

Volume VIII
Part 5.
Biospecimen Shipping Procedures



November 30, 2009

General Biospecimen Shipping Information

1.1 Overview

Throughout the study, biospecimens collected from study participants will be shipped from local Specimen Processing and Shipping Centers (SPSC) at Study Centers to the central National Children’s Study (NCS) repository and the central NCS histology laboratory. All biospecimen types will be shipped to the NCS repository except placenta and umbilical cord specimens, which will be shipped directly to the central NCS histology laboratory. Specimens will be processed and stored long-term at the central repository until they are requisitioned by the Program Office for analysis.

Study Centers will ship biospecimens according to the established NCS biospecimen shipping schedule using study-contracted shipping vendors. Specimens will be packed, labeled, and shipped according to the specifications in this manual. Part 5 describes temperature and regulatory requirements, required supplies, step-by-step procedures for packing and labeling shipments, and procedures for the documentation and monitoring of shipping activities using the Biological and Environmental Sample Tracking system (BEST).

1.2 Shipping Regulations for Biospecimens

To ensure the safe and successful transfer of study specimens from Study Centers to the central NCS repository or histology laboratory, the centers must adhere to U.S. Department of Transportation (DOT) and International Air Transport Association (IATA) regulations that govern air transport of dangerous goods. Category B biospecimens and the dry ice used to ship them are classified as dangerous goods by IATA because they pose a health or safety risk if exposure occurs. Biospecimens are classified as either Category B substances (i.e., urine, vaginal swabs, and blood specimens) or Exempt Human Specimens (i.e., saliva, hair, and nail specimens). Specific packing and labeling procedures must be followed to meet shipping



regulations for each classification. Instructions for preparing each class of shipment are provided in Chapters 2–4 of this part and volume.

Study Centers are responsible for adhering to the IATA regulations when shipping biospecimens, and failure to follow these regulations can result in shipment delays or fines for non-compliance. For more information concerning IATA regulations, refer to the IATA website (www.iata.org).

1.3 Training Requirements for Biospecimen Shipping

IATA regulations require that individuals who ship dangerous goods including dry ice receive appropriate training. Staff must be trained and certified by the biospecimen trainer to perform these activities. In addition to the training provided by the Coordinating Center on NCS biospecimen shipping procedures, at least one staff person at the Study Center must attend or must have attended a formal training course on Shipping of Dangerous Goods within the previous 2 years. This staff person may be the biospecimen trainer or another individual at the Study Center; however, it is recommended that the biospecimen trainer receive this training. Although the procedures presented during NCS training and in the NCS Manual of Operations and Procedures (MOP) for packing, labeling, and shipping NCS biospecimens meet IATA regulations, it is the Study Center's responsibility to ensure that IATA regulations are met for all biospecimen shipping activities. Study Centers may contact the Coordinating Center if they need additional information on meeting this training requirement.

1.4 Biospecimen Shipping Schedule

Biospecimens will be shipped according to the temperature requirements and shipping frequency shown in Table 1-1. Refrigerated specimens will be shipped daily, frozen specimens will be shipped weekly, and with the exception of ACD blood tubes (T1 father and T3 mother events only) and fixed placenta specimens, ambient specimens will be shipped monthly.



Table 1-1. Biospecimen shipping frequency by biospecimen type and shipping temperature

| Biospecimen Type and Shipping Temperature | Shipping Frequency | | |
|---|--------------------|--------|---------|
| | Daily | Weekly | Monthly |
| Refrigerated Specimens (Shipped on Cold Packs) | | | |
| Whole and centrifuged blood tubes* | X | | |
| Cord blood (CB01) | X | | |
| Placenta and Umbilical Cord (fresh) (PC01) | X | | |
| Frozen Specimens (Shipped on Dry Ice) | | | |
| 3 mL Lavender blood tubes (LP10) | | X | |
| PAXgene blood tubes (PX10) | | X | |
| Protein Saver infant blood spot cards (B009) | | X | |
| Urine (UR01, PU01, BU01) | | X | |
| 2-day saliva (SL01-SL06) | | X | |
| Vaginal swabs (VS01, VS02) | | X | |
| Meconium (MC01) | | X | |
| Breast milk (BM01) | | X | |
| Infant formula (FM01) | | X | |
| Ambient Specimens | | | |
| ACD blood tubes (AD10) | X | | |
| Placenta and Umbilical Cord (fixed) (PC01) | | X | |
| FTA [®] Mini infant blood spot cards (B010) | | | X |
| Vaginal specimen slides (VL01) | | | X |
| BNC Saliva (SB01) | | | X |
| Hair (HR01) | | | X |
| Toenails (NL01) | | | X |

*All blood tubes except 3 mL Lavender tubes (LP10) and PAXgene tubes (PX10) are shipped daily.

Note: FTA = Flinders Technology Associates

FedEx will be used to ship all weekly and monthly shipments. Study Centers may be assigned a specific day of each week and month to make weekly and monthly shipments to the repository. The Coordinating Center will work with each Study Center to make arrangements for pick-up schedules prior to study initiation. If on occasion the Study Center cannot accommodate a regularly scheduled pick-up date and time or has no specimens to ship, it must contact FedEx in advance of the pick-up date and time to cancel or reschedule as needed.

1.4.1 Shipping Schedule for Blood Tubes

For all visits but birth, blood tubes will be shipped on the same day they are collected from study participants or the following day if the blood was collected and processed after the established daily vendor pick-up time. It is recommended that all blood tubes be shipped within 24 hours of collection whenever possible. Blood specimens collected at the birth visit should be shipped to the repository within 48 hours of collection.

All refrigerated and ambient blood tubes will be shipped overnight to the central NCS repository, which will receive blood tube shipments 7 days a week. Two different shipping vendors will be used to ship blood tubes depending on the day of the week the shipment is sent. Overnight blood shipments leaving the SPSC Monday through Friday will be shipped via FedEx overnight Priority 1 delivery, for delivery at the repository the following day. Overnight blood shipments leaving the SPSC on Saturdays and Sundays will be shipped via World Courier. The Coordinating Center will work with each Study Center to make arrangements for pick-up schedules prior to study initiation. Note that FedEx and World Courier require compliance with IATA regulations for packing and labeling shipments containing dangerous goods.

1.4.2 Holidays

Study Centers should not ship specimens that would arrive at the repository or the histology laboratory on a major holiday. If the weekly shipping day falls on a day before a national holiday, the shipping date will need to be rescheduled to the next day following the holiday.

1.4.3 Weather Delays

Occasionally, inclement weather can cause problems with shipment of biospecimens. Shipment delays due to weather conditions can threaten specimen integrity if the appropriate shipping temperature is not maintained until the shipment reaches its destination. To prevent potential specimen loss, Study Centers should determine whether any weather conditions may adversely affect shipping to the destination prior to making a shipment.

1.5 Biospecimen Shipping Supplies

The Coordinating Center will provide Study Centers with all materials and supplies needed to ship biospecimens, except dry ice (see Section 1.5.1 for more information regarding dry ice). Study Centers must use the packaging materials and supplies provided by NCS to ship biospecimens. These packaging materials have been tested and certified to comply with the current version of the IATA Shipping Regulations for Dangerous Goods. In addition to using the proper materials, it is the shipper's responsibility to ensure that all prepared packages meet the requirements of the IATA Packing Instructions.

Each Study Center should maintain a sufficient supply of shipping supplies for making regularly scheduled shipments to the repository. Refer to Appendix 6-D in Part 1 of this volume for a list of biospecimen shipping supplies provided by the Coordinating Center.

1.5.1 Dry Ice

All frozen specimens will be packed on dry ice for shipment. Dry ice also will be used to transport frozen specimens from the site of specimen collection to the SPSC. Study Centers are responsible for ensuring that each SPSC is supplied with dry ice for both local transport and shipping. For local transport of frozen specimens, enough dry ice should be used for the specimens to remain frozen until they are received at the SPSC. Frozen shipments to the repository should include enough dry ice for the contents to remain frozen for up to 48 hours to allow for possible delays en route. If insufficient dry ice is used during transport or shipping, specimens may thaw before reaching their destination. For specific instructions regarding the quantity of dry ice that should be used when packing frozen shipments, refer to Chapter 3 of this



part. Staff should follow the appropriate safety precautions and guidelines when handling dry ice, including wearing dry ice gloves provided by NCS.

1.6 Use of BEST for Shipping Activities

BEST will be used by Study Centers, the NCS repository, and the histology laboratory to document all biospecimen shipping activities for NCS. Study Centers will use the system when preparing biospecimen shipments at the SPSC and to send electronic notifications of shipments. The repository and histology laboratory will access BEST at the time shipments are received and update the status of each shipment to confirm its receipt. For detailed instructions on how to use BEST in the conduct of shipping activities, refer to the BEST User Guide.

1.6.1 Use of BEST for Preparing Shipments

SPSC staff should follow the procedures in Chapters 2–4 of this part and volume to prepare refrigerated, frozen, and ambient biospecimen shipments. When preparing a shipment, the shipping technician will wand the bar code label into BEST for each storage unit that will be packed for shipping, which will assign specimens to a specific shipment. Once specimens have been assigned to the shipment, the shipping technician will generate a Biospecimen Shipping Manifest Form from BEST. A separate Biospecimen Shipping Manifest Form will be sent inside each package and should include an accurate itemized list of the contents of the package.

If BEST is temporarily unavailable at the SPSC, Study Centers should ship only daily blood specimens until the system becomes available. Preparation of weekly and monthly shipments should be postponed until BEST is operational. In this case, it will be necessary to notify the shipping vendor to reschedule the pick-up if a predetermined pick-up date and time have been arranged. To prepare daily blood shipments if BEST is unavailable, a hard copy backup Biospecimen Shipping Manifest Form should be completed. A copy of the form and field-by-field instructions can be found in Appendices 1-A and 1-B. A copy of the shipping manifest should be kept at the SPSC and the data should be entered in BEST when the system becomes available. Instructions for entering data from backup shipping manifest forms into BEST can be found in the document “Guide to BEST Data Entry from Backup Biospecimen Forms” (located on the NCS Collaboration Portal).

After each package is properly packed and labeled according to the instructions provided, the shipping technician must prepare a shipping label (Airbill for Fedex, Waybill for World Courier). It is anticipated that shipping labels will be manually completed (handwritten or preferably typewritten or computer-generated), but at a later time shipping labels will be prepared electronically and printed from BEST. The shipping labels must contain all the required information, including the amount of dry ice contained within the package (frozen shipments only) and a FedEx or World Courier tracking number. Airbills or Waybills should be completed according to the instructions provided in Appendices 1-C and 1-D.

1.6.2 Use of BEST for Tracking and Notification of Biospecimen Shipments

After a biospecimen shipment has been picked up by the shipping vendor, the shipping clerk will use BEST to send an email notification to the repository or histology laboratory. This notification includes tracking information and an electronic version of the Biospecimen Shipping Manifest Form. If BEST is not available, the shipping clerk must notify the repository by email or phone regarding details of the shipment, including anticipated arrival date and contents. Contact information for the repository will be provided by the Coordinating Center.

If a shipment is not received at the repository within 24 hours of pick-up from the SPSC, the repository will notify the Study Center immediately. The Study Center will be responsible for initiating tracking procedures to follow up on shipments that have not reached their destination.

All biospecimen shipments will be receipted in BEST by the repository or histology laboratory on the date they are received. Upon receipt of specimens, the repository or laboratory will reconcile the specimen identification numbers (ID) listed on the Biospecimen Shipping Manifest Form with the contents of each shipment and will notify the Study Center immediately by telephone or fax to report any discrepancies. The repository also will notify the Study Center of any other problems with the shipment, such as broken vials or tubes, thawed samples (for frozen shipments), or missing labels.

1.7 Resolving Problems with Biospecimen Shipments

Several types of discrepancies can occur between specimens that are listed on the Biospecimen Shipping Manifest Form and specimens that are actually received by the repository:

1. A specimen that is in the shipment is not on the Biospecimen Shipping Manifest Form.
2. A specimen that is on the Biospecimen Shipping Manifest Form is not in the shipment.
3. The unit number on the Biospecimen Shipping Manifest Form does not match the number on the unit that was received.

When discrepancies occur in shipments to the repository, repository personnel will notify the Study Center. The Study Center should investigate the error and make any necessary corrections in BEST. If the Study Center is not able to correct the error reported by the repository, the Study Center should contact the repository contact person for NCS and the Coordinating Center to assist in the resolution of the error.

Part 5

Appendix 1-A

Hard Copy Backup Biospecimen Shipping Manifest Form

Appendix 1-A.
Hard Copy Backup Biospecimen Shipping Manifest Form

| | |
|---|--|
|  | <p>National Children's Study Biospecimen Shipping Manifest Form</p> |
|---|--|

(Only use for daily blood shipments when BEST is not available)

| | | |
|---|--|---------------|
| A. Administrative | | |
| <div style="border: 1px solid black; height: 60px; margin-bottom: 10px; text-align: center; font-size: 12px;">Affix SPSC Address Label Here</div> <p>Date shipped: <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="font-size: 8px; margin-left: 20px;">m m / d d / y y y y</p> <p>Time packed <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.</p> <p>Shipped 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"/></p> <p>Temperature of shipment: <input type="checkbox"/> Ambient <input type="checkbox"/> Refrigerated</p> <p>Total number of bags: <input type="text"/></p> | <div style="border: 1px solid black; height: 60px; margin-bottom: 10px; text-align: center; font-size: 12px;">Affix Destination Address Label Here</div> <p>Total number of specimens: <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Shipment tracking number: <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>Receipt 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="font-size: 8px; margin-left: 20px;">m m / d d / y y y y</p> <p>Time received <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.</p> <p>Received by: _____ (Name of Repository staff member)</p> | |
| B. Specimens Shipped | | |
| Storage Unit number | Specimen ID | Specimen type |
| <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"/> <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"/> | |
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| <p>Specimen type codes BLD= Blood BLDC=Cord blood PLC=Placenta</p> | <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"/> | |
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**Appendix 1-A.
Hard Copy Backup Biospecimen Shipping Manifest Form (continued)**

| Storage Unit number | Specimen ID | Specimen type |
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| | <input type="text"/> - <input type="text"/> | |
| | <input type="text"/> - <input type="text"/> | |
| | <input type="text"/> - <input type="text"/> | |
| Specimen type codes BLD=Blood BLDC=Cord blood PLC=Placenta | <input type="text"/> - <input type="text"/> | |
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Data Collector ID for data entry:

Date entered in BEST: / / 20
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Part 5

Appendix 1-B

Hard Copy Backup Biospecimen Shipping Manifest Form:
Field-by-Field Instructions

**Appendix 1-B.
Hard Copy Backup Biospecimen Shipping Manifest Form: Field-by-Field Instructions**

**BIOSPECIMEN SHIPPING MANIFEST FORM:
FIELD-BY-FIELD INSTRUCTIONS**

This form is to be completed by the staff member performing the Study Center biospecimen shipping role. This form is to be used for daily blood shipments only when Biospecimen and Environmental Sample Tracking system (BEST) is not available. A separate Biospecimen Shipping Manifest Form should be completed for each box that is shipped. Instructions for completing each item of the form are provided in this field-by-field.

After Completing the Form

- Before placing the form in the shipper, make sure that all of the appropriate boxes are completely filled and no stray marks are on the form.
- Make a photocopy of the form so that the data can be entered when BEST is available.
- The staff person who performs data entry in BEST should record the date of data entry and her data collector identification number (ID) in the spaces provided on the last page of the form.



National Children's Study Biospecimen Shipping Manifest Form

(Only use for daily blood shipments when BEST is not available)

| A. Administrative | | |
|---|--|---------------|
| <div style="border: 1px solid black; width: 90%; margin: 0 auto; padding: 10px; text-align: center;">Affix SPSC Address Label Here</div> <p>Date shipped: <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="font-size: small; text-align: center;">m m d d y y y y</p> <p>Time packed <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.</p> <p>Shipped 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"/></p> <p>Temperature of shipment: <input type="checkbox"/> Ambient <input type="checkbox"/> Refrigerated</p> <p>Total number of bags: <input type="checkbox"/></p> | <div style="border: 1px solid black; width: 90%; margin: 0 auto; padding: 10px; text-align: center;">Affix Destination Address Label Here</div> <p>Total number of specimens: <input type="text"/> <input type="text"/> <input type="text"/></p> <p>Shipment tracking number: <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"/></p> <p>Receipt 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="font-size: small; text-align: center;">m m d d y y y y</p> <p>Time received <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.</p> <p>Received by: _____ (Name of Repository staff member)</p> | |
| B. Specimens Shipped | | |
| Storage Unit number | Specimen ID | Specimen type |
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BIOSHM01.00EN



Part A: Administrative Section

- *SPSC Address Label*—Affix a preprinted Specimen Processing and Shipping Center (SPSC) address label to the form in the space provided.
- *Destination Address Label*—Affix the preprinted address label for the correct destination in the space provided. The destination will be the repository.
- *Date Shipped*—Record the date that the specimens were shipped. 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.
- *Time packed*—Record the time that the packing of the specimens was completed. Be sure to use zeros to fill the spaces when necessary and to mark the box to indicate “a.m.” or “p.m.” For example if the packing of the specimens is completed at 2:05 record “02:05” and mark the box corresponding to “p.m.”
- *Shipped by*—Record the data collector ID of the person who packed and shipped the specimens.
- *Temperature of shipment*—Mark the box that corresponds to the temperature at which the specimens are being shipped.
- *Total number of bags*—Record the total number of pressure bags being shipped in the box.
- *Total number of specimens*—Record the total number of specimens in the shipment.
- *Shipment tracking number*—This is the tracking number that is on the FedEx Airbill or World Courier Waybill.
- *Receipt date*—This item will be completed by the person who receives the shipment at the repository. This form should be used to record information only if BEST is not available.
- *Time received*—This item will be completed by the person who receives the shipment at the repository. This form should be used to record information only if BEST is not available. Be sure to use zeros to fill the spaces when necessary and to mark the box to indicate “a.m.” or “p.m.”
- *Received by*—The person who receives the shipment at the repository will print his or her name in the space provided. This form should be used to record information only if BEST is not available.

Part B: Specimens Shipped

- *Storage Unit number*—Record the number that appears on the label that is affixed to each pressure bag.
- *Specimen ID*—Record the 13-character ID that appears on each of the specimens contained in the pressure bag.
- *Specimen type*—Using the specimen type codes listed on the left side of the form, record the code that corresponds to each specimen contained in the pressure bag.

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Part 5

Appendix 1-C

FedEx Airbill: Field-by-Field Instructions

**Appendix 1-C.
FedEx Airbill: Field-by-Field Instructions**

Enter the information from this field-by-field on the FedEx Airbill. Please use black pen. Mark in the box next to the appropriate choice. For items on the FedEx Airbill requiring written comments, please write legibly. Be sure to press firmly when filling out the FedEx Airbill to ensure that multiple copies of the Airbill are legible.

Please note: FedEx should only be used to send biospecimen shipments on Mondays–Fridays. For shipments leaving the Specimen Processing and Shipping Center (SPSC) on Saturdays and Sundays, World Courier should be used.

RETAIN THIS COPY FOR YOUR RECORDS.

1 From Please print and print hard.
 Date _____
 Sender's Name _____
 Company _____
 Address _____
 City _____ State _____ ZIP _____

2 Your Internal Billing Reference
 First 24 characters will appear on invoice.

3 To
 Recipient's Name _____
 Company _____
 Recipient's Address _____
 Address _____
 City _____ State _____ ZIP _____

Sender's Copy

0200

4a Express Package Service
 FedEx Priority Overnight
 FedEx Standard Overnight
 FedEx Express Saver
 FedEx 2Day
 FedEx 1Day Freight

4b Express Freight Service
 FedEx 1Day Freight
 FedEx 2Day Freight
 FedEx 3Day Freight

5 Packaging
 FedEx Envelope
 FedEx Pak
 FedEx Tube
 FedEx Box
 Other

6 Special Handling
 SATURDAY Delivery
 HOLD Weekend at FedEx Location
 HOLD Saturday at FedEx Location
 YES (Yes, this shipment contains dangerous goods)
 NO (No, this shipment does not contain dangerous goods)
 YES (Yes, this shipment contains dangerous goods)
 NO (No, this shipment does not contain dangerous goods)

7 Payment Bill to:
 Sender
 Recipient
 Third Party
 Credit Card
 Cash/Check

8 Residential Delivery Signature Options
 No Signature Required
 Direct Signature
 Indirect Signature

Total Packages: _____ Total Weight: _____ Total Declared Value: \$ _____

520

Store your addresses at fedex.com
Simplify your shipping. Manage your account. Access all the tools you need.

1. Sender Information

- *Date*—Enter the date of the shipment.
- *Sender's FedEx Account No.*—Leave blank. The NCS FedEx account number should be preprinted in Section 7- Payment.
- *Sender's Name*— Enter the specific name of the SPSC from which you are shipping,
- *Phone*—Enter the SPSC phone number.
- *Company*— Enter the specific code for the SPSC from which you are shipping. *Please note the code entered must be the official NCS code for your location.* The code must be entered as specified by NCS for emergency response purposes.
- *Address, City, State, Zip*—Enter the SPSC address.

2. Your Internal Billing Reference

- Enter 8208.01.13.01 BIO for biospecimen shipments if not already preprinted.

3. Recipient Information

- a. Repository shipments leaving the SPSC Mondays – Thursdays only
 - *Recipient's Name*—Enter the repository contact: Audrey Chang.
 - *Phone*—Enter the repository contact phone: 301.315.8544.
 - *Company*—Enter the repository name: Fisher BioServices.
 - *Address, City, State, Zip*—Enter the repository address:
14665 Rothgeb Drive, Rockville, MD 20850
- b. Repository Shipments leaving the SPSC Fridays only
 - *Recipient's Name*—Enter the repository name: Fisher BioServices. It is not necessary to enter an individual's name.
 - *Phone*—Enter the repository contact phone: 301-366-7284.
 - *Company*—Enter the repository name: Fisher BioServices.
 - *Address, City, State, Zip*—Enter the FedEx Saturday hold location address:
7331 Calhoun Place, Rockville, MD 20855

RETAIN THIS COPY FOR YOUR RECORDS.

1 From Please print and print hard.
 Date: _____
 Sender's Name: _____
 Company: _____
 Address: _____
 City: _____ State: _____ ZIP: _____

2 Your Internal Billing Reference
 First 24 characters will appear on invoice. _____

3 To Please print and print hard.
 Recipient's Name: _____
 Company: _____
 Recipient's Address: _____
 Address: _____
 City: _____ State: _____ ZIP: _____

Sender's Copy

Phone () _____

Sender's FedEx Account Number: **8673 3647 8482**

Tracking Number: **0200**

4a Express Package Service Packages up to 150 lbs.

FedEx Priority Overnight Next business morning. Saturday Delivery NOT available.

FedEx Standard Overnight Next business afternoon. Saturday Delivery NOT available.

FedEx Express Saver Next business day. Saturday Delivery NOT available.

FedEx 2Day Next business day. Saturday Delivery NOT available.

FedEx 1Day Freight* Next business day. Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.

4b Express Freight Service Packages over 150 lbs.

FedEx 2Day Freight Second business day. Saturday Delivery NOT available.

FedEx 3Day Freight Third business day. Saturday Delivery NOT available.

FedEx Pak* FedEx Envelope* FedEx Tube* Other*

5 Packaging *In most locations. **In some locations.

FedEx Pak* (includes FedEx Small Pak, FedEx Large Pak, and FedEx County Pak)

FedEx Envelope* (includes FedEx address label)

FedEx Tube (includes FedEx address label)

Other* (includes FedEx address label)

6 Special Handling

SATURDAY Delivery (Not available for FedEx First Overnight, FedEx Express Saver, or FedEx 2Day Freight.)

HOLD Weekend at FedEx Location (Not available for FedEx First Overnight, FedEx Express Saver, or FedEx 2Day Freight.)

HOLD Sunday at FedEx Location (Not available for FedEx First Overnight, FedEx Express Saver, or FedEx 2Day Freight.)

Does this shipment contain dangerous goods?
 No Yes (Yes: specify hazard class, quantity, and destination. Shipper's Declaration not required.)

Dangerous goods (including dry ice) cannot be shipped in FedEx packaging.

7 Payment Bill to: Enter FedEx Acct. No. or Credit Card No. below.

Sender (Acct. No. Section 1 will be billed.)

Recipient

Third Party

Credit Card

Cash/Check

Total Packages: _____ **Total Weight:** _____ **Total Declared Value:** \$ _____

8 Residential Delivery Signature Options If you require a signature, check Direct or Indirect.

No Signature Required (Package will be left without obtaining a signature for delivery.)

Direct Signature (Signature may sign for recipient's address.)

Indirect Signature (Signature may sign for a neighboring address.)

Signature required for delivery. **520**

Rev. Date: 10/09/09 (P) 1/15/09 (C) 1/19/04 - 2008 FedEx. PRINTED IN U.S.A. SRY

Please note: *This shipment address is only to be used for shipments that will arrive at the Repository on Saturdays.* Please also note that these procedures will be implemented during the initial phase of the pilot study only. The Coordinating Center will provide updated procedures for weekend shipping as the pilot study progresses.

- 4a. Express Package Service
 - Mark the option, “FedEx Priority Overnight.”
- 4b. Express Freight Service
 - Leave blank.
5. Packaging
 - Mark the option, “Other” to indicate you are using non-FedEx packaging materials.
6. Special Handling
 - Repository shipments leaving the SPSC Mondays – Thursdays only
 - Leave blank.
 - Repository Shipments leaving the SPSC Fridays only
 - Mark the option, “HOLD Saturday at FedEx location”. The address listed in Section 3 should be the FedEx hold location address.
 - Does this shipment contain dangerous goods?
 - For exempt human specimen shipments, mark “No.”
 - For category B specimen shipments, mark “Yes—Shipper’s Declaration not Required.”
 - *Dry Ice*
 - For all frozen shipments, mark the box and enter the weight of dry ice used in the shipment in Kg (1 kg = 2.2 pounds).
7. Payment
 - Mark “Third Party” and enter the NCS FedEx account number if not already preprinted: 1829-0009-5.
8. Residential Delivery Signature Options
 - Leave blank.

This page deliberately blank.

Part 5

Appendix 1-D

World Courier Waybill: Field-by-Field Instructions

Appendix 1-D.
World Courier Waybill: Field-by-Field Instructions

Enter the information from this field-by-field on the World Courier Waybill. Please use blue or black pen. Mark in the box next to the appropriate choice. For items requiring written comments, please write legibly. Be sure to press firmly when filling out the Waybill to ensure that multiple copies are legible. If preprinted Waybills are provided, complete only the remaining sections as needed.

General Biospecimen Shipping Information



NON-NEGOTIABLE WAYBILL

| | | | | | | |
|--|------------------------------|------------------------------|--|---|--|---|
| ACCOUNT #: | BILLING REFERENCE: | REC'D BY WC (NAME): | P/U TIME: | P/U DATE: | ORIGIN: | DESTINATION: |
| FROM (SHIPPER) | | | TO (CONSIGNEE) | | | |
| NAME: | TELEPHONE #: | NAME: | TELEPHONE #: | | | |
| COMPANY: | FLOOR/DEPT.: | COMPANY: | FLOOR/DEPT.: | | | |
| ADDRESS: | | ADDRESS: | | | | |
| CITY: | STATE/COUNTRY: | POST CODE: | CITY: | STATE/COUNTRY: | POST CODE: | |
| SHIPMENT INFORMATION | | | | | | |
| FULL DESCRIPTION OF CONTENTS: | | | SPECIAL HANDLING: | | | |
| # OF PCS. | WEIGHT: | <input type="checkbox"/> KGS | DIMENSIONS: | <input type="checkbox"/> CM | DOES THIS SHIPMENT CONTAIN DANGEROUS GOODS? | |
| | <input type="checkbox"/> LBS | | X X | <input type="checkbox"/> IN | <input type="checkbox"/> NO | <input type="checkbox"/> YES <small>(Per attached shipper's declaration)</small> |
| COUNTRY OF ORIGIN: | DECLARED VALUE FOR CUSTOMS: | DECLARED VALUE FOR CARRIAGE: | CHECK IF SURCHARGE ELECTED: | <input type="checkbox"/> | | |
| <p>WORLD COURIER'S LIABILITY IS LIMITED. By tendering this shipment to World Courier, shipper agrees to Conditions described below. World Courier's liability for loss, damage, or delay of this shipment will not exceed this shipment's declared value, depreciated value, replacement cost, repair cost, or US\$150, whichever is less. Said amount may be increased if shipper states in this Waybill a declared value of this shipment higher than US\$150 and pays the required surcharge. This shipment may also be subject to the rules relating to liability established by the Warsaw Convention and other international treaties and provisions. Under no circumstances shall World Courier be liable for special, consequential, indirect, or incidental damages or losses. PLEASE SEE BELOW FOR CONDITIONS OF CARRIAGE.</p> | | | | <p>WARNING: These commodities, technology or software were exported from the United States in accordance with the Export Administration Regulations. Diversion contrary to U.S. Law prohibited.</p> | | |
| PRINT NAME OF SHIPPER OR SHIPPER'S AGENT: | | DATE: | PRINT NAME OF CONSIGNEE OR CONSIGNEE'S AGENT: | | DATE: | |
| SIGNATURE OF SHIPPER OR SHIPPER'S AGENT: | | TIME: | SIGNATURE OF CONSIGNEE OR CONSIGNEE'S AGENT: | | TIME: | |
| X | | | X | | | |

BASIC CONDITIONS OF CARRIAGE

1. Definitions. "Carriage": the holding, transport, delivery and other services undertaken with respect to the Shipment. "Conditions": this waybill, the Full Conditions and the Tariff. "Courier Organization": World Courier and its subsidiaries and affiliates and their respective directors, officers, employees, agents and independent contractors. "Full Conditions": World Courier's Full Conditions of Carriage, as amended periodically. "Shipment": the item tendered to, and accepted by World Courier for Carriage pursuant to the Conditions. "Shipper": the one listed above as shipper. "Shipping Parties": Shipper, the consignee, the receiver, and the owner of the Shipment, and anyone else having an interest therein. "Tariff": World Courier's tariff applicable to where the Shipment is tendered for Carriage or otherwise agreed to by World Courier and a Shipping Party, as amended periodically. "World Courier": the subsidiary of World Courier Group, Inc. (a Delaware, USA corporation) initially accepting the Shipment for Carriage. 2. Agreement to Conditions. Shipper agrees the Shipping Parties agreed to, will comply with, and are bound by the Conditions, which are available at any World Courier office. Their agreement is confirmed by a Shipping Party requesting a Shipment's Carriage, tendering it for Carriage or signing this waybill. 3. No Warranties. World Courier makes no warranties, express or implied. No delivery date or time is guaranteed. Anyone in the Courier Organization may perform World Courier's obligations. 4. Special Authorization. Shipper hereby grants everyone in the Courier Organization a power of attorney and all other necessary authority to perform all export and/or import functions, appoint other agents to act on behalf of Shipper, and complete, execute and file on Shipper's behalf any and all declarations, documents and other requirements to be filed with any governmental or regulatory authority to comply with any law, rule or regulation affecting the Shipment or its Carriage. The Courier Organization is not responsible or liable for any information or filing. 5. Liability Limited. Liability of the Courier Organization for loss, damage or delay in the delivery of the Shipment will not exceed US\$150, which may be increased to a higher declared value if, when tendering the Shipment for Carriage, Shipper states on this waybill a higher declared value of up to US\$50,000 and pays the required surcharge listed in the Full Conditions (the "Surcharge"). See details in the Full Conditions. 6. No Liability. No one in the Courier Organization shall be liable for any damages or losses that are special, consequential, indirect, incidental or listed in the Full Conditions. 7. Warsaw Convention. For Carriage by air of the Shipment involving an ultimate destination or stop in a country other than the country of departure and certain other Carriage of the Shipment, the Convention for the Unification of Certain Rules Relating to International Transportation by Air, concluded on October 12, 1929, and its amendments and protocols may apply and govern. Generally, it limits liability for losses or damages from all causes to US\$9.07 per lb. or US\$20 per kilo, or to 7.7112 Special Drawing Rights per lb. or 17 Special Drawing Rights per kilo, unless a higher value is declared and the Surcharge is paid. See details in the Full Conditions. For purposes of said Convention: Shipper's address above is the place of departure and execution of this waybill and the contract of Carriage, the recipient's address above is the place of destination, the date shown above next to Shipper's name or agent is the date it is signed, and the Section titled "Delivery" in the Full Conditions amends said Convention's Articles 12 through 14. 8. CMR. The Convention on the Contract for the International Carriage of Goods by Road (CMR) (Geneva, 19 May 1956) (the "CMR") applies to the Carriage of goods by road for a fee from one country to a destination in another, of which at least one is a party to the CMR. Said Carriage is subject, notwithstanding any clause to the contrary, to the provisions of the CMR, which include limitations on the Courier Organization's liability. See details in the Full Conditions. For purposes of the CMR: Shipper's address above is where the waybill is made out and the goods are taken over, and the date when Shipper signs this waybill is the date of this waybill and of the goods being taken over. 9. Certain Indemnifications. The Shipping Parties shall, jointly and severally, be liable for, and indemnify and hold harmless the Courier Organization for and against, any and all loss, reasonable attorneys' fees and other items listed in the Full Conditions. 10. Misc. See the Full Conditions for, among other provisions: fee payment terms; the representations, warranties and agreements made by Shipper; rights reserved by those in the Courier Organization; insurance unavailability; and requirements for claims and amendments of the Conditions. The Conditions constitute the entire Agreement between World Courier and the Shipping Parties with respect to the Shipment. The Full Conditions control in a conflict between them and any other item comprising the Conditions. If any provision in the Conditions is deemed entirely or partly invalid or unenforceable by a court of competent jurisdiction, the Conditions will be ineffective to the extent of such invalidity or unenforceability, without rendering invalid or unenforceable the remaining Conditions. 11. Applicable Law. Claims with respect to the Shipment or otherwise arising under the Conditions shall be determined exclusively in accordance with the laws of the country where a Shipment originates. See the Full Conditions for claims brought in the USA.



1. Account # and Billing Reference

- Enter the appropriate information as supplied by the Coordinating Center.

2. From (Shipper)

- *Name*—Enter the specific name of the Specimen Processing and Shipping Center (SPSC) from which you are shipping.
- *Telephone #*—Enter the SPSC phone number.
- *Company*—Enter the specific code for the SPSC from which you are shipping. *Please note the code entered must be the official NCS code for your location.* The code must be entered as specified by NCS for emergency response purposes.
- *Address, City, State, Zip*—Enter the SPSC address.

3. To (Consignee)

- *Name*—Enter the repository name: Fisher BioServices. It is not necessary to enter an individual's name.
- *Telephone#*—Enter the repository phone: 301-366-7284 (Saturday delivery); 301-315-8544 (Sunday delivery). This phone number will be contacted when necessary regarding notification of delivery.
- *Company*—Enter the repository name: Fisher BioServices. It is not necessary to enter an individual's name.
- *Address, City, State, Zip*—Enter address of repository:

14665 Rothgeb Drive, Rockville, MD 20850

4. Shipment Information

- *Full Description of Contents*—Describe contents of shipment (e.g., “6 blood tubes and 6 ice packs”).
- *Special Handling*—This section will be prefilled by World Courier with specific information related to the study and shipping location.
- *# of Pcs.*—Enter number of boxes to be shipped. If multiple boxes are being sent to the same destination, a separate Waybill is not required for each box.
- *Weight*—Enter the package weight.

General Biospecimen Shipping Information



NON-NEGOTIABLE WAYBILL

| | | | | | | |
|--|------------------------------|------------------------------|--|---|--|---|
| ACCOUNT #: | BILLING REFERENCE: | REC'D BY WC (NAME): | P/U TIME: | P/U DATE: | ORIGIN: | DESTINATION: |
| FROM (SHIPPER) | | | TO (CONSIGNEE) | | | |
| NAME: | TELEPHONE #: | NAME: | TELEPHONE #: | | | |
| COMPANY: | FLOOR/DEPT.: | COMPANY: | FLOOR/DEPT.: | | | |
| ADDRESS: | | ADDRESS: | | | | |
| CITY: | STATE/COUNTRY: | POST CODE: | CITY: | STATE/COUNTRY: | POST CODE: | |
| SHIPMENT INFORMATION | | | | | | |
| FULL DESCRIPTION OF CONTENTS: | | | SPECIAL HANDLING: | | | |
| # OF PCS. | WEIGHT: | <input type="checkbox"/> KGS | DIMENSIONS: | <input type="checkbox"/> CM | DOES THIS SHIPMENT CONTAIN DANGEROUS GOODS? | |
| | <input type="checkbox"/> LBS | | X X | <input type="checkbox"/> IN | <input type="checkbox"/> NO | <input type="checkbox"/> YES <small>(Per attached shipper's declaration)</small> |
| COUNTRY OF ORIGIN: | DECLARED VALUE FOR CUSTOMS: | DECLARED VALUE FOR CARRIAGE: | CHECK IF SURCHARGE ELECTED: <input type="checkbox"/> | | | |
| <p>WORLD COURIER'S LIABILITY IS LIMITED. By tendering this shipment to World Courier, shipper agrees to Conditions described below. World Courier's liability for loss, damage, or delay of this shipment will not exceed this shipment's declared value, depreciated value, replacement cost, repair cost, or US\$150, whichever is less. Said amount may be increased if shipper states in this Waybill a declared value of this shipment higher than US\$150 and pays the required surcharge. This shipment may also be subject to the rules relating to liability established by the Warsaw Convention and other international treaties and provisions. Under no circumstances shall World Courier be liable for special, consequential, indirect, or incidental damages or losses. PLEASE SEE BELOW FOR CONDITIONS OF CARRIAGE.</p> | | | | <p>WARNING: These commodities, technology or software were exported from the United States in accordance with the Export Administration Regulations. Diversion contrary to U.S. Law prohibited.</p> | | |
| PRINT NAME OF SHIPPER OR SHIPPER'S AGENT: | | DATE: | PRINT NAME OF CONSIGNEE OR CONSIGNEE'S AGENT: | | DATE: | |
| SIGNATURE OF SHIPPER OR SHIPPER'S AGENT: | | TIME: | SIGNATURE OF CONSIGNEE OR CONSIGNEE'S AGENT: | | TIME: | |
| X | | | X | | | |

BASIC CONDITIONS OF CARRIAGE

1. Definitions. "Carriage": the holding, transport, delivery and other services undertaken with respect to the Shipment. "Conditions": this waybill, the Full Conditions and the Tariff. "Courier Organization": World Courier and its subsidiaries and affiliates and their respective directors, officers, employees, agents and independent contractors. "Full Conditions": World Courier's Full Conditions of Carriage, as amended periodically. "Shipment": the item tendered to, and accepted by World Courier for Carriage pursuant to the Conditions. "Shipper": the one listed above as shipper. "Shipping Parties": Shipper, the consignee, the receiver, and the owner of the Shipment, and anyone else having an interest therein. "Tariff": World Courier's tariff applicable to where the Shipment is tendered for Carriage or otherwise agreed to by World Courier and a Shipping Party, as amended periodically. "World Courier": the subsidiary of World Courier Group, Inc. (a Delaware, USA corporation) initially accepting the Shipment for Carriage. 2. Agreement to Conditions. Shipper agrees the Shipping Parties agreed to, will comply with, and are bound by the Conditions, which are available at any World Courier office. Their agreement is confirmed by a Shipping Party requesting a Shipment's Carriage, tendering it for Carriage or signing this waybill. 3. No Warranties. World Courier makes no warranties, express or implied. No delivery date or time is guaranteed. Anyone in the Courier Organization may perform World Courier's obligations. 4. Special Authorization. Shipper hereby grants everyone in the Courier Organization a power of attorney and all other necessary authority to perform all export and/or import functions, appoint other agents to act on behalf of Shipper, and complete, execute and file on Shipper's behalf any and all declarations, documents and other requirements to be filed with any governmental or regulatory authority to comply with any law, rule or regulation affecting the Shipment or its Carriage. The Courier Organization is not responsible or liable for any information or filing. 5. Liability Limited. Liability of the Courier Organization for loss, damage or delay in the delivery of the Shipment will not exceed US\$150, which may be increased to a higher declared value if, when tendering the Shipment for Carriage, Shipper states on this waybill a higher declared value of up to US\$50,000 and pays the required surcharge listed in the Full Conditions (the "Surcharge"). See details in the Full Conditions. 6. No Liability. No one in the Courier Organization shall be liable for any damages or losses that are special, consequential, indirect, incidental or listed in the Full Conditions. 7. Warsaw Convention. For Carriage by air of the Shipment involving an ultimate destination or stop in a country other than the country of departure and certain other Carriage of the Shipment, the Convention for the Unification of Certain Rules Relating to International Transportation by Air, concluded on October 12, 1929, and its amendments and protocols may apply and govern. Generally, it limits liability for losses or damages from all causes to US\$9.07 per lb. or US\$20 per kilo, or to 7.7112 Special Drawing Rights per lb. or 17 Special Drawing Rights per kilo, unless a higher value is declared and the Surcharge is paid. See details in the Full Conditions. For purposes of said Convention: Shipper's address above is the place of departure and execution of this waybill and the contract of Carriage, the recipient's address above is the place of destination, the date shown above next to Shipper's name or agent is the date it is signed, and the Section titled "Delivery" in the Full Conditions amends said Convention's Articles 12 through 14. 8. CMR. The Convention on the Contract for the International Carriage of Goods by Road (CMR) (Geneva, 19 May 1956) (the "CMR") applies to the Carriage of goods by road for a fee from one country to a destination in another, of which at least one is a party to the CMR. Said Carriage is subject, notwithstanding any clause to the contrary, to the provisions of the CMR, which include limitations on the Courier Organization's liability. See details in the Full Conditions. For purposes of the CMR, Shipper's address above is where the waybill is made out and the goods are taken over, and the date when Shipper signs this waybill is the date of this waybill and of the goods being taken over. 9. Certain Indemnifications. The Shipping Parties shall, jointly and severally, be liable for, and indemnify and hold harmless the Courier Organization for and against, any and all loss, reasonable attorneys' fees and other items listed in the Full Conditions. 10. Misc. See the Full Conditions for, among other provisions: fee payment terms; the representations, warranties and agreements made by Shipper; rights reserved by those in the Courier Organization; insurance unavailability; and requirements for claims and amendments of the Conditions. The Conditions constitute the entire Agreement between World Courier and the Shipping Parties with respect to the Shipment. The Full Conditions control in a conflict between them and any other item comprising the Conditions. If any provision in the Conditions is deemed entirely or partly invalid or unenforceable by a court of competent jurisdiction, the Conditions will be ineffective to the extent of such invalidity or unenforceability, without rendering invalid or unenforceable the remaining Conditions. 11. Applicable Law. Claims with respect to the Shipment or otherwise arising under the Conditions shall be determined exclusively in accordance with the laws of the country where a Shipment originates. See the Full Conditions for claims brought in the USA.

- *Dimensions*
 - Enter 10” x 6” x 6” for a small (ambient) box.
 - Enter 11” x 9” x 10” for a medium (refrigerated) box.
 - Enter 15” x 13” x 12” for a large (refrigerated) box.
- *Does this shipment contain dangerous goods?*—Mark “YES” (Shipper’s declaration not required)
- *Country of Origin*—Leave blank.
- *Declared Value for Customs*—Leave blank.
- *Declared Value for Carriage*—Leave blank.
- *Check if Surcharge Elected*—Leave blank.
- *Print Name of Shipper*—Enter your name.
- *Date*—Enter today’s date.
- *Signature of Shipper*—Sign your name.

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Shipping Procedures for Refrigerated Biospecimens

All refrigerated blood specimens will be shipped to the central National Children’s Study (NCS) repository daily using FedEx or World Courier. For information regarding which shipping vendor to use when shipping blood specimens, see Section 1.4 of this part and volume. Fresh placenta specimens will be shipped daily to the central NCS histology laboratory. Table 2-1 shows the refrigerated specimens to be shipped daily for all study events through birth.

Table 2-1. Refrigerated biospecimens to be shipped daily

| Event Type | Specimen Type | Specimen ID |
|------------|------------------|------------------------------------|
| P1 Mother | Blood tubes | LV10, RD10, RD11, PP10, SS10 |
| T1 Mother | Blood tubes | LV10, RD10, RD11, PP10, SS10, PN10 |
| T1 Father | Blood tubes | LV11, RD12 |
| T3 Mother | Blood tubes | LV10, RD11, RD13, PP10, SS10, PN10 |
| Birth | Blood tubes | RD14, RD15, RD16 |
| Birth | Placenta (fresh) | PC01 |
| Birth | Cord blood | CB01 |

To streamline shipping procedures and minimize specimen handling, storage units will be packed directly into shippers when preparing biospecimen shipments. Procedures for packing and labeling refrigerated specimens are presented in the following sections.

2.1 Packing and Labeling Refrigerated Biospecimen Shipments

2.1.1 Packing Refrigerated Blood Tube Shipments

The following provides basic procedures for the preparation of refrigerated blood tube shipments. Refer to the BEST User’s Guide for more detailed instructions on how to use the Biological and Environmental Sample Tracking (BEST) system to implement these procedures.

To preserve specimen integrity, refrigerated blood tube shipments should be packed within 2 hours of the scheduled shipping vendor pick-up time.

1. Put on a lab coat and gloves.
2. Determine the number of refrigerated storage units to be shipped and the number of medium size shippers needed. One refrigerated storage unit corresponds to one refrigerated pressure bag. All pressure bags containing refrigerated blood tubes must be shipped daily. A maximum of two refrigerated pressure bags can be shipped in one medium size shipper. If more than two pressure bags are to be shipped, additional medium shippers must be used.
3. Refrigerated shipments to the repository must include enough cold packs to maintain a refrigerated temperature (2–8° C) for up to 48 hours to allow for possible delays en route. If an insufficient amount of cold packs is used during shipping, or if cold packs have not been frozen according to recommended specifications (see Section 6.3.1 in Part 1 of this volume), specimens may become too warm and the stability of blood analytes may be compromised. Requirements for the number of cold packs needed to pack each shipment according to the shipment contents are provided in Table 2-2. Six cold packs are required for shipments containing one pressure bag and for shipments containing two pressure bags. However, the packing configuration of these shipments will differ. See Exhibits 2-1 and 2-2 for the proper packing configurations for each of these shipments.

Table 2-2. Number of cold packs required per shipper by number of pressure bags

| Size of Shipper | Number of Pressure Bags | Number of Blood Tubes | Required Number of Cold Packs |
|----------------------------|-------------------------|-----------------------|-------------------------------|
| Medium (11" x 9" x 10") | 1 | 1–12 | 6 |
| Medium (11" x 9" x 10") | 2 | 13–24 | 6 |

4. Assemble the materials needed to prepare each package:
 - Medium size (11" x 9" x 10") shipper (outer box with insulated Styrofoam chest)
 - Six -1° C cold packs
 - One upper threshold (20° C) temperature monitor (stored refrigerated)
 - One lower threshold (0° C) temperature monitor
 - Packing material
 - Plastic envelope

- 2" packing tape
 - UN 3373 label
 - Shipping Airbill or Waybill (FedEx or World Courier, respectively)
 - Study Center address label (preprinted)
 - Repository address label (preprinted)—The shipment address and contact information for the repository will be provided by the Coordinating Center.
5. Create a new shipment in BEST. Record the upper and lower temperature threshold monitors' information when creating the refrigerated shipment.
 6. Place four or six cold packs on the bottom of the insulated shipper, depending on the contents of the shipment, as shown in Exhibit 2-1 or 2-2. The cold packs should be stacked on top of each other and should not line any side of the shipper to avoid contact with the pressure bags.

Exhibit 2-1. Packing configuration for one pressure bag



Exhibit 2-2. Packing configuration for two pressure bags



7. Place one layer of packing material on top of the cold packs. To avoid freezing, the pressure bags should not be in direct contact with the cold packs.
8. Retrieve the pressure bags to be shipped from the refrigerator, according to the storage location indicated in BEST. Each pressure bag may contain a maximum of two amber bags.
9. Access the shipment in BEST and add storage units to the shipment by wanding the storage label on each pressure bag with the bar code scanner.
10. Generate a Biospecimen Shipping Manifest Form from BEST. For detailed instructions on generating the form, refer to the BEST User's Guide. If BEST is not available at the time the daily shipment is prepared, the hard copy back-up version of the form must be used (see Appendices 1-A and 1-B for form and field-by-field instructions). Follow the instructions provided to complete the form.
11. Verify that the contents of the shipment match the Biospecimen Shipping Manifest Form. The storage unit number on each pressure bag should match what is listed on the form. If discrepancies are found, reconcile the shipment contents in BEST and generate a new Biospecimen Shipping Manifest Form.
12. Retrieve one upper threshold (20° C) temperature monitor from the refrigerator and one lower threshold (0° C) temperature monitor. Place the lower threshold monitor in one of the unsealed pressure bags. Activate the upper threshold monitor by pulling the tab and immediately place it inside the same pressure bag. Immediately seal each pressure bag in accordance with the printed instructions found on the reverse side of the bag.
13. Place the pressure bag or bags in the insulated shipper on top of the packing material.
14. If packing two pressure bags, place another layer of packing material on top of the pressure bags. Place two additional cold packs on top of the packing material as shown in Exhibit 2-2.
15. Pack the top of the insulated cooler with additional packing material to stabilize package contents.
16. Place the foam lid on the cooler.
17. Affix a plastic envelope to the top of the foam lid and place the Biospecimen Shipping Manifest Form in the envelope. If using the hard copy backup version of the manifest form, be sure to make a photocopy of the form for your records before placing it in the envelope.
18. Close the outer fiberboard box and tape all seams or flaps with packing tape.
19. Complete the FedEx Airbill or World Courier Waybill (see Appendices 1-C and 1-D of this part and volume). Be sure to complete all required sections of the Airbill.

20. Enter the shipment tracking number in BEST by typing in the eye-readable number on the Airbill or wand the bar code if applicable.
21. Insert the Airbill in a plastic sleeve or affix it directly to the outside of the shipping box.
22. Label the outer fiberboard box according to the instructions in Section 2.1.4.

2.1.2 Packing Cord Blood Shipments

The following provides basic procedures for the preparation of cord blood shipments. Refer to the BEST User's Guide for more detailed instructions on how to use the BEST system to implement these procedures.

Refrigerated shipments must include enough cold packs to maintain a refrigerated temperature (2–8° C) for up to 48 hours to allow for possible delays en route. If an insufficient amount of cold packs is used during shipping or if cold packs have not been frozen according to recommended specifications (see Section 6.3.1 in Part 1 of this volume), specimens may become too warm and the stability of blood analytes may be compromised.

To preserve specimen integrity, cord blood shipments should be packed within 2 hours of the scheduled shipping vendor pick-up time.

1. Put on a lab coat and gloves.
2. Assemble the following materials, which are needed to prepare each package (one cord blood specimen may be shipped in each medium shipper):
 - Medium size (11" x 9" x 10") shipper (outer box with insulated Styrofoam chest)
 - Eight -1° C cold packs
 - One upper threshold (20° C) temperature monitor (stored refrigerated)
 - One lower threshold (0° C) temperature monitor
 - Packing material
 - Plastic envelope
 - 2" packing tape

- UN 3373 label
 - Shipping Airbill or Waybill (FedEx or World Courier, respectively)
 - Study Center address label (preprinted)
 - Repository address label (preprinted)—The shipment address and contact information for the repository will be provided by the Coordinating Center.
3. Create a new shipment in BEST. Record the upper and lower temperature threshold monitors' information when creating the refrigerated shipment.
 4. Place eight cold packs on the bottom of the insulated shipper. The cold packs should be stacked on top of each other and should not line any side of the shipper to avoid direct contact with the pressure bag.
 5. Place a layer of packing material on top of the cold packs. To avoid exposure to freezing temperature, the pressure bag should not be in direct contact with the cold packs.
 6. Retrieve the pressure bag to be shipped from the refrigerator, according to the storage location indicated in BEST.
 7. Access the shipment in BEST and add the storage unit to the shipment by wanding in the storage label on the pressure bag with the bar code scanner.
 8. Generate a Biospecimen Shipping Manifest Form from BEST. For detailed instructions on generating the form, refer to the BEST User's Guide. If BEST is not available at the time the daily shipment is prepared, the hard copy back-up version of the form must be used (see Appendices 1-A and 1-B for the form and field-by-field instructions). Follow the instructions provided to complete the form.
 9. Verify that the contents of the shipment match the Biospecimen Shipping Manifest Form. The storage unit number on the pressure bag should match what is listed on the form. If discrepancies are found, reconcile the shipment contents in BEST and generate a new Biospecimen Shipping Manifest Form.
 10. Retrieve one upper threshold (20° C) temperature monitor from the refrigerator and one lower threshold (0° C) temperature monitor. Place the lower threshold monitor inside the unsealed pressure bag. Activate the upper threshold monitor by pulling the tab and immediately place it inside the pressure bag. Immediately seal the pressure bag in accordance with the printed instructions found on the reverse side of the bag.
 11. Place the pressure bag in the insulated shipper on top of the packing material.
 12. Pack the top of the insulated cooler with additional packing material to stabilize package contents.
 13. Place the foam lid on the cooler.

14. Affix a plastic envelope to the top of the foam lid and place the Biospecimen Shipping Manifest Form in the envelope. If using the hard copy backup version of the manifest form, be sure to make a photocopy of the form for your records before placing it in the envelope.
15. Close the outer fiberboard box and tape all seams or flaps with packing tape.
16. Complete the FedEx Airbill or World Courier Waybill (see Appendices 1-C and 1-D of this part and volume). Be sure to complete all required sections of the Airbill.
17. Enter the shipment tracking number in BEST by typing in the eye-readable number on the Airbill or wand in the bar code if applicable.
18. Insert the Airbill in a plastic sleeve or affix it directly to the outside of the shipping box.
19. Label the outer fiberboard box according to the instructions in Section 2.1.4.

2.1.3 Packing Fresh (Unfixed) Placenta Shipments

Fresh placenta shipments (i.e., not fixed in formalin) should be shipped daily to the central NCS histology laboratory by using either FedEx or World Courier. Overnight shipments leaving the Specimen Processing and Shipping Center (SPSC) Monday through Friday will be shipped via FedEx. Overnight shipments leaving the SPSC on Saturdays and Sundays will be shipped via World Courier.

The following provides basic procedures for preparing fresh placenta shipments. Refer to the BEST User's Guide for more detailed instructions on how to use BEST to implement these procedures.

To preserve specimen integrity, fresh placenta shipments should be packed within 2 hours of the scheduled shipping vendor pick-up time. During the pilot phase of the study, two different shipping systems will be used to ship fresh placenta specimens. These two systems will be evaluated during the pilot study. The two sections below outline the packing procedures to be followed when using each type of shipping system.

2.1.3.1 Shipping with the Credo™ Thermal Packaging Solution

The Credo Series 4-1748 thermal packaging solution must be preconditioned according to the manufacturer's instructions before placing the placenta specimen into the shipping system. Follow the instructions provided in the manufacturer's User Guide to precondition and assemble the system.

1. Put on a laboratory coat and gloves.
2. Assemble the materials needed to prepare the package:
 - Credo Series 4-1748 shipping system
 - One upper threshold (20° C) temperature monitor (stored refrigerated)
 - One lower threshold (0° C) temperature monitor
 - Extra 500 mL absorbent pads
 - Cardboard sheet (to keep placenta flat)
 - Packing material
 - Packing tape
 - Clear plastic envelope (for shipping manifest)
 - Shipping Airbill or Waybill (FedEx or World Courier, respectively)
 - UN3373 label
 - Emergency contact information label (preprinted Avery label)
 - Study Center address label (preprinted Avery label)
 - Histology Laboratory address label (preprinted Avery label)—The shipment address and contact information for the histology laboratory will be provided by the Coordinating Center.
3. Before packing the fresh placenta specimen into the shipper, precondition the shipper according to the manufacturer's instructions.
 - Place the TIC components flat in the -30 °C freezer for a minimum of 12 hours until frozen hard.

- Before placing the placenta specimen into the shipping box, let the TIC components stand at room temperature for 25 minutes or until surface frost melts.
- 4. Follow the manufacturer instructions to assemble the system.
- 5. Create a new shipment in BEST. Record the upper and lower temperature threshold monitors' information when creating the refrigerated shipment.
- 6. After the shipper has been assembled, retrieve the placenta specimen to be shipped, according to the storage location indicated in BEST. The specimen should be enclosed within two (or three if leaks were present upon specimen receipt) sealed polyethylene bags, within a large pressure bag.
- 7. Verify that the secondary polyethylene bag contains a 500 mL absorbent pad. If no 500 mL absorbent pad is inside the secondary bag, place one inside the bag.
- 8. Retrieve one upper threshold (20° C) temperature monitor from the refrigerator and one lower threshold (0° C) temperature monitor. Place the lower threshold monitor inside the unsealed pressure bag. Activate the upper threshold monitor by pulling the tab and immediately place it inside the pressure bag. Both temperature monitors should be located outside of the secondary polyethylene bag, as close to the specimen as possible.
- 9. Gently remove excess air from the pressure bag and seal the bag in accordance with the printed instructions on the reverse side of the bag.
- 10. Access the shipment in BEST and add the storage unit to the shipment by wanding the storage label on the pressure bag with the bar code scanner.
- 11. Generate a Biospecimen Shipping Manifest Form from BEST. For detailed instructions on generating the form, refer to the BEST User's Guide.
- 12. Verify that the contents of the shipment match the Biospecimen Shipping Manifest Form. The storage unit number on the bag should match what is listed on the form. If discrepancies are found, reconcile the shipment contents in BEST and generate a new Biospecimen Shipping Manifest Form.
- 13. Place the sealed pressure bag on the bottom of the shipper, being careful to keep the placenta as flat as possible.
- 14. Place a cardboard sheet on top of the pressure bag to keep the contents flat.
- 15. Fill the box to the top with packing material. The box should be packed tightly to avoid movement or shifting of the contents inside the shipping box.
- 16. Place the TIC lid over the payload area.

17. Place the insulator lid over the TIC lid making sure it rests flat and level without forcing.
18. Affix a plastic envelope to the top of the insulator lid and place the Biospecimen Shipping Manifest Form in the envelope.
19. Close and secure the outer box with packing tape where indicated.
20. Complete the FedEx or World Courier Airbill or Waybill (see Appendix 1-C or 1-D of this part and volume). Be sure to complete all required sections of the Airbill.
21. Enter the shipment tracking number in BEST by typing in the eye-readable number on the Airbill or wand the bar code if applicable.
22. Insert the Airbill in the plastic pouch and affix it to the outside of the shipping box.
23. Label the outside of the box according to the instructions in Section 2.1.4.

2.1.3.2 Shipping with Cold Packs

Shippers must be preconditioned for 1 hour before placing the placenta specimen into the shipping box, as indicated in step 3.

1. Put on a laboratory coat and gloves.
2. Assemble the materials needed to prepare the package:
 - Large (15" x 13" x 12") size shipper (outer box with insulated Styrofoam chest)
 - Two ECOGEL™ cold packs, 48 oz
 - Two Saf-T-Temp™ 2/8 SoftPaks (STP-319)
 - One upper threshold (20° C) temperature monitor (stored refrigerated)
 - One lower threshold (0° C) temperature monitor
 - Extra 500 mL absorbent pads
 - Cardboard sheet (to keep placenta flat)
 - Packing material
 - Packing tape

- Clear plastic envelope (for shipping manifest)
 - Shipping Airbill or Waybill (FedEx or World Courier, respectively)
 - Two orientation arrow labels (if red or black arrows are not preprinted on shipper)
 - UN3373 label
 - Emergency contact information label (preprinted Avery label)
 - Study Center address label (preprinted Avery label)
 - Histology Laboratory address label (preprinted Avery label)—The shipment address and contact information for the histology laboratory will be provided by the Coordinating Center.
3. Before packing the fresh placenta specimen into the shipper, precondition the shipper as follows:
- Ensure that 48 oz ECOGEL cold packs have been frozen for a minimum of 24 hours before use.
 - Ensure that Saf-T-Temp SoftPaks have been stored at ROOM temperature (approximately 20 to 26 °C) for a minimum of 24 hours before use. If the softpaks are hard/rigid (crystalline), place them in warm water until they are soft and pliable.
 - Place two frozen 48 oz ECOGEL cold packs flat on the bottom of the insulated shipper so that they cover the bottom completely. Be sure to use the appropriate size (48 oz) cold packs when preparing the shipment.
 - Place two Saf-T-Temp SoftPaks on top of the cold packs so that they completely cover the cold packs. Adjust the softpaks as needed to create a flat surface. It is important to maintain the placenta as flat as possible during shipping.
 - Place the foam lid on the insulated Styrofoam chest and allow the system to sit at room temperature for one hour before placing the placenta specimen inside. This will allow time for the softpaks to reach the appropriate temperature.
4. Create a new shipment in BEST. Record the upper and lower temperature threshold monitors' information when creating the refrigerated shipment.
5. After the shipper has been preconditioned for 1 hour, retrieve the placenta specimen to be shipped, according to the storage location indicated in BEST. The specimen

- should be enclosed within two (or three if leaks were present upon specimen receipt) sealed polyethylene bags, within a large pressure bag.
6. Verify that the secondary polyethylene bag contains a 500 mL absorbent pad. If no 500 mL absorbent pad is inside the secondary bag, place one inside the bag.
 7. Retrieve one upper threshold (20° C) temperature monitor from the refrigerator and one lower threshold (0° C) temperature monitor. Place the lower threshold monitor inside the unsealed pressure bag. Activate the upper threshold monitor by pulling the tab and immediately place it inside the pressure bag. Both temperature monitors should be located outside of the secondary polyethylene bag, as close to the specimen as possible.
 8. Gently remove excess air from the pressure bag and seal the bag in accordance with the printed instructions on the reverse side of the bag.
 9. Access the shipment in BEST and add the storage unit to the shipment by wand the storage label on the pressure bag with the bar code scanner.
 10. Generate a Biospecimen Shipping Manifest Form from BEST. For detailed instructions on generating the form, refer to the BEST User's Guide.
 11. Verify that the contents of the shipment match the Biospecimen Shipping Manifest Form. The storage unit number on the bag should match what is listed on the form. If discrepancies are found, reconcile the shipment contents in BEST and generate a new Biospecimen Shipping Manifest Form.
 12. Place the sealed pressure bag in the shipper on top of the preconditioned softpaks, being careful to keep the placenta as flat as possible.
 13. Place a cardboard sheet on top of the pressure bag to keep the contents flat.
 14. Fill the box to the top with packing material. The box should be packed tightly to avoid movement or shifting of the contents inside the shipping box. Place the foam lid on the Styrofoam chest.
 15. Affix a plastic envelope to the top of the foam lid and place the Biospecimen Shipping Manifest Form in the envelope.
 16. Close the fiberboard box and tape all seams or flaps with packing tape.
 17. Complete the FedEx or World Courier Airbill or Waybill (see Appendix 1-C or 1-D of this part and volume). Be sure to complete all required sections of the Airbill.
 18. Enter the shipment tracking number in BEST by typing in the eye-readable number on the Airbill or wand the bar code if applicable.
 19. Insert the Airbill in the plastic pouch and affix it to the outside of the shipping box.

20. Label the outside of the box according to the instructions in Section 2.1.4.

2.1.4 Labeling Refrigerated Biospecimen Shipments

All shipments containing refrigerated biospecimens must be labeled as described in this section. The instructions given in this section meet Federal regulations for Category B substances, the International Air Transportation Association (IATA) Regulations for the Transport of Dangerous Goods, and shipping vendor requirements for the labeling of biologic specimens for shipment.

The UN 3373 label must be affixed to a vertical side of the fiberboard box, not the top or bottom, and the Airbill and address labels should be placed on the top of the package. It is important that all labels are securely attached to the fiberboard box and that the labels do not overlap. If the box has preprinted up arrows, avoid placing labels over the arrows. Use only the labels provided by the Coordinating Center, which meet the specific font and format labeling requirements.

Use the following instructions to label each outer box:

1. Affix a UN 3373 label designating the UN identification number (ID) for Category B substances. This label also includes the required text to identify the proper shipping name: “Biological Substance, Category B.”
2. If the shipping box does not have preprinted red or black “up” orientation arrows, affix one orientation arrow label on each of two opposite vertical sides of the box, with the arrows pointing in the correct upright direction.
3. Affix a preprinted label with the complete name and address of the Study Center SPSC (i.e., the shipper). Note that this action is required in addition to recording this information on the Airbill.
4. Attach a preprinted label with the complete name and address of the repository or histology laboratory (i.e., the consignee). Note that this action is required in addition to recording this information on the Airbill.
5. Hand write legibly or attach a preprinted label with the name and telephone number of the party responsible in case of emergency. This information will be provided by the Coordinating Center and will be used in the event of an emergency response situation. Note that this action is required to meet IATA regulations for shipping Category B shipments.

Shipping Procedures for Refrigerated Biospecimens

6. Notify the shipping vendor of the shipment pick-up time and location, unless there is a regularly scheduled pick-up. Store prepared shipments in a cool, dry location prior to pick-up.

After the shipment is picked up by the shipping vendor, use the following steps:

1. Access the shipment in BEST and click “SHIP.” This action makes the shipment available for either the repository or histology laboratory to view and receipt the shipment in BEST. *Do not click “SHIP” until the shipment is picked up by the vendor.*
2. Click “EZ-NOTIFY” to send an electronic notification that the shipment is underway. An electronic version of the shipping manifest will automatically be attached to the email. If BEST is not available, the repository (or histology laboratory for placenta shipments) must be contacted via email or telephone for notification of the shipment.



Shipping Procedures for Frozen Biospecimens

All frozen specimens will be shipped to the central National Children’s Study (NCS) repository weekly using FedEx. Table 3-1 shows the specimens to be shipped weekly for all study events.

Table 3-1. Frozen biospecimens to be shipped weekly to the repository

| Event Type | Specimen Type | Specimen ID |
|------------|--------------------------------------|-------------|
| P1 Mother | Whole Blood | LP10 |
| | Urine | UR01 |
| | Vaginal Swabs | VS01, VS02 |
| (post-P1) | Pregnancy Urine | PU01 |
| T1 Mother | Whole Blood | LP10 |
| | Urine | UR01 |
| | 2-day Saliva | SL01-SL06 |
| | Vaginal Swabs | VS01, VS02 |
| T3 Mother | Whole Blood | PX10 |
| | Urine | UR01 |
| | 2-day Saliva | SL01-SL06 |
| | Vaginal Swabs | VS01, VS02 |
| T1 Father | Whole Blood | LP10 |
| | Urine | UR01 |
| Birth | Meconium | MC01 |
| | Protein Saver Infant Blood Spot Card | B009 |
| | Breast Milk | BM01 |
| | Infant Formula | FM01 |
| | Whole Blood | LP10 |
| 6-Month | Infant Urine | BU01 |
| | Adult 2-day Saliva | SL01-SL06 |
| | Breast Milk | BM01 |
| | Infant Formula | FM01 |

To streamline procedures and minimize specimen handling, storage units will be packed directly into shippers when preparing biospecimen shipments to the repository. Procedures for packing and labeling frozen specimens are presented in this chapter.

3.1 Packing and Labeling Frozen Biospecimen Shipments

Please note that if the Biological and Environmental Sample Tracking (BEST) system is not available, preparation of weekly frozen shipments must be postponed until the system is operational. In this case, notify the shipping vendor to cancel or reschedule if a regularly scheduled pick-up date has been arranged.

3.1.1 Packing Frozen Biospecimen Shipments

The following provides basic procedures for the preparation of frozen biospecimen shipments. Refer to the BEST User Guide for more detailed instructions on how to use BEST to implement these procedures.

To preserve specimen integrity, frozen shipments should be packed within 2 hours of the shipping vendor pick-up time. Frozen specimens always should remain in the freezer until the shipper has been prepared with dry ice to avoid thawing.

1. Put on a lab coat and gloves.
2. Determine the number of frozen storage units to be shipped and the number of medium or large size shippers needed. One frozen storage unit corresponds to one frozen pressure bag or frozen Ziplock storage bag. All storage bags containing frozen specimens must be shipped weekly. A maximum of three frozen pressure bags can be shipped in one medium size shipper. If there are more than three pressure bags to be shipped, a large shipper must be used. A maximum of eight pressure bags can be shipped in one large size shipper. Frozen Ziplock storage bags containing Protein Saver infant blood spot cards may be packed inside a medium or large size shipper depending on available space.
3. Frozen shipments to the repository must include enough dry ice for the contents to remain frozen for up to 48 hours to allow for possible delays en route. If insufficient dry ice is used during shipping, specimens may thaw, compromising their integrity. Requirements for the minimum quantity of dry ice needed to pack each shipment according to the shipper size and contents are provided in Table 3-2.

Table 3-2. Number of pressure bags and minimum quantity of dry ice required per shipper

| Size of Shipper | Number of Pressure Bags | Minimum Quantity of Dry Ice |
|----------------------------|-------------------------|-----------------------------|
| Medium (11" x 9" x 10") | 1-3 | 5 lbs |
| Large (15" x 13" x 12") | 4-8 | 12 lbs |

4. Assemble the following materials needed to prepare each package:
 - Medium (11" x 9" x 10") or large (15" x 13" x 12") size shipper (outer box with insulated Styrofoam chest)
 - Dry ice gloves
 - Dry ice
 - Scale
 - Packing material
 - Plastic envelope
 - 2" packing tape
 - FedEx Airbill
 - UN 3373 label
 - UN 1845/Class 9 label
 - Study Center address label (preprinted)
 - Repository address label (preprinted)—The shipment address and contact information for the repository will be provided by the Coordinating Center.
5. Create a new shipment in BEST.
6. Cover the bottom of the insulated shipper with one-half of the required minimum amount of dry ice, depending on the size and contents of the shipper.
7. Retrieve the pressure bags to be shipped from the freezer, according to the storage location indicated in BEST.
8. Seal each pressure bag in accordance with the printed instructions found on the reverse side of the bag.

9. Access the shipment in BEST and add storage units to the shipment by wanding the storage label on each pressure bag with the bar code scanner.
10. Generate a Biospecimen Shipping Manifest Form from BEST. For detailed instructions on generating the form, refer to the BEST User Guide.
11. Verify that the contents of the shipment match the Biospecimen Shipping Manifest Form. The storage unit number on each pressure bag must match what is listed on the form. If discrepancies are found, reconcile the shipment contents in BEST and generate a new Biospecimen Shipping Manifest Form.
12. Lay the remaining amount of dry ice on top of the pressure bags.
13. Use crumpled packing material to fill in any holes or spaces and to keep the dry ice in place around the pressure bags.
14. Place the foam lid on the cooler.
15. Affix a plastic envelope to the top of the foam lid and place the Biospecimen Shipping Manifest Form in the envelope.
16. Close the outer fiberboard box and tape all seams or flaps with packing tape.
17. Complete the FedEx Airbill as shown in Appendix 1-C. Be sure to complete all required sections of the Airbill, including the amount of dry ice used in the shipment.
18. Enter the shipment tracking number in BEST by typing in the eye-readable number on the Airbill or wanding the bar code if applicable.
19. Insert the Airbill in a plastic sleeve or affix it directly to the outside of the shipping box.
20. Label the outer fiberboard box as according to the instructions in the following section.

3.1.2 Labeling Frozen Biospecimen Shipments

All shipments containing frozen biospecimens must be labeled as instructed in this section. The instructions meet Federal regulations for Category B substances, the International Air Transportation Association (IATA) Regulations for the Transport of Dangerous Goods, and shipping vendor requirements for the labeling of biologic specimens for shipment.

UN 3373 and UN 1845 labels must be affixed to a vertical side of the fiberboard box, not the top or bottom, and the Airbill and address labels should be placed on the top of the package. It is

important that all labels are securely attached to the fiberboard box and that the labels do not overlap. If the box has preprinted up arrows, avoid placing labels over the arrows. Use only the labels provided by the Coordinating Center, which meet the specific font and format labeling requirements.

Use the following instructions to label each fiberboard box:

1. Affix a UN 3373 label designating the UN identification number (ID) for Category B substances. This label also includes the required text to identify the proper shipping name: “Biological Substance, Category B.”
2. Affix a combined UN 1845/Class 9 Dry Ice label designating the UN ID for Dry Ice, a dangerous good.
3. On the UN 1845/Class 9 label, record the weight (in kilograms) of dry ice contained in the box. The weight *must* be recorded in kilograms, not in pounds. To calculate an approximation for kilograms, divide the measure of pounds by 2.2.
4. Affix a preprinted label with the complete name and address of the Study Center Specimen Processing and Shipping Center (SPSC; i.e., the shipper). Note that this action is required in addition to recording this information on the Airbill.
5. Affix a preprinted label with the complete name and address of the repository (i.e., the consignee). Note that this action is required in addition to recording this information on the Airbill.
6. Hand write legibly or attach a preprinted label with the name and telephone number of the party responsible in case of emergency. This information will be provided by the Coordinating Center and will be used in the event of an emergency response situation. Note that this action is required to meet IATA regulations for shipping Category B shipments.
7. Notify the shipping vendor of the shipment pick up time and location, unless there is a regularly scheduled pick-up. Store prepared shipments in a cool, dry location prior to pick-up.

After the shipment is picked up by the shipping vendor:

1. Access the shipment in BEST and click “SHIP.” This action makes the shipment available for the repository to view and receipt the shipment in BEST. Do not click “SHIP” until the shipment is picked up by the vendor.
2. Click “EZ-NOTIFY” to send an electronic notification to the repository that the shipment is underway. An electronic version of the shipping manifest will

Shipping Procedures for Frozen Biospecimens

automatically be attached to the email. If BEST is not available, the repository must be contacted via email or telephone for notification of the shipment.

Shipping Procedures for Ambient Biospecimens

Depending on the specimen type, ambient specimens will be shipped to the central National Children’s Study (NCS) repository either daily (for ACD blood tubes) or monthly (for all other ambient specimens). Fixed placenta specimens will be shipped Mondays through Wednesdays to the central NCS histology laboratory. Table 4-1 shows the ambient specimens to be shipped for all study events through birth.

Table 4-1. Ambient biospecimens to be shipped

| Specimen Type | Specimen ID | Shipping Frequency |
|---|-------------|--------------------|
| ACD Blood Tubes | AD10 | Daily |
| Placenta (fixed) | PC01 | Weekly (M-W) |
| Vaginal Slides | VL01 | Monthly |
| BNC Saliva | SB01 | Monthly |
| Hair | HR01 | Monthly |
| Toenails | NL01 | Monthly |
| FTA [®] Mini Infant Blood Spot Cards | B010 | Monthly |

Note: BNC = blood not collected; FTA = Flinders Technology Associates

To streamline shipping procedures and minimize specimen handling, storage units will be packed directly into shippers when preparing biospecimen shipments. Procedures for packing and labeling ambient specimens are presented in this chapter.

4.1 Packing and Labeling Ambient Shipments

The following sections present procedures for packing and labeling ambient shipments. Sections 4.1.1 and 4.1.2 contain procedures for daily ambient blood tube shipments (ACD tubes only), Sections 4.2.1 and 4.2.2 contain procedures for ambient (fixed) placenta shipments, and Sections 4.3.1 and 4.3.2 contain procedures for monthly ambient shipments (all other ambient specimens). Note that daily shipments of ACD blood tubes are subject to packing and labeling requirements for Category B specimens, whereas shipments of monthly ambient specimens are subject to

requirements for shipping exempt human specimens. Fixed placenta shipments should be shipped only on Mondays through Wednesdays using FedEx. Fixed placenta shipments should *not* be shipped using World Courier on weekends.

Please note that if the Biological and Environmental Sample Tracking system (BEST) is temporarily unavailable at the Specimen Processing and Shipping Center (SPSC), Study Centers should ship only daily blood specimens, including ambient ACD tubes, until the system becomes available. Preparation of monthly ambient shipments should be postponed until BEST is operational. In this case, notify the shipping vendor to cancel or reschedule if a regularly scheduled pick-up date has been arranged.

4.1.1 Packing Ambient Blood Tube Shipments

The following provides basic procedures for the preparation of ambient blood tube shipments. Refer to the BEST User's Guide for more detailed instructions on how to use BEST to implement these procedures.

1. Put on a lab coat and gloves.
2. Determine the number of ambient blood storage units to be shipped and the number of small shipping boxes that are needed. One ambient blood storage unit corresponds to one ambient pressure bag containing one ACD tube. A maximum of three ambient pressure bags or three ACD blood tubes can be shipped in one small shipping box. If more than three ACD tubes are to be shipped, additional small shipping boxes must be used.
3. Assemble the materials needed to prepare each package:
 - Small (10" x 6" x 6") size shipping box
 - One lower threshold (0° C) temperature monitor per pressure bag
 - Packing material
 - Plastic envelope
 - 2" packing tape
 - UN 3373 label
 - Two orientation arrow labels

- Shipping Airbill or Waybill (FedEx or World Courier, respectively)
 - Study Center address label (preprinted)
 - Repository address label (preprinted)—The shipment address and contact information for the repository will be provided by the Coordinating Center.
4. Create a new shipment in BEST. Record the status of the lower temperature threshold monitor when creating the shipment.
 5. Retrieve the ambient blood storage units to be shipped, according to the storage location indicated in BEST. Each pressure bag should contain one ACD tube.
 6. Access the shipment in BEST and add storage units to the shipment by wanding the storage label on each pressure bag with the bar code scanner.
 7. Generate a Biospecimen Shipping Manifest Form from BEST. For detailed instructions on generating the form, refer to the BEST User's Guide. If BEST is not available at the time the daily shipment is prepared, the hard copy back-up version of the form must be used (see Appendices 1-A and 1-B for form and field-by-field instructions). Follow the instructions provided to complete the form.
 8. Verify that the contents of the shipment match the Biospecimen Shipping Manifest Form. The storage unit number on each bag should match what is listed on the form. If discrepancies are found, reconcile the shipment contents in BEST and generate a new Biospecimen Shipping Manifest Form.
 9. Retrieve one lower threshold (0° C) temperature monitor for each ACD tube to be shipped. Place a monitor in the available tube slot inside each foam tube holder. Place the foam tube holder back in the pressure bag along with the absorbent pad.
 10. Seal the pressure bag in accordance with the printed instructions found on the reverse side of the bag.
 11. Place a layer of crumpled packing material on the bottom of the fiberboard box.
 12. Place the pressure bag/s in the insulated shipper on top of the packing material.
 13. Place packing material on top of the bags and fill in any holes or spaces to stabilize the package contents.
 14. Place the Biospecimen Shipping Manifest Form in a plastic envelope and place it in the box.
 15. Close the fiberboard box and tape all seams or flaps with packing tape.
 16. Complete the FedEx Airbill or World Courier Waybill (see Appendices 1-C and 1-D of this part and volume).

17. Enter the shipment tracking number in BEST by typing in the eye-readable number on the Airbill or Waybill or wanding the bar code if applicable.
18. Insert the Airbill in a plastic sleeve or affix it directly to the outside of the shipping box.
19. Label the outside of the fiberboard box according to the instructions in the following section.

4.1.2 Labeling Ambient Blood Tube Shipments

All shipments containing ambient blood specimens must be labeled as described in this section. The instructions given in this section meet Federal regulations for Category B substances, the International Air Transportation Association (IATA) Regulations for the Transport of Dangerous Goods, and shipping vendor requirements for the labeling of biologic specimens for shipment.

The UN 3373 label must be affixed to a vertical side of the fiberboard box, not the top or bottom, and the Airbill should be placed on the top of the package. It is important that all labels are securely attached to the fiberboard box and that the labels do not overlap. Use only the labels provided by the Coordinating Center, which meet the specific font and format labeling requirements.

Use the following instructions to label each fiberboard box.

1. Affix a UN 3373 label designating the UN identification number (ID) for Category B substances. This label also includes the required text to identify the proper shipping name: “Biological Substance, Category B.”
2. Affix one orientation arrow label on each of two opposite vertical sides of the box, with the arrows pointing in the correct upright direction.
3. Affix a preprinted label with the complete name and address of the Study Center SPSC (i.e., the shipper). Note that this action is required in addition to recording this information on the Airbill.
4. Attach a preprinted label with the complete name and address of the repository (i.e., the consignee). Note that this action is required in addition to recording this information on the Airbill.
5. Handwrite legibly or attach a preprinted label with the name and telephone number of the party responsible in case of emergency. This information will be provided by

the Coordinating Center and will be utilized in the event of an emergency response situation. Note that this action is required to meet IATA regulations for shipping Category B shipments.

6. Notify the shipping vendor of the shipment pick-up time and location, unless there is a regularly scheduled pick-up. Store prepared shipments in a cool, dry location prior to pick-up.

After the shipment is picked up by the shipping vendor, use the following steps:

1. Access the shipment in BEST and click “SHIP.” This action makes the shipment available for the repository to view and receipt the shipment in BEST. Do not click “SHIP” until the shipment is picked up by the vendor.
2. Click “EZ-NOTIFY” to send an electronic notification to the repository that the shipment is underway. An electronic version of the shipping manifest will automatically be attached to the email. If BEST is not available, the repository must be contacted via email or telephone for notification of the shipment.

4.2 Packing and Labeling Ambient (Fixed) Placenta Shipments

4.2.1 Packing Ambient (Fixed) Placenta Shipments

Fixed placenta specimens will be shipped to the NCS histology laboratory. Please note that these shipments should only be shipped using FedEx on Mondays–Wednesdays.

The following provides basic procedures for the preparation of ambient (fixed) placenta shipments. Refer to the BEST User’s Guide for more detailed instructions on how to use BEST to implement these procedures.

1. Put on a laboratory coat and gloves (face shield or goggles are recommended)
2. Assemble the materials needed to prepare the package (two to three fixed placenta specimens may be shipped in one package)
 - Large (15” x 13” x 12”) size shipper (outer box with insulated styrofoam chest)
 - Cardboard sheets (to keep placentas flat)
 - Extra formalin resistant absorbent pads

- Packing material
 - Packing tape
 - Clear plastic envelope (for shipping manifest)
 - Shipper's Declaration for Dangerous Goods, four copies (see Appendix 4-A for sample form and instructions)
 - Plastic pouch (for Shipper's Declaration)
 - FedEx Airbill
 - Two orientation arrow labels (if red or black arrows are not preprinted on shipper)
 - Combined UN3334/Class 9/Formalin hazard label
 - Emergency contact information label (preprinted Avery label)
 - Study Center address label (preprinted Avery label)
 - Histology Laboratory address label (preprinted Avery label)—The shipment address and contact information for the histology laboratory will be provided by the Coordinating Center.
3. Create a new shipment in BEST.
 4. Retrieve the placenta specimen to be shipped, according to the storage location indicated in BEST. The specimen and formalin solution should be enclosed within two (or three if leaks were present upon specimen receipt) sealed formalin resistant polyethylene bags, within a large pressure bag.
 5. Confirm that the secondary polyethylene bag contains a 500 mL absorbent pad. If no 500 mL absorbent pad is inside the secondary bag, place one inside the bag.
 6. Confirm that the pressure bag contains a formalin resistant absorbent pad. If no formalin resistant absorbent pad is inside the pressure bag, place one inside the bag.
 7. Gently remove excess air from the pressure bag and seal the bag in accordance with the printed instructions on the reverse side of the bag.
 8. Access the shipment in BEST and add the storage unit to the shipment by wand in the storage label on the pressure bag with the bar code scanner.
 9. Generate a Biospecimen Shipping Manifest Form from BEST. For detailed instructions on generating the form, refer to the BEST User's Guide.

10. Verify that the contents of the shipment match the Biospecimen Shipping Manifest Form. The storage unit number on each bag should match what is listed on the form. If discrepancies are found, reconcile the shipment contents in BEST and generate a new Biospecimen Shipping Manifest Form.
11. Place the sealed pressure bag on the bottom of the insulated shipper, being careful to keep the placenta as flat as possible.
12. Place a cardboard sheet on top of the pressure bag to keep the contents flat. If packing multiple fixed placentas, place a cardboard sheet between each specimen.
13. Fill the box to the top with packing material. The box should be packed tightly to avoid movement or shifting of the contents inside the shipping box. Place the foam lid on the styrofoam chest.
14. Affix a plastic envelope to the top of the foam lid and place the Biospecimen Shipping Manifest Form in the envelope.
15. Close the fiberboard box and tape all seams or flaps with packing tape.
16. Complete the FedEx Airbill (see Appendix 1-C of this part and volume). Be sure to complete all required sections of the Airbill. Be sure to check the box that indicates that a Shipper's Declaration is required (see the Airbill's Section 6—Special Handling).
17. Enter the shipment tracking number in BEST by typing in the eye-readable number on the Airbill or wand in the bar code if applicable.
18. Insert the Airbill in the plastic pouch and affix it to the outside of the shipping box.
19. Complete four copies of the Shipper's Declaration for Dangerous Goods form following the instructions provided in Appendix 4-A. *All four copies of the form must be printed in color with a red hatched border.* Black and white copies are not acceptable. Specific fields must be typed and may not be handwritten.
20. Place three copies of the Shipper's Declaration for Dangerous Goods inside the plastic pouch on the outside of the box. Do not seal the pouch for FedEx courier inspection.
21. Retain and file one copy of the Shipper's Declaration for Dangerous Goods at the SPSC.
22. Label the outside of the box according to the instructions in Section 4.2.2.

4.2.2 Labeling Ambient (Fixed) Placenta Shipments

All shipments containing fixed placenta specimens in formalin must be labeled as instructed in this section. These instructions meet Federal and IATA regulations and shipping vendor requirements for the shipping of biologic specimens and formalin (an aviation regulated liquid).

UN 3334 and Class 9 labels must be affixed to a vertical side of the fiberboard box, not the top or bottom, and the Airbill and address labels should be placed on the top of the package. It is important that all labels are securely attached to the fiberboard box and that the labels do not overlap. If the box has preprinted “up” arrows, avoid placing labels over the arrows. Use only the labels provided by the Coordinating Center, which meet the specific font and format labeling requirements.

Use the following instructions to label each fiberboard box:

1. Affix a combined UN 3334/Class 9/Formalin hazard label to the box. This label designates the appropriate UN identification number (ID), class, and proper shipping name for formalin: Aviation Regulated Liquid, N.O.S. (10% Buffered Formalin).
2. Affix a preprinted label with the complete name and address of the Study Center SPSC (i.e., the shipper). Note that this action is required in addition to recording this information on the Airbill.
3. Affix a preprinted label with the complete name and address of the histology laboratory (i.e., the consignee). Note that this action is required in addition to recording this information on the Airbill.
4. Hand write legibly or attach a preprinted label with the name and telephone number of the party responsible in case of emergency. This information will be provided by the Coordinating Center and will be used in the event of an emergency response situation. Note that this action is required to meet IATA regulations.
5. If the shipper does not have preprinted red or black orientation arrows (“up” arrows), affix one orientation arrow label on each of two opposite vertical sides of the outer box, with the arrows pointing in the correct upright direction.
6. Notify the shipping vendor of the shipment pick up time and location, unless there is a regularly scheduled pick-up. Store prepared shipments in a cool, dry location prior to pick-up.

After the shipment is picked up by the shipping vendor, do the following:

1. Access the shipment in BEST and click “SHIP.” *Do not click “SHIP” until after the shipment is picked up by the vendor.*
2. Click “EZ-NOTIFY” to send an electronic notification that the shipment is underway. An electronic version of the shipping manifest will automatically be attached to the email. If BEST is not available, the histology laboratory must be contacted via email or telephone for notification of the shipment.

4.3 Packing and Labeling Ambient Non-Blood Shipments

4.3.1 Packing Ambient Non-Blood Shipments

Ambient non-blood shipments include hair, toenails, vaginal slides, BNC saliva, and Flinders Technology Associates (FTA) mini infant blood spot cards. All storage units containing ambient non-blood specimens should be shipped monthly using FedEx.

The following provides basic procedures for the preparation of ambient non-blood specimen shipments. Refer to the BEST User’s Guide for more detailed instructions on how to use BEST to implement these procedures.

1. Put on a lab coat and gloves.
2. Determine the number of ambient storage units to be shipped and the number of small size shippers needed. One ambient storage unit corresponds to one ambient pressure bag, one ambient gallon-size Ziplock bag, or one multi-barrier pouch for infant blood spot cards.
3. Assemble the materials needed to prepare each package:
 - Small (10” x 6” x 6”) size shipping box
 - Bubble wrap (for slides only)
 - Rubber band (for slides only)
 - Packing material
 - Clear plastic envelope
 - Packing tape

- Preprinted label—Exempt Human Specimen
 - FedEx Airbill
 - Study Center address label (preprinted)
 - Repository address label (preprinted)—The shipment address and contact information for the repository will be provided by the Coordinating Center.
4. Create a new shipment in BEST.
 5. Retrieve the ambient storage units to be shipped, according to the storage location indicated in BEST.
 6. Seal each pressure bag in accordance with the printed instructions found on the reverse side of the bag.
 7. Remove the cardboard slide holders containing the vaginal slides from the Ziplock bag and wrap them securely in bubble wrap to prevent breakage of slides during shipping. Secure with a rubber band. Place the wrapped slides back in the Ziplock bag and seal the bag.
 8. Place a layer of crumpled packing material on the bottom of the fiberboard box.
 9. Access the shipment in BEST and add storage units to the shipment by wand the storage label on each pressure bag with the bar code scanner.
 10. Generate a Biospecimen Shipping Manifest Form from BEST. For detailed instructions on generating the form, refer to the BEST User's Guide.
 11. Verify that the contents of the shipment match the Biospecimen Shipping Manifest Form. The storage unit number on each bag should match what is listed on the form. If discrepancies are found, reconcile the shipment contents in BEST and generate a new Biospecimen Shipping Manifest Form.
 12. Place packing material on top of the bags and fill in any holes or spaces to stabilize the package contents.
 13. Affix a plastic envelope to the top of the foam lid and place the Biospecimen Shipping Manifest Form in the envelope.
 14. Close the fiberboard box and tape all seams or flaps with packing tape.
 15. Complete the FedEx Airbill (see Appendix 1-C of this part and volume). Be sure to complete all required sections of the Airbill.
 16. Enter the shipment tracking number in BEST by typing in the eye-readable number on the Airbill or wand the bar code if applicable.

17. Insert the Airbill in a plastic sleeve or affix it directly to the outside of the shipping box.
18. Label the outside of the fiberboard box as according to the instructions in the following section.

4.3.2 Labeling Ambient Non-Blood Shipments

All shipments containing ambient non-blood biospecimens must be labeled as described in this section. The instructions meet Federal regulations for exempt human specimens and shipping vendor requirements for the labeling of biologic specimens for shipment.

Labels must be affixed to a vertical side of the fiberboard box, not the top or bottom, and the Airbill should be placed on top of the package. It is important that all labels are securely attached to the fiberboard box and that the labels do not overlap. Use only the labels provided by the Coordinating Center, which meet the specific font and format labeling requirements.

Use the following instructions to label each fiberboard box:

1. Affix an Exempt Human Specimen label on a vertical side of the package.
2. Affix a preprinted label with the complete name and address of the Study Center SPSC (i.e., the shipper). Note that this action is required in addition to recording this information on the Airbill.
3. Affix a preprinted label with the complete name and address of the repository (i.e., the consignee). Note that this action is required in addition to recording this information on the Airbill.
4. Notify the shipping vendor of the shipment pick-up time and location, unless there is a regularly scheduled pick-up. Store prepared shipments in a cool, dry location prior to pick-up.

After the shipment is picked up by the shipping vendor:

1. Access the shipment in BEST and click “SHIP.” This action makes the shipment available for the repository to view and receipt the shipment in BEST. *Do not click “SHIP” until the shipment is picked up by the vendor.*
2. Click “EZ-NOTIFY” to send an electronic notification to the repository that the shipment is underway. An electronic version of the shipping manifest will

Shipping Procedures for Ambient Biospecimens


automatically be attached to the email. If BEST is not available, the repository must be contacted via fax or phone for notification of the shipment.

Part 5

Appendix 4-A

Shipper's Declaration for Dangerous Goods:
Instructions and Sample Form

**Appendix 4-A.
Shipper's Declaration for Dangerous Goods:
Instructions and Sample Form**

| SHIPPER'S DECLARATION FOR DANGEROUS GOODS | | | | (Provide at least three copies to the airline.) | | |
|--|---|--|-----------------|--|---------------|---------------|
| Shipper Study Center SPSC address | | Air Waybill No. 1234 5678 9999 Page 1 of 1 Pages Shipper's Reference Number <i>(optional)</i> | | | | |
| Consignee NCS Histology Laboratory address | |  | | | | |
| <i>Two completed and signed copies of this Declaration must be handed to the operator</i> | | WARNING Failure to comply with all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. | | | | |
| TRANSPORT DETAILS | | | | Shipment type: <i>(delete non-applicable)</i> <input type="checkbox"/> NON-RADIOACTIVE <input checked="" type="checkbox"/> RADIOACTIVE | | |
| This shipment is within the limitations prescribed for: <i>(delete non applicable)</i> | | Airport of Departure | | | | |
| <input type="checkbox"/> PASSENGER AND CARGO AIRCRAFT | <input checked="" type="checkbox"/> CARGO AIRCRAFT ONLY | | | | | |
| Airport of Destination: | | | | | | |
| NATURE AND QUANTITY OF DANGEROUS GOODS | | | | | | |
| Dangerous Goods Identification | | | | | | |
| UN or ID No. | Proper Shipping Name | Class or Division (Subsidiary Risk) | Pack- ing Group | Quantity and type of packaging | Packing Inst. | Authorization |
| UN 3334 | Aviation regulated liquid, n.o.s. (10% buffered formalin) | 9 | | # mL Double bagged inside a 95kPa pressure bag. All packaged in an outer fiberboard box. | 906 | |
| Additional Handling Information | | | | | | |
| I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable International and National Governmental Regulations. I declare that all of the applicable air transport requirements have been met. | | | | Name/Title of Signatory Shipper's name Place and Date City, state and today's date Signature <small>[A typed signature may be used if the origin and destination are in the United States or its territories.] (see warning above)</small> | | |
| (123) 555-1212 | | | | Emergency Telephone Number | | |
| FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT, THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT. ADR EUROPEAN TRANSPORT STATEMENT: CARRIAGE IN ACCORDANCE WITH 1.1.4.2.1 | | | | | | |

Shipping Procedures for Ambient Biospecimens

Please note the following important instructions before completing the Shipper's Declaration for Dangerous Goods. This form must be completed for all fixed placenta shipments containing 10 percent formalin solution.

1. FedEx provides interactive Shipper's Declaration for Dangerous Goods form templates that may be downloaded from the following website in either a PDF or Microsoft Word format:
<http://www.fedex.com/us/services/options/dangerousgoods/declarationforms.html>
2. All four copies of the form *must* be printed in color and must have a red hatched border; *black and white copies are not acceptable*. Three copies of the form should be placed in the plastic pouch on the outside of the shipping box. One copy should be retained at the SPSC.
3. Specific fields on the form *must* be typed and may not be handwritten. The following fields should be completed electronically using the template provided. The remaining fields may be completed manually.
 - UN ID Number
 - Proper Shipping Name
 - Class or Division
 - Quantity and type of packaging
 - Packing Instruction
 - Emergency Telephone Number

To complete the form, follow these instructions:

1. Shipper
 - Enter the shipper's name and the address of the Study Center SPSC.
2. Consignee
 - Enter the name and address of the NCS Histology Laboratory.
3. Air Waybill No.
 - Enter the tracking number from the FedEx Airbill.

4. Page __ of __ Pages
 - Enter “1” of “1”
5. Transport Details
 - Select “Passenger and Cargo Aircraft.”
6. Airport of Departure
 - Leave blank.
7. Airport of Destination
 - Leave blank.
8. Shipment Type
 - Select “Non-Radioactive.”
9. UN or ID No. (*must be typed*)
 - Enter “UN3334”.
10. Proper Shipping Name (*must be typed*)
 - Enter “Aviation regulated liquid, n.o.s. (10% buffered formalin)”.
11. Class or Division (Subsidiary Risk) (*must be typed*)
 - Enter “9”.
12. Quantity and type of packaging (*must be typed*)
 - Enter the total number of mL of 10 percent formalin contained in the package, estimating the volume as approximately 500 mL per fixed placenta.
 - Describe the type of packaging used.
13. Packing Inst. (*must be typed*)
 - Enter “906.”
14. Emergency Telephone Number (*must be typed*)
 - Enter the contact number provided by the Coordinating Center.

Shipping Procedures for Ambient Biospecimens

15. Name/Title of Signatory

- Enter name of person responsible for shipping package.

16. Place and date

- Enter the city and state and today's date.

17. Signature

- Sign the form inside the box. The signature must be legible. By signing the form, you are signing the shipper's declaration printed on the left side of the form.