. Click “Save” to save the data entered in the Results window.
- h. Wand the bar code label on each tube to obtain the storage unit assignment. This automatically records the storage time. BEST will assign a specific storage unit (i.e., refrigerated pressure bag) to store the tubes, given that there are available storage units that have been pre-labeled and created in BEST. If no storage unit is available, follow the instructions in the BEST User’s Guide to create a new storage unit. Retrieve the pressure bag designated by BEST.
- i. Place all the tubes in one tube sleeve.
- j. Immediately place the tube sleeve in an amber bag and seal the bag. Place the amber bag in the assigned pressure bag. Do not seal the pressure bag until the time the shipment is prepared. This is important because temperature threshold monitors will need to be placed inside the pressure bag before shipping. The pressure bag should be kept refrigerated until the shipment to the repository is

prepared. For shipping procedures for refrigerated specimens, see Chapter 2 of Part 5 in this volume.

*3 mL Lavender Tubes (LP10) and PAXgene Tubes (PX10)*—LP10 and PX10 tubes are not centrifuged and will be stored frozen in a pressure bag together with frozen urine and frozen vaginal swab specimens collected from the same study participant at one study visit. The pressure bag used to store the specimens in the freezer then will be used to ship the specimens weekly to the repository.

- a. Retrieve the refrigerated clamshell and remove the LP10 tube from the clamshell.
- b. Wand the bar code label on the tubes in BEST to receipt the tube and to document the storage time.
- c. BEST will assign a specific storage unit (i.e., frozen pressure bag) to store the 3 mL lavender blood tube, given that there are available storage units that have been pre-labeled and created in BEST. If no storage unit is available, follow the instructions in the BEST User's Guide to create a new storage unit. Retrieve the pressure bag designated by BEST.
- d. Place the tube in a tube sleeve.
- e. Place the tube sleeve in the assigned pressure bag. Do not seal the pressure bag until the shipment is prepared. For shipping procedures for frozen specimens, see Chapter 3 of Part 5 in this volume.
- f. Store the pressure bag *on its side* in the freezer storage bin. Confirm the master storage unit location (i.e., upper or lower freezer compartment) in BEST. If the location is not accurate, update the storage location information.
- g. The pressure bag should be stored on its side until the 3 mL lavender tube is frozen to reduce the possibility of tube breakage. Once the 3 mL lavender tube is frozen, the pressure bag may be placed in an upright position and should be kept frozen until the shipment to the repository is prepared. For shipping procedures for frozen specimens, see Chapter 3 of Part 5 in this volume.

*ACD Tubes (AD10)*—AD10 tubes are not centrifuged and will be stored ambient in a pressure bag. The pressure bag used to store the specimen then will be used to ship the specimen to the repository.

- a. Retrieve the ambient tube holder and remove the AD10 tube.
- b. Wand the bar code label on the tube in BEST to receipt the tube. This action automatically records the storage time.
- c. BEST will assign a specific storage unit (i.e., ambient pressure bag) to store the ACD blood tube, given that there are available storage units that have been

prelabeled and created in BEST. If no storage unit is available, follow the instructions in the BEST User's Guide to create a new storage unit. Retrieve the pressure bag designated by BEST.

- d. Place the tube in a Styrofoam 2-tube shipper and close the lid.
  - e. Place the 2-tube shipper in the assigned pressure bag along with an absorbent strip. Do not seal the pressure bag until the shipment is prepared.
  - f. Keep the pressure bag at ambient temperature until the shipment to the repository is prepared. For shipping procedures for ambient blood tube specimens, see Chapter 3 of Part 5 in this volume.
10. After completing the receipt and storage procedures for blood specimens, complete the biospecimen receipt and storage procedures in Part 3 of this volume to receipt and store the other biospecimen types collected at the study visit.

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Part 4

Appendix 2-A

Blood Receipt Form – P1 Mother



**Appendix 2-A.  
Blood Receipt Form – P1 Mother**

	<p><b>National Children's Study Blood Specimen Receipt Form P1 Mother</b></p>
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(For Use When BEST Is Not Functioning)

<b>Part A: Administrative</b>	
Assignment ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Date received at SPSC: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>m m d d y y y y</small>
Received by: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>(Data collector ID)</small>	Time received: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <small>h h m m</small>
<input type="checkbox"/> a.m. <input type="checkbox"/> p.m.	
<b>Part B: Transport Temperatures</b>	
Temperature of refrigerated chamber upon arrival at SPSC: <input type="text"/> <input type="text"/> . <input type="text"/> °C	
Refrigerated Chamber Warm Mark Threshold Monitor has a visible color change (pink)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, mark the box that corresponds to the number of circles with the color change.	
<input type="checkbox"/> 1 circle <input type="checkbox"/> 2 circles <input type="checkbox"/> 3 circles	
Refrigerated Chamber Cold Mark Threshold Monitor has a visible color change (purple)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Ambient Chamber Cold Mark Threshold Monitor has a visible color change (purple)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>Part C: Time of Centrifugation at the SPSC</b>	
Time Spin B (PP10, RD10, RD11, and SS10) began: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <small>h h m m</small>	
<input type="checkbox"/> a.m. <input type="checkbox"/> p.m.	
Temperature of centrifuge at time of Spin B: <input type="text"/> <input type="text"/> °C <input type="checkbox"/> Not able to measure	

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**Appendix 2-A.  
Blood Receipt Form – P1 Mother (continued)**

<b>Part D: Specimens Received</b>				
<b>Specimen</b>	<b>Received</b>	<b>Time stored</b>	<b>Hemolyzed</b>	<b>Problems</b>
<b>LP10</b> 3mL Prescreened Lavender	<input type="checkbox"/> Yes  <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.  <b>Storage Unit Number:</b> [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] Location _____	<input type="checkbox"/> Yes  <input type="checkbox"/> No	_____ _____ _____
<b>SS10</b> Serum Separator tube	<input type="checkbox"/> Yes  <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes  <input type="checkbox"/> No	_____ _____ _____
<b>RD10</b> 10mL Red Top 10	<input type="checkbox"/> Yes  <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes  <input type="checkbox"/> No	_____ _____ _____
<b>RD11</b> 10 mL Red Top 11	<input type="checkbox"/> Yes  <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes  <input type="checkbox"/> No	_____ _____ _____
<b>LV10</b> 6 mL Lavender	<input type="checkbox"/> Yes  <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes  <input type="checkbox"/> No	_____ _____ _____
<b>PP10</b> Plasma Preparation Tube	<input type="checkbox"/> Yes  <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes  <input type="checkbox"/> No	_____ _____ _____

**Data collector ID for QC:** [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

**Data collector ID for data entry:** [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

**Date entered into BEST:** [ ] [ ] / [ ] [ ] / 2 0 [ ] [ ]  
m m d d y y y y

Part 4

Appendix 2-B

Blood Receipt Form – T1 Mother



Appendix 2-B.  
Blood Receipt Form – T1 Mother

	<p><b>National Children's Study</b> <b>Blood Specimen Receipt Form</b> <b>T1 Mother</b></p>
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(For Use When BEST Is Not Functioning)

<b>Part A: Administrative</b>	
Assignment ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Date received at SPSC: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 2 0 <input type="text"/> <input type="text"/>
Received by: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (Data collector ID)	Time received <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
<b>Part B: Transport Temperatures</b>	
Temperature of refrigerated chamber upon arrival at SPSC <input type="text"/> <input type="text"/> . <input type="text"/> °C	
Refrigerated Chamber Warm Mark Threshold Monitor has a visible color change (pink) <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, mark the box that corresponds to the number of circles with the color change	
<input type="checkbox"/> 1 circle <input type="checkbox"/> 2 circles <input type="checkbox"/> 3 circles	
Refrigerated Chamber Cold Mark Threshold Monitor has a visible color change (purple) <input type="checkbox"/> Yes <input type="checkbox"/> No	
Ambient Chamber Cold Mark Threshold Monitor has a visible color change (purple) <input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>Part C: Time of Centrifugation at the SPSC</b>	
Time Spin B (PP10, RD10, RD11, and SS10) began <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.	
Temperature of centrifuge at time of Spin B <input type="text"/> <input type="text"/> °C <input type="checkbox"/> Not able to measure	

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**Appendix 2-B.  
Blood Receipt Form – T1 Mother (continued)**

Part D: Specimens Received				
Specimen	Received	Time stored	Hemolyzed	Problems
<b>LP10</b> 3mL Prescreened Lavender	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.  <b>Storage Unit Number:</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Location: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
<b>SS10</b> Serum Separator tube	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
<b>RD10</b> 10mL Red Top 10	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
<b>RD11</b> 10mL Red Top 11	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
<b>LV10</b> 6mL Lavender	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
<b>PP10</b> Plasma Preparation Tube	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____
<b>PN10</b> P100 Tube	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____

Data Collector ID for QC:

Data Collector ID for data entry:

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

Part 4

Appendix 2-C

Blood Receipt Form – T1 Father



Appendix 2-C.  
Blood Receipt Form – T1 Father

	<p>National Children's Study <b>Adult Blood Specimen Receipt Form</b> <b>T1 Father</b></p>
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(For Use When BEST Is Not Functioning)

<b>Part A: Administrative</b>	
Assignment ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Date received at SPSC: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 2 0 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>m m d d y y y y</small>
Received by: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>(Data collector ID)</small>	Time received: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m. <small>h h m m</small>
<b>Part B: Transport Temperatures</b>	
Temperature of refrigerated chamber upon arrival at SPSC <input type="text"/> <input type="text"/> . <input type="text"/> °C	
Refrigerated Chamber Warm Mark Threshold Monitor has a visible color change (pink)? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, mark the box that corresponds to the number of circles with the color change. <input type="checkbox"/> 1 circle <input type="checkbox"/> 2 circles <input type="checkbox"/> 3 circles	
Refrigerated Chamber Cold Mark Threshold Monitor has a visible color change (purple)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Ambient Chamber Cold Mark Threshold Monitor has a visible color change (purple)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>Part C: Time of Centrifugation at the SPSC</b>	
Time Spin B (RD12) began: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m. <small>h h m m</small>	
Temperature of centrifuge at time of spin: <input type="text"/> <input type="text"/> °C <input type="checkbox"/> Not able to measure	

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Appendix 2-C.  
Blood Receipt Form – T1 Father (continued)

Part D: Specimens Received				
Specimen	Receive	Time Stored	Hemolyzed	Problems
<b>LP10</b> Prescreened 3mL Lavender	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h    h            m    m <input type="checkbox"/> p.m.  <b>Storage Unit Number:</b> [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] Location: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____
<b>RD12</b> 10 mL Red Top 12	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h    h            m    m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____
<b>LV11</b> 6 mL Lavender 11	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h    h            m    m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____
<b>AD10</b> ACD Tube	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h    h            m    m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____

Data collector ID for QC: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Data collector ID for data entry: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Date entered into BEST: [ ] [ ] / [ ] [ ] / 2 0 [ ] [ ]  
m m d d y y y y

Part 4

Appendix 2-D

Blood Receipt Form – T3 Mother



**Appendix 2-D.  
Blood Receipt Form – T3 Mother**

	<b>National Children's Study Adult Blood Specimen Receipt Form T3 Mother</b>
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(For Use When BEST Is Not Functioning)

Part A: Administrative				
Assignment ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Time received: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m. h h m m		
Date received at SPSC: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 2 0 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> m m d d y y y y				
Received by: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (Data collector ID)				
Part B: Transport Temperatures				
Temperature of refrigerated chamber upon arrival at SPSC: <input type="text"/> <input type="text"/> . <input type="text"/> °C				
Refrigerated Chamber Warm Mark Threshold Monitor has a visible color change (pink)? <input type="checkbox"/> Yes <input type="checkbox"/> No				
If yes, mark the box that corresponds to the number of circles with the color change.				
<input type="checkbox"/> 1 circle <input type="checkbox"/> 2 circles <input type="checkbox"/> 3 circles				
Refrigerated Chamber Cold Mark Threshold Monitor has a visible color change (purple)? <input type="checkbox"/> Yes <input type="checkbox"/> No				
Ambient Chamber Cold Mark Threshold Monitor has a visible color change (purple)? <input type="checkbox"/> Yes <input type="checkbox"/> No				
Part C: Time of Centrifugation at the SPSC				
Time Spin B (PP10, RD11, RD13, and SS10) began:		<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m. h h m m		
Temperature of centrifuge at time of Spin B:		<input type="text"/> <input type="text"/> °C <input type="checkbox"/> Not able to measure		
Part D: Specimens Received				
Specimen	Received	Time stored	Hemolyzed	Problems
<b>SS10</b> Serum Separator tube	<input type="checkbox"/> Yes  <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m. h h m m	<input type="checkbox"/> Yes  <input type="checkbox"/> No	_____ _____ _____

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**Appendix 2-D.  
Blood Receipt Form – T3 Mother (continued)**

Specimen	Received	Time stored	Hemolyzed	Problems
<b>RD11</b> 10mL Red Top 11	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____
<b>RD13</b> 10 mL Red Top 13	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____
<b>LV10</b> 6 mL Lavender 10	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____
<b>PP10</b> Plasma Preparation Tube	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____
<b>AD10</b> ACD Tube	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____
<b>PN10</b> P100 Tube	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____
<b>PX10</b> PaxGene Tube	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____

Data collector ID for QC:

Data collector ID for data entry:

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

Part 4

Appendix 2-E

Blood Receipt Form – Birth Mother



Appendix 2-E.  
Blood Receipt Form – Birth Mother

	<p>National Children's Study <b>Blood Specimen Receipt Form – Birth Mother</b></p>
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(For Use When BEST Is Not Functioning)

<b>Part A: Administrative</b>	
Assignment ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Time received: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.
Date received at SPSC: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 2 0 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>m m d d y y y y</small>	Received by: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (Data collector ID)
<b>Part B: Transport Temperatures</b>	
Temperature of refrigerated chamber upon arrival at SPSC: <input type="text"/> <input type="text"/> . <input type="text"/> °C	
Refrigerated Chamber Warm Mark Threshold Monitor has a visible color change (pink)? <input type="checkbox"/> Yes <input type="checkbox"/> No  If yes, mark the box that corresponds to the number of circles with the color change. <input type="checkbox"/> 1 circle <input type="checkbox"/> 2 circles <input type="checkbox"/> 3 circles	
Refrigerated Chamber Cold Mark Threshold Monitor has a visible color change (purple)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Ambient Chamber Cold Mark Threshold Monitor has a visible color change (purple)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Time Spin B (RD14, RD15, and RD16) began: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.	
Temperature of centrifuge at time of Spin B <input type="text"/> <input type="text"/> °C <input type="checkbox"/> Not able to measure	

BSRFBM01.00EN

Appendix 2-E.  
Blood Receipt Form – Birth Mother (continued)

Part D: Specimens Received				
Specimen	Received	Time stored	Hemolyzed	Problems
<b>LP10</b> 3mL Prescreened Lavender	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m. <b>Storage Unit Number:</b> [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] Location _____	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____
<b>RD14</b> 10mL Red Top 14	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____
<b>RD15</b> 10mL Red Top 15	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____
<b>RD16</b> 10mL Red Top 16	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h h m m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____

Data collector ID for QC: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Data collector ID for data entry: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Date entered into BEST: [ ] [ ] / [ ] [ ] / 2 0 [ ] [ ]  
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Part 4

Appendix 2-F

Blood Receipt Form: Field-by-Field Instructions



**Appendix 2-F.  
Blood Receipt Form: Field-by-Field Instructions**

**BLOOD SPECIMEN RECEIPT FORM  
FIELD-BY-FIELD INSTRUCTIONS**

This form is only to be completed when the Biological and Environmental Sample Tracking System (BEST) is not available at the Specimen Processing and Shipping Center (SPSC) following a P1 mother, T1 mother, T1 father, T3 mother, or Birth data collection visit. This form is to be completed by the biospecimen receipt technician who receives blood specimens at the SPSC. There is a unique Blood Specimen Receipt Form for each event type; however, the information required on the forms is consistent for all events. Instructions for completing each item on the form are provided in this field-by-field. The included example is the T1 mother version of the form. Note that the blood tubes received for each study event type will differ.

**After Completing the Form**

- *Data collector identification number (ID) for quality control (QC)*
  - The form should be checked to make sure that it is accurate, legible, and complete.
  - Record the data collector ID of the person who performs the QC of the form.
- *Data collector ID for data entry*
  - The data on this form must be entered in BEST once the system becomes available.
  - Record the data collector ID of the person who enters the data into BEST.
- *Date entered into BEST*
  - Record the date of data entry into BEST.
  - The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002).



### Part A: Administrative Section

- *Assignment ID*
  - Record the appropriate assignment ID in the spaces provided.
  - The assignment ID consists of the first eight characters on the subject label.
- *Date received at SPSC*
  - Record the date the blood specimens were received at the SPSC.
  - The month, day, and the last 2 digits of the year should be recorded (e.g., 02/07/2002).
- *Received by*
  - Record the data collector ID of the person who receives the blood specimens at the SPSC.
- *Time received*
  - Record the time that the blood specimens were received at the SPSC.
  - Be sure to use zeros to fill the spaces when necessary. For example, if the kit is received at 2:05 p.m., record “02:05.”
  - Mark the box to indicate “a.m.” or “p.m.”

### Part B: Transport Temperatures

- *Temperature of refrigerated chamber upon arrival at SPSC*
  - Record the temperature that appears on the digital thermometer inside the refrigerated chamber.
  - Use zeros to fill the space when necessary. For example, if the temperature is 7° C, record “07.0.”
- *Refrigerated Chamber Warm Mark Threshold Monitor has a visible color change (pink)*
  - Mark the box that corresponds to “Yes” to indicate that the color in the Warm Mark Threshold Monitor has changed to pink.
  - Mark the box that corresponds to “No” to indicate that the color in the Warm Mark Threshold Monitor has not changed to pink.
- *If yes, mark the box that corresponds to the number of circles with the color change*
  - Mark the box that corresponds to the number of circles that are pink.
  - If a circle contains any pink color at all, it should be considered pink.



**Part B: Transport Temperatures (continued)**

- *Refrigerated Chamber Cold Mark Threshold Monitor has a visible color change (purple)*
  - Mark the box that corresponds to “Yes” to indicate that the color in the Cold Mark Threshold Monitor has changed to purple.
  - Mark the box that corresponds to “No” to indicate that the color in the Cold Mark Threshold Monitor has not changed to purple.
- *Ambient Chamber Cold Mark Threshold Monitor has a visible color change (purple)*
  - Mark the box that corresponds to “Yes” to indicate that the color in the Cold Mark Threshold Monitor has changed to purple.
  - Mark the box that corresponds to “No” to indicate that the color in the Cold Mark Threshold Monitor has not changed to purple.

**Part C: Time of Centrifugation at the SPSC**

*Time Spin B began*

- Record the time that Spin B was started.
- Be sure to zero fill the spaces when necessary. For example, if the spin began at 2:05 p.m., record “02:05.”
- Mark the box to indicate “a.m.” or “p.m.”
- *Temperature of centrifuge at time of Spin B*
  - Record the temperature from the thermometer on top of the centrifuge at the time of Spin B.
  - Mark the box that corresponds to “Not able to measure” if you are unable to measure the temperature at the time of Spin B.
  - Use zeros to fill the space when necessary. For example, if the temperature is 7° C, record “07.0.”

**Adult Blood Transport, Processing, and Storage Procedures**

Part D: Specimens Received				
Specimen	Received	Time stored	Hemolyzed	Problems
<b>LP10</b> 3mL Prescreened Lavender	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h   h   m   m <input type="checkbox"/> p.m. <b>Storage Unit Number:</b> [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] Location: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____
<b>SS10</b> Serum Separator tube	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h   h   m   m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____
<b>RD10</b> 10mL Red Top 10	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h   h   m   m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____
<b>RD11</b> 10mL Red Top 11	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h   h   m   m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____
<b>LV10</b> 6mL Lavender	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h   h   m   m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____
<b>PP10</b> Plasma Preparation Tube	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h   h   m   m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____
<b>PN10</b> P100 Tube	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ] [ ] : [ ] [ ] <input type="checkbox"/> a.m. h   h   m   m <input type="checkbox"/> p.m.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_____ _____ _____

Data Collector ID for QC: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Data Collector ID for data entry: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Date entered into BEST: [ ] [ ] / [ ] [ ] / 2 0 [ ] [ ]  
m m d d y y y y

## Part D: Specimens Received

Record the following information for each blood tube that is supposed to be drawn for the event type designated on the Blood Receipt Form.

- *Received*
  - Mark the box that corresponds to “Yes” to indicate that the blood tube has been received.
  - Mark the box that corresponds to “No” to indicate that the blood tube has not been received.
- *Time stored*
  - Record the time that each blood tube was placed in the refrigerator or freezer.
  - Be sure to use zeros to fill the spaces when necessary. For example, if a blood tube was placed in the refrigerator at 2:05 p.m., record “02:05.”
  - Mark the box to indicate “a.m.” or “p.m.”
- *Storage Unit Number*
  - Record the storage unit ID that appears on the pressure bag where each blood tube is stored.
- *Location*
  - Record the location of the pressure bag within the freezer. For example, “3rd shelf, first row, 2nd from the left.”
  - This information only needs to be recorded for frozen tubes (LP10, PX10).
- *Hemolyzed*
  - Mark the box that corresponds to “Yes” to indicate that the blood specimen was hemolyzed upon receipt at the SPSC.
  - Mark the box that corresponds to “No” to indicate that the blood specimen was not hemolyzed upon receipt at the SPSC.
- *Problems*
  - Use the space provided to record any problems with a blood specimen that are not recorded in the comment section of the associated Biospecimen Transmittal Form. Problems that would be recorded here include faulty labels and/or tubes.

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