

## **CHAPTER 8 NIDDK DNA REPOSITORY SAMPLE COLLECTION, PROCESSING AND SHIPMENT**

Along with providing samples directly to the NIDDK Biosample Repository at Fisher BioServices, clinical centers are asked to draw a single 10 ml EDTA blood tube for shipment to the NIDDK DNA Repository at the Fred Hutchinson Cancer Research Center in Seattle, WA. There the blood will be processed for DNA extraction and short-term storage. With the exception of phlebotomy draw kits and package sealing tape, all materials for this portion of the HFM Study will be provided directly to the clinical centers by the NIDDK DNA Repository in the form of “DNA Collection Kits”. Each clinical center will receive five pre-constructed kits from the NIDDK DNA Repository prior to study opening. Once the clinical center gets down to two kits, the clinical center should contact the NIDDK DNA Repository to request replacements.

### **8.1 Tubes for Collecting Specimens (Lavender Top EDTA Tube for DNA Extraction)**

Whole blood for DNA procurement is to be drawn using one 10ml Vacutainer™ tube containing the anticoagulant EDTA. This tube will be included in the DNA collection kit supplied to the clinical center by the NIDDK DNA Repository. If any problems arise and replacement tubes are required immediately, the standard tube being used is a 10 ml K<sub>2</sub>EDTA/lavender top tube (BD product #366643).

In addition to the 10 ml K<sub>2</sub>-EDTA Vacutainer™ Blood Draw Tube, a standard phlebotomy draw kit is required. The **clinical center** is responsible for all supplies associated with standard phlebotomy draw kits:

- Vacutainer™ holders/hub/needles
- Alcohol wipes or swabs
- Sterile cotton or 2x2 sterile gauze pads/band aids
- Adhesive tape
- Disposable latex gloves
- Tourniquets
- Biohazard labels/needle disposal boxes/bags
- Parafilm to secure blood tube lid to tube

### **8.2 Mailing Supplies**

Several supplies are needed to ensure that the shipment not only delivers a viable sample to the NIDDK DNA Repository but also meets the United States and International regulations governing the transport of diagnostic specimens (International Air Transport Association: IATA):

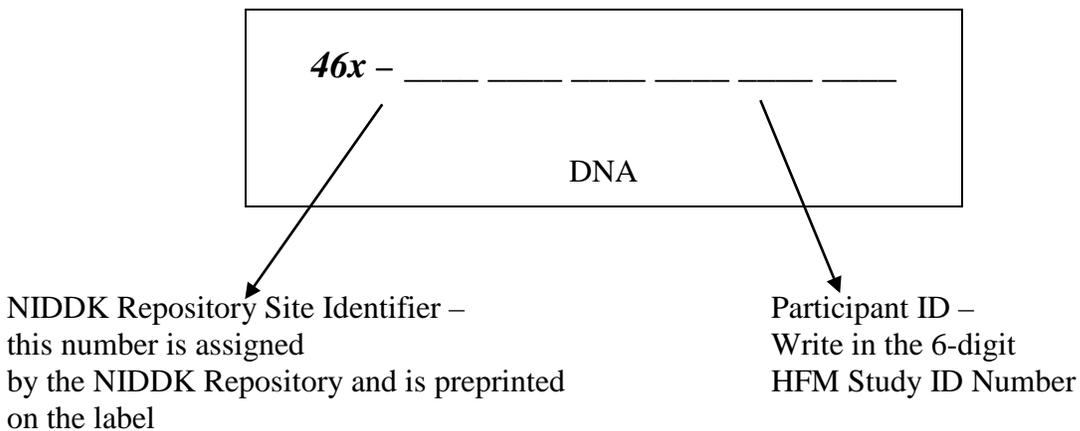
Fisher Scientific 0352825: ThermoSafe Diagnostic Shipper w/out tubes (4.25x3.88x5.75). Conforms with DOT, USPS, IATA packing instruction 650. Includes absorbent material, poly bag, carton.

- Fisher Scientific 0352826: Three tube EPS foam mailer with lid
- Fisher Scientific NC9071872: ThermoSafe Polar Pack 8 oz (Ambient use only)
- FedEx Large Clinic Pak with FedEx US Air Bill Pouch
- Package sealing tape
- Preprinted FedEx mailing labels OR online FedEx Account Manager Access.

All materials necessary for shipment to the NIDDK DNA Repository will be supplied to the clinical center in kit form. The repository will construct a complete kit of the above mailing supplies plus one 10 ml EDTA blood collection tube. The only materials that will need to be supplied by the clinical center are the materials for the phlebotomy kits and clear package sealing tape.

### 8.3 Tube Labels

Patient ID labels will be provided to the clinical center by the DCC. The labels serve as a sample de-identifier and link the different participant samples (e.g., serum, DNA, tissue) together. The paper label will consist of the NIDDK clinical center identifier, the patient ID and the sample type (DNA).



Prior to venipuncture, the label is placed by the coordinator/phlebotomist on the collection tube. Use Scotch tape to secure labels if they appear to be coming off or are not adhesive enough to remain on tube during shipment. It is important for all samples to arrive at the NIDDK DNA Repository with the proper label attached.

A duplicate ID label should also be affixed to the HFM Study DNA/Plasma Specimen to NIDDK/ DNA Repository Mailing Form 607. Form 607 contains additional draw information such as date/time of draw, and any issues experienced during draw. Form 607 should be completed after the draw and included in the blood shipment to the NIDDK DNA Repository. All correspondence referencing the participant should be done using the patient ID to protect patient identity during transport and beyond.

### 8.4 Instructions for Drawing Blood for DNA

One standard 10 ml K<sub>2</sub>-EDTA (lavender top tube) blood tube is to be collected on each

participant for the purposes of this study. Approved clinical center procedures for the collection and processing of blood should be followed, while observing Universal Precautions. Only trained personnel should perform the procedures.

After tube is filled (10 ml), invert 10 times to ensure complete mixture with anticoagulant and the prevention of clotting. No spinning is required. The tube needs to remain at **ROOM TEMPERATURE** until shipped. At no point during the draw/shipping process should the sample be refrigerated or frozen.

At the time of draw, complete HFM Study DNA/Plasma Specimen to NIDDK/ DNA Repository Mailing Form 607 (provided by DCC) with clinical center address, contact numbers and collection information. Make one copy of the form and retain for clinical center records. Include the original form in the shipment with the EDTA blood sample to the NIDDK DNA Repository in Seattle.

### **8.5 Sample Storage and Mailing to DNA Processing Facility**

It is preferable that EDTA blood samples be shipped on day of draw for arrival to the NIDDK DNA Repository within 24 hours. Priority Overnight Federal Express Courier will be the required shipping method and samples must be sent at ambient temperature (no refrigeration or ice necessary).

The NIDDK DNA Repository will be open for specimen receipt 7:00 am to 5:00 pm **Pacific Time** Monday through Friday excluding bank holidays. Saturday delivery is also acceptable with proper notification to the NIDDK DNA Repository.

If problems are experienced, remember two simple rules:

**Ship as soon as possible**

**ALWAYS keep samples at room temperature.**

It is recommended that the clinical center contact the NIDDK DNA Repository if sample shipment is delayed, if issues arise or if there are any questions.

1. To pack the specimen properly for shipment:
2. Ensure rubber stopper of each filled specimen tube is tight. Secure with parafilm.
3. Verify tube is labeled correctly and label is well adhered to tube surface. Secure with Scotch tape if necessary. Verify tube label matches label placed on associated paperwork.
4. Place tube into the body of the foam mailer and cover the tube with the absorbent material.
5. Place the lid of the foam mailer over the tubes and the absorbent material. Press lid firmly until all sides of the lid meet the sides of the body.
6. Secure the lid to the body of the foam mailer using the supplied red, waterproof tape by wrapping the tape around the seam, overlapping the ends by one inch.
7. Place the sealed foam mailer into the press-lock bag (do not zip shut\*); include folded and completed HFM Study DNA/Plasma Specimen to NIDDK/ DNA Repository Mailing Form 607 in bag.
8. Slide foam mailer in unsealed bag into the corrugated mailing carton.
9. Slide **ambient temperature** gel pack (8 oz) into remaining space of corrugated mailing carton. Seal the press-lock bag tightly\*. Close locking tabs.
  - *If press-lock bag is sealed before placement of foam mailer and gel pack into corrugated carton the air pressure can damage the bag.*
10. Use package-sealing tape over the locking tabs of the mailer.
11. Place entire mailer inside of FedEx Large Collection center Pak. Seal pak tightly. Place provided UN3373 diagnostic specimen sticker (IATA 650 compliance) on outside of FedEx Pak
12. Complete and Affix pre-labeled FedEx Air bill (see below) to outside of pak and notify FedEx of pickup.
13. Email NIDDK DNA Repository to alert of pending shipment ([rcb@fhcrc.org](mailto:rcb@fhcrc.org)).



The procedures for packing specimens outlined above comply with current shipping regulations for diagnostic specimens, but it is recommended that sites receive formal training in IATA Packaging and Shipping Procedures.

You have the option of generating shipping labels via the online FedEx Ship Manager or using the pre-labeled FedEx Air bill labels supplied by the NIDDK DNA Repository with the shipping supplies.

If using the pre-labeled FedEx Air Bill supplied by the NIDDK DNA Repository:

Along with supplying sender information in section 1, ensure the following boxes are checked:

- 4a Express Package Service: FedEx Priority Overnight
- 5 Packaging: FedEx Pak
- 6 Special Handling:
- ‘No’ for “Does this shipment contain hazardous goods?”
- Blood, packaged properly, is not considered a hazardous good by FedEx standards.
- ‘Saturday Delivery’ if shipped on Friday.
- 7 Payment: Recipient

Account number for NIDDK DNA Repository: 151716687

Retain top copy of airbill for clinical center records and attach remaining copies on the outside of the FedEx UN3373 Pak via the US Domestic Air Bill Sleeve. Bring to designated FedEx drop-off. If Saturday delivery is necessary, ensure “Saturday delivery” stickers are also affixed to outside of pack.

Example of completed FedEx US Air Bill:

		FedEx Tracking Number: <b>8704 9168 4389</b>	Form ID No. <b>0215</b>	Sender's Copy
<b>1 From</b> <small>Please print and press hard</small>		Sender's FedEx Account Number: <b>SENDER NA</b>	<b>4a Express Package Service</b> <small>** To most locations.</small>	
Date: <b>11.20.09</b>	Sender's Name: <b>Miguel Vazquez</b>	Phone: <b>(254) 132-1450</b>	<input checked="" type="checkbox"/> FedEx Priority Overnight <small>Next business morning. * Prior shipments will be delivered on Monday unless SATURDAY Delivery is selected.</small>	<input type="checkbox"/> FedEx Standard Overnight <small>Saturday Delivery NOT available.</small>
Company: <b>University of Florida</b>	Address: <b>2100 University Avenue</b>	City: <b>Gainesville</b>	<input type="checkbox"/> FedEx 2Day <small>Second business day. ** Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected.</small>	<input type="checkbox"/> FedEx Express Saver <small>Third business day. ** Saturday Delivery NOT available.</small>
State: <b>FL</b>	ZIP: <b>32611</b>	City: <b>Gainesville</b>	<b>4b Express Freight Service</b> <small>** To most locations.</small>	
State: <b>FL</b>	ZIP: <b>32611</b>	City: <b>Gainesville</b>	<input type="checkbox"/> FedEx 1Day Freight <small>Next business day. ** Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected.</small>	<input type="checkbox"/> FedEx 2Day Freight <small>Second business day. ** Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected.</small>
State: <b>FL</b>	ZIP: <b>32611</b>	City: <b>Gainesville</b>	<input type="checkbox"/> FedEx 3Day Freight <small>Third business day. ** Saturday Delivery NOT available.</small>	<input type="checkbox"/> FedEx 3Day Freight <small>Third business day. ** Saturday Delivery NOT available.</small>
<b>2 Your Internal Billing Reference</b> <small>FedEx ClientReference will appear on invoice.</small>	<b>207062</b>	City: <b>Gainesville</b>	<b>5 Packaging</b> <small>* Declared value limit \$500</small>	
Recipient's Name: <b>GARY OLSEM D2-345</b>	Phone: <b>(206) 667-3756</b>	City: <b>Gainesville</b>	<input type="checkbox"/> FedEx Envelope*	<input checked="" type="checkbox"/> FedEx Pak* <small>Includes FedEx SurePost Pak, FedEx Large Pak, and FedEx Study Pak.</small>
Company: <b>FRED HUTCHINSON CR</b>	Address: <b>1100 FAIRVIEW AVE N</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> FedEx Box	<input type="checkbox"/> FedEx Tube
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> Other	<input type="checkbox"/> Other
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<b>6 Special Handling and Delivery Signature Options</b>	
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> SATURDAY Delivery <small>NOT available for FedEx Standard Overnight, FedEx First Overnight, FedEx Express Saver, or FedEx 3Day Freight.</small>	<input type="checkbox"/> No Signature Required <small>Package may be left without obtaining a signature for delivery.</small>
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> Direct Signature <small>Someone at recipient's address may sign for delivery. See options.</small>	<input type="checkbox"/> Indirect Signature <small>If no one is available at recipient's address, someone at a neighboring address may sign for delivery. See options.</small>
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<b>Does this shipment contain dangerous goods?</b>	
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <small>As per attached Shipper's Declaration, not required.</small>
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> Yes <small>As per attached Shipper's Declaration, not required.</small>	<input type="checkbox"/> Dry Ice <small>Dry Ice 9, IATA 1845</small>
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> Cargo Aircraft Only	<input type="checkbox"/> Cargo Aircraft Only
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State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> Sender <small>Account No. in Section 1 will be billed.</small>	<input checked="" type="checkbox"/> Recipient
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> Third Party	<input type="checkbox"/> Credit Card
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> Cash/Check	<input type="checkbox"/> Cash/Check
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	FedEx Acct. No. <b>1541-8338-8</b>	FedEx Acct. No. <b>1541-8338-8</b>
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	Total Packages: <b>1</b>	Total Weight: <b>1</b>
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State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> Signature Required <small>Signature of recipient or authorized agent required.</small>	<input type="checkbox"/> Signature Required <small>Signature of recipient or authorized agent required.</small>
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> Signature Required <small>Signature of recipient or authorized agent required.</small>	<input type="checkbox"/> Signature Required <small>Signature of recipient or authorized agent required.</small>
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> Signature Required <small>Signature of recipient or authorized agent required.</small>	<input type="checkbox"/> Signature Required <small>Signature of recipient or authorized agent required.</small>
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State: <b>WA</b>	ZIP: <b>98109-4433</b>	City: <b>SEATTLE</b>	<input type="checkbox"/> Signature Required <small>Signature of recipient or authorized agent required.</small>	<input type="checkbox"/> Signature Required <small>Signature of recipient or authorized agent required.</small>
State: <b>WA</b>	ZIP: <b>98109-4433</b>	City:		

If using the online FedEx Ship Manager:

In order to use the online FedEx Ship Manager to generate shipping labels, the clinical center will need to have/create a FedEx account. Once that is set up, login to [www.FedEx.com](http://www.FedEx.com) and create clinical center's log in/password. Log in and proceed as outlined below.

Fill in Recipient Information as follows:

- Research Cell Bank  
c/o Jenna Gravley  
1100 Fairview Ave N D2-346  
Seattle, WA 98109  
1.206.667.3756
- Service Type: Priority Overnight
- Package Type: FedEx Pack
- No of Packages: 1
- Weight: 1 lbs
- Declared Value: \$0
- Bill transportation to: Third Party
- Account number: 151716687
- Your reference: HFM Study
- Email Notification: Set up to send "Ship" email to [rcb@fhcrc.org](mailto:rcb@fhcrc.org)

Verify shipping information and print packing slip.

Insert slip into FedEx US Domestic Air Bill Sleeve, place on package and bring to designated FedEx pick up. If Saturday delivery is necessary, ensure "Saturday delivery" stickers are also affixed to outside of pack and shipping slip is marked appropriately.

### **8.6 Contact and Shipping Information for NIDDK DNA Repository**

The EDTA DNA blood sample should be sent to the NIDDK DNA Repository at the below address. Use this contact for any questions or problems regarding the shipment or any part of the draw procedures listed in Section 8.

Complete Form 607 Mailing Form. Enter information into HFM Study Database, keep copy, and send original to the NIDDK DNA Repository.

NIDDK DNA Repository:

Research Cell Bank  
Fred Hutchinson Cancer Research Center  
c/o Jenna Gravley  
1100 Fairview Ave N  
D2-346  
Seattle, WA 98109

1.206.667.3756 or 1.206.667.1450  
[rcb@fhcrc.org](mailto:rcb@fhcrc.org) or [jgravley@fhcrc.org](mailto:jgravley@fhcrc.org)  
1.206.667.5255 Fax

## **8.7 Certification Shipments**

Each clinical center will be required to ship one certification test sample before being cleared for official HFM Study sample shipments. Follow instructions outlined in section 8 of the MOP. In place of blood, 10 ml of water placed in the EDTA tube can be used to mimic a blood sample during shipment. Once received at the NIDDK DNA Repository, the box/shipment/sample/paperwork will be assessed and any discrepancies from the MOP will be noted along with a “pass” or “fail” designation. This information will then be forwarded to both the clinical center and the DCC. A “pass” designation is required before clinical centers are allowed to ship official HFM Study patient samples to the NIDDK DNA Repository. If a “fail” designation is filed, the clinical center will be asked to correct the errors and repeat the shipment.

## **8.8 DNA Biorepository Sample Processing and Specimen Transfer to NIDDK Repository**

Once the 10 ml EDTA blood sample has been received in Seattle, the NIDDK DNA Repository will log in the sample, extract DNA with applicable quality control measurements and provide short-term storage for the resulting DNA stock cryonunc. Upon completion of the HFM Study program, the DNA stocks will be shipped to the long-term NIDDK Biosample Repository at Fisher BioServices in Germantown, Maryland.

### **8.8.1 Receipt and logging of EDTA blood**

The NIDDK DNA Repository will track shipments of specimens from clinical centers through FedEx tracking numbers provided by the clinical center upon packaging. The NIDDK DNA Repository is located in a facility that has 24-hour package receipt, every day of the year. However, the NIDDK DNA Repository itself will maintain the following receipt/processing schedule:

M-F: 7:00 am – 5:00 pm Pacific Time

Sat: Upon notification of pending shipment

Sun: Closed

National Bank Holidays: Closed

Shipments received after hours, without proper prior notification or on days the lab is closed will be processed as soon as possible at open of the next business day.

Upon receipt, the NIDDK DNA Repository will inspect the shipment and note any irregularities in both packing and paperwork. If problems are experienced, both clinical center and DCC will be notified to correct or highlight any issues. Once unpacked, patient ID's will be entered into the NIDDK DNA Repository database along with all demographic data received with the shipment (date and time of collection, etc). This information will be used to not only track specimens through the NIDDK DNA Repository but also to generate internal barcoded labels used during the DNA extraction

process and long-term storage.

HFM Study DNA/Plasma Specimen to NIDDK/ DNA Repository Mailing Form 607 will be stored by date in the DNA processing facility until the end of the project.

### **8.8.2 Processing of EDTA blood specimen**

The overall scope of the NIDDK DNA Repository is to produce high quality DNA stocks through extraction of the 10 ml EDTA blood tube. Various quality control methods will be employed to ensure not only sample purity/quality but also to maintain sample ID throughout the extraction process. All DNA stocks created will be stored in -80°C ultralow freezers maintained by the NIDDK DNA Repository and continuously monitored by the facility's engineering department through remote alarms.

After receipt into specimen database, the EDTA blood tubes will be spun to access volume, plasma and buffy coat (1200rpm, 5 min, ambient), then mixed with 3 volumes of Red Blood Cell Lysis Buffer (Ammonium Chloride, EDTA, Sodium Bicarbonate) in 14 ml tubes. Samples are inverted to mix and incubated at room temperature for 5 minutes. After centrifugation (3000rpm, 10 min, ambient) the supernate is discarded and pellets resuspended in 4 ml White Cell Lysis buffer (Tris, EDTA, SDS) with 20 ul RNase. Samples are vortexed and placed in overnight +37°C incubation to ensure complete lysis of white cell pellet and activation of RNase enzyme.

Once pellets are fully dissolved and cooled to room temperature, 1/3 WCLB volume of Protein Precipitation Solution (Sodium Chloride, Ammonium Acetate) is added. *Note: Samples will not be extracted upon receipt into NIDDK DNA Repository. Rather samples will be placed into white cell lysis buffer (WCLB) and held until a specified batch size is received. DNA is stable in WCLB for a period of 8 weeks.* Samples are vortexed for 20 seconds prior to centrifugation (3000 rpm, 15 min, ambient). Supernates are transferred to clean 14 ml tubes and protein pellets discarded. 5 ml 100% Isopropanol is added to supernatants. To precipitate the DNA, the samples are inverted gently 50 times and centrifuged (3000rpm, 5 min, ambient). The supernatants are decanted and the DNA is resuspended in 4 ml 70% ethanol followed by centrifugation (3000rpm, 5 min, ambient). After decanting, the DNA is air dried for 10 minutes. The DNA will be hydrated by adding various amounts of DNA Hydration Solution (10mM Tris, 1mM EDTA) depending on visual strand size.

### **8.8.3 Quality control of DNA**

After isolation and rehydration at room temperature, genomic DNA is rotated and mixed to facilitate complete hydration. The amount of DNA is determined by Spectromax spectrophotometer optical density measurement at 260 nm; the relative purity by OD 260/280 ratio. 20% of DNA stocks will also be assayed on a 1.0% agarose gel using standardized size and quantity markers. Any sample falling outside of recommended ranges for purity or gel observance will be re-extracted if possible or noted as degraded in the specimen database.

### **8.8.4 Storage and shipment of DNA**

DNA will remain as stock tubes to facilitate better long-term storage conditions unless otherwise determined by DCC as HFM Study project evolves. As previously noted, all

samples will be stored in -80°C ultralow freezers. All DNA samples generated through the HFM Study project will remain in the DNA processing biorepository during the collection period. Upon close of project, samples will be batch shipped to the long-term NIDDK Biosample Repository. Prior to shipment, the NIDDK DNA Repository will notify NIDDK Biosample Repository of shipping intent. Once approved for shipment, sample ID's will be scanned directly from tubes into the HFM Study DNA Shipment to NIDDK Biosample Repository Form (Form #606). Sample demographics (location in box, amount, quality, date collected, etc) will be added to the form from the NIDDK DNA Repository database. Samples will be packed on dry ice and shipped, along with NIDDK shipping form, via priority overnight to NIDDK Biosample Repository. Upon receipt at NIDDK, samples will again be scanned to verify shipping forms and placed into long-term storage.