

PREVENT-HD: PREPARING FOR PREVENTIVE CLINICAL TRIALS IN HUNTINGTON'S DISEASE (PHD3) Manual of Procedures

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Section	Change
Document Footer	Updated to “Version (April 2025)”
Throughout Document	Minor changes made to phrasing and wording. No alterations to procedures were made.



National Institute of Neurological Disorders and Stroke
Biorepository:

BioSpecimen Exchange for Neurological Disorders, BioSEND

Biospecimen Collection, Processing, and Shipment Manual for
PREVENT-HD: PREPARING FOR PREVENTIVE CLINICAL TRIALS IN
HUNTINGTON'S DISEASE (PHD3)

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1.0 PURPOSE

The purpose of this manual is to provide collection site staff (PIs, study coordinators, and the sample collection and processing teams) at various study sites with instructions for collection and submission of biological samples. It includes instructions for biospecimen submission to the BioSpecimen Exchange for Neurological Disorders (BioSEND) located at Indiana University.

This manual includes instructions for the collection, processing, aliquoting and shipping of the following samples:

- Plasma
- Buffy Coat (for DNA extraction)
- Whole Blood (for banking)
- CSF

These procedures are relevant to all study personnel responsible for processing blood specimens to be submitted to BioSEND.

2.0 ABBREVIATIONS

BioSEND	BioSpecimen Exchange for Neurological Disorders
CSF	Cerebrospinal Fluid
EDTA	Ethylene Diamine Tetra-acetic Acid
IATA	International Air Transport Association
PDBP	Parkinson's Disease Biomarkers Program
RBC	Red Blood Cells
RCF	Relative Centrifugal Force
RPM	Revolutions Per Minute

3.0 BioSEND INFORMATION

3.1 BioSEND Contacts

Tatiana Foroud, PhD, Principal Investigator

Claire Wegel, Project Manager

Email: cwegel@iu.edu

General BioSEND Contact Information

Phone: 317-278-6158

Email: biosend@iu.edu

Website: www.BioSEND.org

Sample Shipment Mailing Address

BioSEND

Indiana University School of Medicine 351

W. 10th Street. TK-217

Indianapolis, IN 46202-5188

3.2 Hours of Operation

Indiana University business hours are from 8 AM to 5 PM Eastern Time, Monday through Friday.

Frozen samples must be shipped Monday- Wednesday only.

For packaging and shipment details, please refer to Appendix K (Frozen Shipping Instructions).

Check the weather reports and the shipping courier website to make sure impending weather events (blizzards, hurricanes, etc.) will not impact the shipping or delivery of the samples. Couriers often report anticipated weather delays on their website.

3.3 Holiday Schedules

- Please note that courier services may observe a different set of holidays. Please be sure to verify shipping dates with your courier prior to any holiday.
- **Weekend/holiday deliveries will not be accepted.**

3.4 Holiday Observations

Date	Holiday
January 1	New Year's Day
3 rd Monday in January	Martin Luther King, Jr Day
4 th Monday in May	Memorial Day
June 19	Juneteenth (observed)
July 4	Independence Day (observed)
1 st Monday in September	Labor Day
4 th Thursday in November	Thanksgiving
4 th Friday in November	Friday after Thanksgiving
December 25	Christmas

Please note that between December 24th and January 2nd (or the first business day after New Year's Day) Indiana University will be open Monday through Friday for essential operations **ONLY** and will re-open for normal operations on January 2nd. If at all possible, biological specimens for submission to Indiana University should **NOT** be collected and shipped to Indiana University between December 24th and January 2nd. Should it be necessary to ship blood samples for DNA extraction to Indiana University during this period, please contact the Indiana University staff before December 24th by e-mailing biosend@iu.edu, so that arrangements can be made to have staff available to process incoming samples. Frozen specimens collected during this period should be held at your site to ship after the first business day in January.

Please see <https://biosend.org/holiday-closures> for additional information.

4.0 BIOSEND SAMPLE REQUIREMENTS

NINDS approves each study for a specific biospecimen collection protocol. Studies and study sites should make every effort to meet their approved biospecimen collection requirements. The expected number of samples from each site that should be returned to BioSEND are listed in [sections 4.1-4.2](#).

If a sample is not obtained at a particular visit, this should be recorded in the notes section of the **Sample Record and Shipment Notification Form (see Appendix I)**. These forms are submitted with your sample shipment to BioSEND.

4.1 Protocol Schedule for Biospecimen Submission to BioSEND- PHD3

Visit	301 (BL)	303 (18- 24M)
Blood sample for banking (EDTA tube, 6ml) frozen	1	1
RNA (PaxGene® Tube, 2.5ml), frozen	2	2
Plasma aliquots, 1.5ml	12	12
CSF aliquots, 1.5ml	13	13
Buffy Coat	4	4

5.0 SPECIMEN COLLECTION KITS, SHIPPING KITS AND SUPPLIES

Research specimen collection kits as well as clinical lab supplies (except dry ice and equipment listed in Section 5.7) will be provided by BioSEND. These materials include blood tubes, LP trays (when applicable), boxes for plasma/serum/CSF aliquots, as well as partially completed shipping labels to send materials to BioSEND. Barcoded kit labels, collection tube labels, and aliquot tube labels will all be provided by BioSEND. For sites collecting CSF, labels will also be included for the CSF aliquots to be returned to BioSEND. Collection tube labels and aliquot tube labels will be pre-printed with study information specific to the type of sample being drawn. BioSEND will provide a sufficient number of labels only for those specimens that are to be shipped back to the BioSEND repository (See the Protocol Schedule for Biospecimen Submission to BioSEND for your site in [Sections 4.1-4.2](#)); any tubes that will remain at the collection site should be labeled accordingly. Ensure that all tubes are properly labeled during processing and at the time of shipment according to [Section 6.2](#).

5.1 Kit Supply to Study Sites

Within the kit request module, there is a drop down menu to request kits based on the Principal Investigator at that site. Kits and individual items can be ordered as required through the kit request module.

The link to the kit request module is shown below:

- PHD3: <http://kits.iu.edu/biosend/PHD3>

Please allow **TWO weeks** for kit orders to be processed and delivered.

5.2 Specimen Collection Kit General Contents

Collection kits contain the following (for each subject) as designated per your protocol and/or NINDS resource development agreement. Kits provide the necessary supplies to collect samples from a given subject. Do not replace or supplement any of the tubes or kit components provided with your own supplies unless you have received approval from the NINDS/BioSEND Study team to do so. Please store all kits at room temperature until use. Note that “supplemental” kits will be provided should you require additional supplies from those contained in the visit specific kits. See the next page for LP Kit contents.

BioSEND Supplies

Available upon request from the online kit request module ([Section 5.1](#))

General Items
25 cell cryobox
Cryovial tube (2 ml) with clear cap
Airway bill envelope
Shipping container for dry ice shipment (shipping and Styrofoam® box)
Plastic biohazard bag
Warning label packet
CSF Items
Needle - Spinal Needle Introducer 20G, 0.90 x 32mm
Needle - Whitacre Needle 24G, 0.55 x 90mm
2 Individually Packaged Sterile 50 ml Conical Tube
Conical centrifuge tubes (15 ml)
Lumbar puncture tray (Sprotte® 24G or 22G) (see Lumbar Puncture Tray Components)
Blood Collection Items
Lavender-top EDTA blood collection tube (10 ml)
Purple-top EDTA blood collection tube (6 ml)
Orange-top 15mL conical tubes for separation of Plasma from Buffy Coat

We realize there may be instances where additional supplies are needed; therefore, one supplemental kit will be provided with the initial kit shipment for new studies. Replacement supplemental kits can be requested on the kit request website. In addition, individual supplies can be requested as well.

Quantity	Lumbar Puncture Tray Components
1	Sprotte® needle, 24G x 90mm <u>OR</u> Sprotte® needle, 22G x 90mm
1	Introducer needle, 1 mm x 30 mm
1	Hypodermic needle, 22G x 1.5"
1	Plastic syringe, (3 ml, luer lock) with 25G x 5/8" needle attached
4	Polypropylene syringe (6 ml, luer lock)
1	Needle stick pad
1	Adhesive bandage
1	Drape, fenestrated, 2 tabs, paper, 18" x 26"
2	Towel, 13.5" x 18"
6	Gauze pad, 2" x 2"
3	Sponge stick applicator
1	Lidocaine 1%, 5 ml
1	Povidone-Iodine Topical Solution, 0.75 oz

5.3 Specimen Collection Kit Contents – PHD3

Specimen Collection Supplies	RNA (2.5mL)	EDTA (10mL)	EDTA (6mL)	Cryovial (2ml)	LP Tray (24 or 22 gauge)	Conical Tube (50ml)	Frozen Shipping Kit
Baseline and Annual visits	2	4	1	29	1	2	1

5.4 Site Required Equipment

The following materials and equipment are necessary for the processing of specimens at the collection site and are to be **supplied by the local site**:

- Personal Protective Equipment: lab coat, nitrile/latex gloves, safety glasses
- Tourniquets
- Alcohol Prep Pads
- Gauze Pads
- Bandages
- Butterfly needles and hubs
- Microcentrifuge tube rack
- Test tube rack
- Sharps bin and lid
- Wet ice bucket (for CSF only)
- Wet ice (for CSF only)

In order to process samples consistently across all projects and ensure the highest quality samples possible, project sites must have access to the following equipment:

- Centrifuge capable of ≥ 1500 rcf ($1500 \times g$) with refrigeration to 4°C
- -80°C Freezer

In order to ship specimens, you must provide:

- Dry ice (approximately 10 pounds per shipment)

6.0 SPECIMEN LABELS

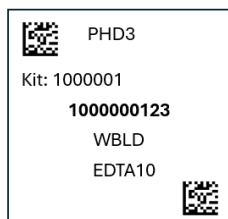
Labels must be affixed on all collection and aliquot tubes to prevent sample mix-ups and ensure chain-of-custody tracking. BioSEND provides labels for all samples being collected and returned to BioSEND. The site is responsible for providing labels for biospecimens that will be retained at the site.

6.1 Types of Labels

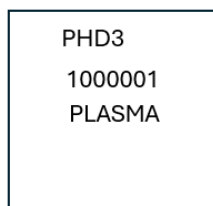
Each kit contains all labels required for the return of biospecimens to BioSEND.



The **Kit Labels** do not indicate a specimen type, but are affixed on BioSEND forms and on specific packing materials. See Appendices I-L for further instructions.



The **Collection Tube Labels for Blood** are placed on all blood collection tubes. For example, the label to the right would be placed on a 10ml EDTA tube.

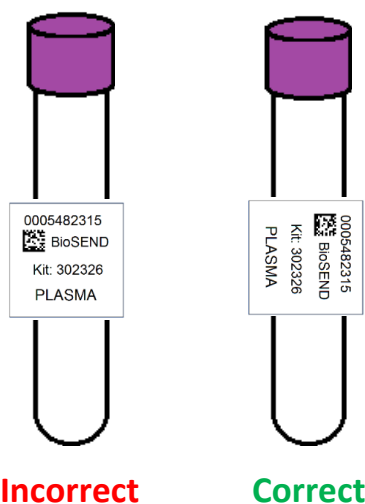


CSF, Plasma, and Buffy Coat Aliquot Tubes indicate the study abbreviation, specimen type, and Kit number. The tube itself will have a unique barcode printed in both 2D format (on bottom of tube) and human readable formats (alongside of tube). The barcoded cryovials in a kit are linked to the ID on the labels provided in that kit in the BioSEND LIMS.

6.2 Affixing Labels

In order to ensure the label adheres properly and remains on the tube, follow these instructions:

- Place blood collection labels on **ALL** collection tubes **BEFORE** sample collection, sample processing, or freezing. This will help to ensure the label properly adheres to the tube before exposure to moisture or different temperatures.
- The blood collection tube labels contain a 2D barcode on the left hand side of the label. When turned horizontally, the barcode should be closer to the top (cap end) of the tube.
- Place label **horizontally** on the tube (wrapped around sideways if the tube is upright); see below.



- For plasma and buffy coat labels, ensure the specimen label is placed on the correct cryovial. The purple cryovials should be labeled for plasma and the grey cryovials should be labeled for buffy coat.
- The barcoded cryovials in a kit are linked to the ID on the labels provided in that kit in the BioSEND LIMS. **Please do not mix the labels and cryovials from different kits.**

7.0 SPECIMEN COLLECTION AND PROCESSING PROCEDURES

Consistency in sample collection and processing is essential for biomarker studies. All samples are drawn in the same order and then processed in a uniform fashion. **Please read the instructions before collecting any specimens. Have all your supplies and equipment out and prepared prior to drawing blood.**

7.1 Order of Specimen Collection

Blood collection should be performed in the following order:

1. PAXgene® tube for RNA
2. EDTA (lavender top) blood collection for plasma and buffy coat
3. EDTA (purple top) blood collection for banking

7.2 Blood Collection Protocols

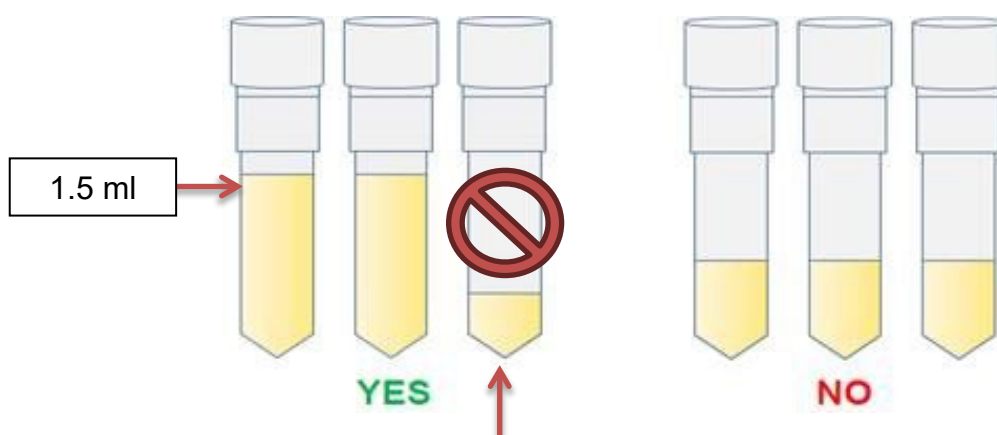
1. PAXgene® tube for RNA (**Appendix A**)
2. EDTA (purple top) blood collection for banking (**Appendix E**)
3. EDTA (lavender top) blood collection for plasma and buffy coat (**Appendix B**)

7.3 Lumbar Puncture Protocol

1. Cerebrospinal Fluid Collection (**Appendix G**)

7.4 Filling Aliquot Tubes (Plasma, Buffy Coat, and CSF)

In order to ensure that BioSEND receives a sufficient amount of sample for processing and storage, and to avoid cracking of the tubes prior to shipment, each aliquot tube should be filled to the assigned volume (refer to detailed processing instructions for average yield per sample). Over-filled tubes may burst once placed in the freezer, resulting in a loss of that sample. Each site is supplied with sufficient collection tubes to provide the specimen volume described in the Protocol Schedules for Biospecimen Submission ([see Section 4](#)). Specimens collected in addition to those described in Section 4 are collected at the site's discretion and are not returned to BioSEND.



Please note: It is critical for the integrity of future studies using these samples that study staff **not submit** residual aliquot tubes (anything under 1.5 ml) to BioSEND.

Each aliquot cryovial will be have a color-coded cap as follows:

Cap Color	Specimen Type
Purple	Plasma
Grey	Buffy Coat
Orange	CSF

Please be sure to use the appropriate colored top for the appropriate sample type.

8.0 Packaging and Shipping Instructions

ALL study personnel responsible for shipping should be certified in biospecimen shipping. If not available at your University, training and certification is available through the CITI training site (Course titled “Shipping and Transport of Regulated Biological Materials” at <https://www.citiprogram.org/>).

8.1 Sample Record and Shipment Notification Form

All sample shipments to BioSEND must include the BioSEND Sample Form). The completed forms are:

- Emailed to BioSEND@iu.edu at the time the samples are being shipped
- Included in the shipment with the samples

8.2 Shipping Instructions

Frozen Shipment (baseline and follow-up). Reference Appendix K for frozen shipping instructions.

- Frozen 1.5 ml aliquots of plasma
- Frozen 1.5 ml aliquots of CSF
- Frozen Buffy Coat
- Frozen Whole Blood (EDTA tube, 6 ml)
- Frozen RNA (PAXGene® tube, 2.5ml)

*****Important Note*****

Include samples for only one subject per shipping container.

For frozen shipments, include no more than two packing envelopes per shipping container in order to have room for a sufficient amount of dry ice to keep samples frozen up to 24 hours.

8.3 Shipping Address

All samples are shipped to the BioSEND laboratory:

BioSEND
Indiana University School of Medicine
351 W. 10th Street. TK-217
Indianapolis, IN 46202-5188

9.0 Data Queries and Reconciliation

Appendix I must be completed the day that samples are collected to capture information related to sample collection and processing. This form includes information that will be used to reconcile sample collection and receipt, as well as information essential to future analyses.

The PREDICT 3.0 Study team will be collaborating with BioSEND to reconcile information captured in the database compared to samples received and logged at BioSEND. Information that appears incorrect in the clinical database will be queried through the standard system. Additional discrepancies that may be unrelated to data entry will be resolved with the Principal Investigator in a separate follow up communication. If applicable, a non-conformance report will be provided to sites.

Data discrepancies with samples shipped and received at BioSEND may result from:

- Missing samples
- Incorrect samples collected and shipped
- Damaged or incorrectly prepared samples
- Unlabeled or mislabeled samples
- Samples frozen and stored longer than three months at the site

10.0 APPENDICES

- Appendix A: Whole Blood Collection for Isolation of RNA
- Appendix B: Whole Blood Collection for Isolation of Plasma
- Appendix C: Whole Blood Collection for Isolation of Buffy Coat
- Appendix E: Whole Blood Collection for banking
- Appendix G: Cerebrospinal Fluid Collection
- Appendix I: Sample Record and Shipment Notification Form
- Appendix K: Frozen Shipping Instructions
- Appendix O: Low Fat Diet Menu Suggestions
- Appendix Q: UPS ShipExec™ Thin Client Instructions

Appendix A – Whole Blood Collection for Isolation of RNA

Whole Blood Collection for Isolation of RNA: 2.5 ml PAXgene® tubes are provided by BioSEND for the collection of blood for RNA isolation.



See training video for blood collection for RNA: (<http://www.preanalytix.com/videos/rna-tube-collection-video/>)

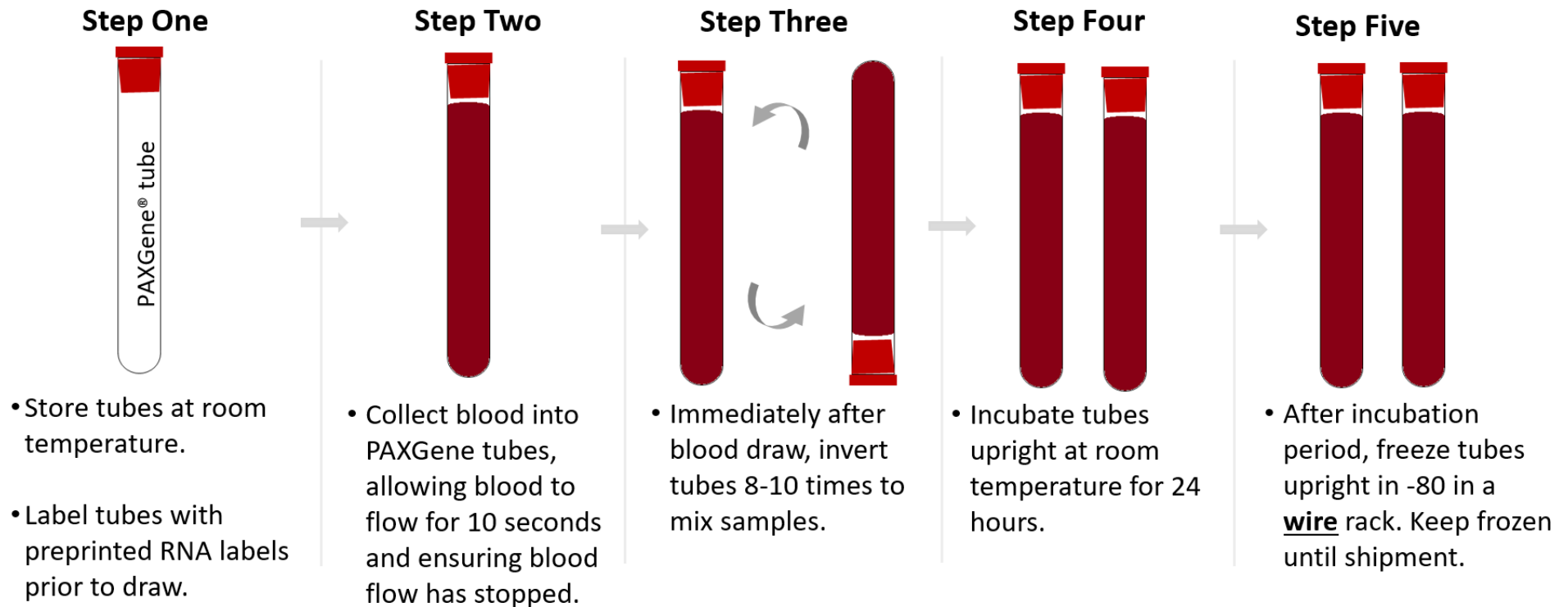
1. **CRITICAL STEP:** Store PAXgene® tube(s) at room temperature 64°F - 77°F (18°C to 25°C) before use.
2. Place pre-printed “RNA” label on the PAXgene® tube(s) prior to blood draw.
3. Using a blood collection set and a holder, collect blood into the PAXgene® tube(s) using your institution's recommended procedure for standard venipuncture technique.

The following techniques shall be used to prevent possible backflow:

- a. Place donor's arm in a downward position.
 - b. Hold tube in a vertical position, below the donor's arm during blood collection.
 - c. Release tourniquet as soon as blood starts to flow into tube.
 - d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.
4. Allow at least 10 seconds for a complete blood draw to take place in each tube. **Ensure that the blood has stopped flowing into the tube before removing the tube from the holder.** The PAXgene® tube with its vacuum is designed to draw 2.5 ml of blood into the tube.
 5. Immediately after blood collection, gently invert/mix (180 degree turns) the PAXgene® tube(s) 8 – 10 times. **Do not shake the tube!**
 6. Place the PAXgene® tube(s) upright in a **WIRE** or **PLASTIC** rack. Do **NOT** use a Styrofoam rack. This will cause the PAXgene® tube(s) to crack when frozen. **Allow the filled PAXgene® tube(s) to incubate upright at room temperature for 24 hours.**
 7. Complete the Sample Record and Shipment Notification form (Appendix I).

8. After samples have incubated at room temperature for 24 hours, transfer the WIRE or PLASTIC rack with the PAXgene® tubes to **-80°C freezer**. Store all samples at **-80°C until shipped** to BioSEND on dry ice.
9. Ship the PAXgene® tubes to BioSEND according to **Appendix K - Frozen Shipping Instructions**.

RNA Collection and Preparation – 2.5 ml PAXgene® Tube

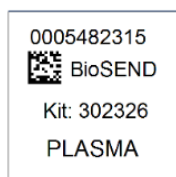


Appendix B – Whole Blood Collection for Isolation of Plasma and Buffy Coat

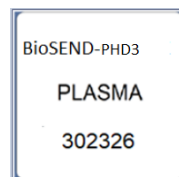
10ml Purple-Top EDTA tube(s) and cryotubes are provided by BioSEND for the collection of plasma and buffy coat



1. **CRITICAL STEP:** Store empty purple-top EDTA tubes at room temperature 64°F – 77°F (18°C to 25°C) prior to use.
2. Place provided “PLASMA” labels on 10 ml purple-top EDTA tubes and twelve 2 ml purple cryotubes. Place “BUFFY COAT” labels on four grey 2ml cryotubes.



Collection Tube Label



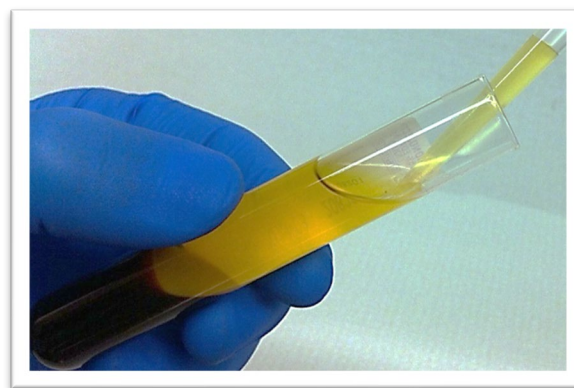
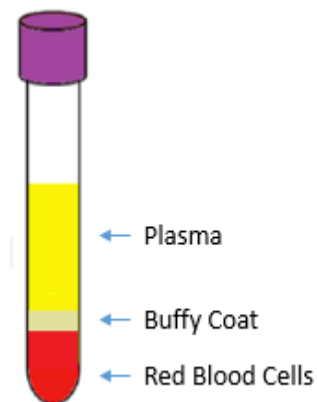
Label on cryotubes

3. Pre-chill the cryotubes on wet ice for at least 5 minutes.
4. Set centrifuge to 4°C to pre-chill before use. Time needed to pre-chill the centrifuge to 4°C will depend on your centrifuge model.
5. Using a blood collection set and a holder, collect blood into the purple top 10 ml EDTA tubes using your institution's recommended procedure for standard venipuncture technique.

The following techniques shall be used to prevent possible backflow:

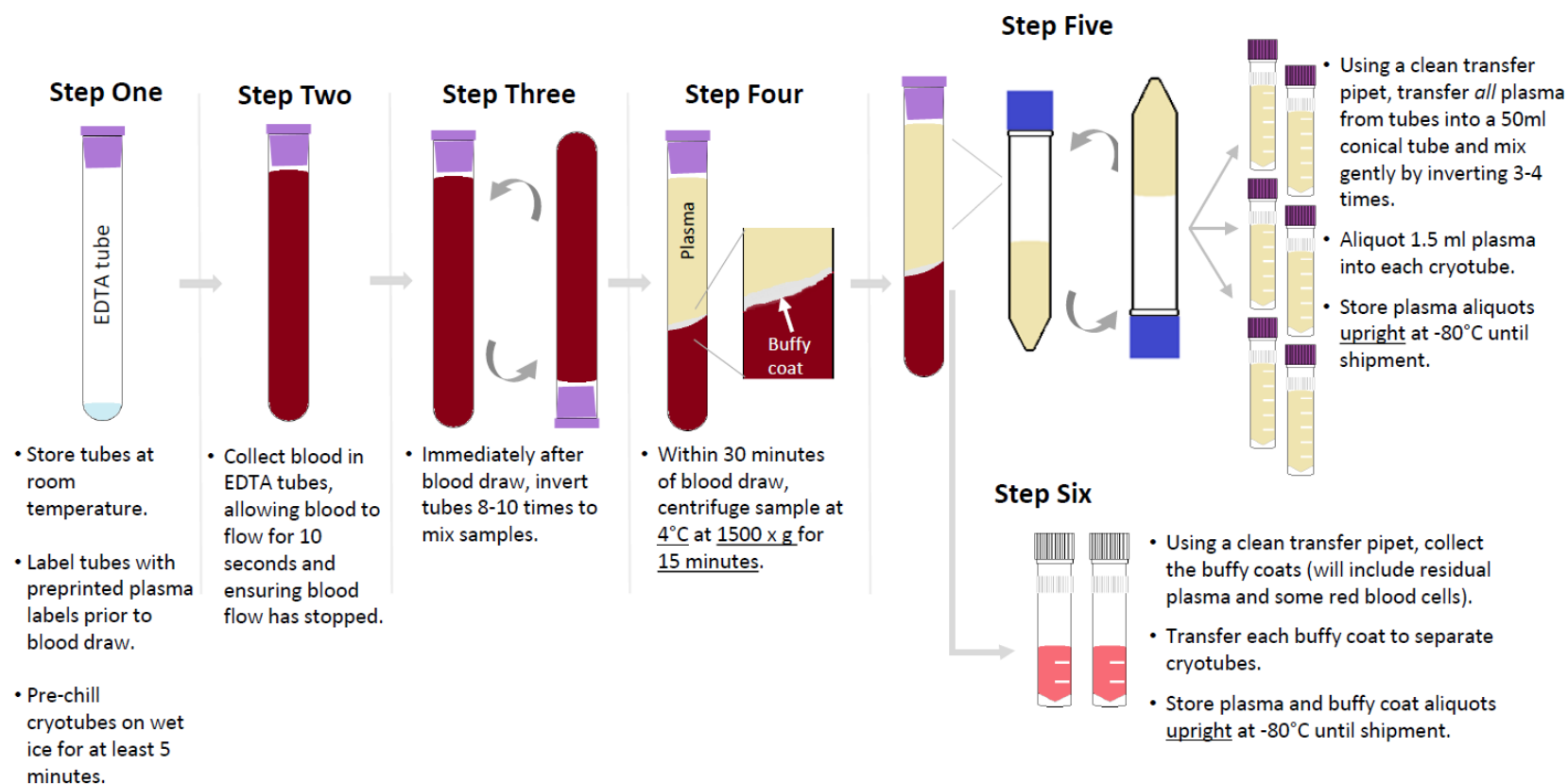
- a. Place donor's arm in a downward position.
- b. Hold tube in a vertical position, below the donor's arm during blood collection.
- c. Release tourniquet as soon as blood starts to flow into the tube.
- d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

6. Allow at least 10 seconds for a complete blood draw to take place in each tube. Ensure that the blood has stopped flowing into the tube before removing the tube from the holder. The tube vacuum is designed to draw 10 ml of blood into the tube.
7. **CRITICAL STEP: Immediately after blood collection, gently invert/mix (180 degree turns) the purple-top EDTA tubes 8 – 10 times. Do not shake the tubes!**
8. Within 30 minutes of blood collection, centrifuge balanced tubes for 15 minutes at 1500 RCF (x g) at 4°C. It is critical that the tubes be centrifuged at the appropriate speed and temperature to ensure proper plasma separation.
9. Remove the plasma by tilting the tube and placing the pipette tip along the lower side of the wall. **Use caution not to touch the buffy coat or packed red blood cells at the bottom of the collection tube so that the plasma is not contaminated** (see below). Using a disposable tipped micropipette, transfer plasma into 50 ml conical tube for homogenization.
10. Once all plasma from the four EDTAs is transferred to 50 ml conical tube, gently invert conical tube 3 times to mix the plasma.
11. Aliquot 1.5 ml into each cryotube. Send 12 x 1.5 ml aliquots to BioSEND. If you cannot obtain the requested number of aliquots, please note “low volume draw” on the Sample Record and Shipment Notification form (Appendix I) under “Notification of Problems”. Each 10 ml EDTA tube should yield, on average, 4-5 ml of plasma.



12. After plasma has been removed from the EDTA purple-top tube (see Appendix B), aliquot buffy coat layer (see figure above) into labeled cryotube with grey cap using a disposable graduated micropipette. All of the buffy coat from a single 10 ml purple-top EDTA tube will be placed into one cryotube. The buffy coat aliquot is expected to have a reddish color from the red blood cells.
13. Complete the **Sample Record and Shipment Notification form (Appendix I)**.
14. Place the labeled cryotubes in the 25 slot cryobox. Place the cryobox UPRIGHT on dry ice. Transfer to **-80°C freezer as soon as possible, within 2 hours of blood draw**. Store all samples at **-80°C until shipped** to BioSEND on dry ice.
15. Ship the frozen plasma and buffy coat aliquots to BioSEND according to **Appendix K – Frozen Shipping Instructions**.

Plasma and Buffy Coat Collection and Preparation – 10 ml K3 EDTA (purple top) Tube



Appendix E – Whole Blood Collection for Isolation of DNA (No Processing)

One 6 ml Purple-Top EDTA Tube is provided by BioSEND for the collection of Whole Blood from which DNA will be extracted. This tube should be shipped to BioSEND FROZEN; no processing required).



1. **CRITICAL STEP:** Store empty Whole Blood EDTA tubes at room temperature, 64°F - 77°F (18°C to 25°C) before use.
2. Place pre-printed Collection and Aliquot “DNA” label on the 6 ml EDTA tube prior to blood draw.
3. Using a blood collection set and a holder, collect whole blood into the 6 ml purple top whole blood tube using your institution’s recommended procedure for standard venipuncture technique.

The following techniques shall be used to prevent possible backflow:

- a. Place donor's arm in a downward position.
 - b. Hold tube in a vertical position, below the donor’s arm during blood collection.
 - c. Release tourniquet as soon as blood starts to flow into tube.
 - d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.
4. **CRITICAL STEP:** Immediately after blood collection, gently invert/mix (180 degree turns) the EDTA tube 8-10 times.
 5. Complete the **Sample Record and Shipment Notification form Appendix I).**
 6. Place the Purple-Top EDTA in a **WIRE** or **PLASTIC** rack. Do **NOT** use a Styrofoam rack. This will cause the Purple-Top EDTA tube to crack when frozen. Place the Purple-Top EDTA tube immediately to a **-80°C Freezer**.
 7. Ship the whole blood tube to BioSEND according to **Appendix K - Frozen Shipping Instructions**.

DNA Preparation (6 ml Lavender Top Tube)



Step One



- Store tube at room temperature.
- Label tube with pre-printed labels prior to blood draw.

Step Two



- Collect blood in tube, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



- Immediately after blood draw, invert tubes three times to mix samples.

Step Four



- Transfer to -80°C freezer. Store upright and keep frozen until shipment BioSend.

Appendix I – Sample Collection and Processing Form

A Sample Collection and Processing Form must be completed for each subject-visit submitted to BioSEND. This form includes a Frozen Shipping Manifest that should be completed in advance of shipping to BioSEND also be physically included in the shipper. The form can be completed via REDCap by following the bellow link:

- **Link to Sample Collection and Processing Form:**

<https://redcap.link/PHD3SampleForm>

Please note that there is a Save & Return option at the bottom of the survey. This may be used if, for example, you are ready to complete the Collection and Processing portion of the form, but not yet ready to complete the Frozen Shipping Manifest.

It is preferred that you complete the form online via the REDCap link above. However, a copy of the printed form is available on the following pages, should you need a back-up option. Please note that if you do not complete the form online, you will need to email a copy of the form directly to biosend@iu.edu prior to shipment.

PHD3 Specimen Collection And Processing Form

Please complete the Specimen Collection and Processing Form, below.

BioSEND PHD3 Study

Study Site ☐ University of Iowa

Email address of staff member completing this form

Note: A copy of the completed sample form and the shipping manifest will be sent to this address.

GUID

Sex (used for DNA quality control) ☐ Male
☐ Female
☐ Other

Visit ☐ 301
☐ 303

Kit Number

(eg, 654321)

Blood Collection and Processing

Date of venipuncture blood collection

Time of venipuncture blood collection

(Use 24 Hour clock)

Date participant last ate

Time participant last ate

(Use 24 Hour clock)

RNA (PAXGene™ tubes, 2.5 mL)

Was blood collected and processed for RNA?

☐ Yes
☐ No

Number of PAXGene™ tubes collected for RNA

Date RNA was frozen

Time RNA was placed in freezer

RNA storage temperature

(degrees Celsius)

RNA notes

PLASMA and BUFFY COAT (Purple-top EDTA tubes, 10 mL)

Was blood collected and processed for PLASMA EDTA?

☐ Yes
☐ No

Time of PLASMA EDTA tube centrifugation

(Use 24 Hour clock)

Duration of PLASMA EDTA tube centrifugation

(minutes)

Rate of PLASMA EDTA tube centrifugation

(x g)

Temperature of PLASMA EDTA tube centrifugation

(degrees Celsius)

Total volume of PLASMA EDTA collected

(mL)

Number of PLASMA EDTA aliquots created

(Each aliquot should be 1.5 mL)

Number of BUFFY COAT aliquots created

Time PLASMA EDTA and BUFFY COAT were placed in freezer

(Use 24 Hour clock.)

PLASMA EDTA and BUFFY COAT storage temperature

(degrees Celsius)

PLASMA EDTA notes

WHOLE BLOOD (EDTA tube, 6 mL)

Was blood collected for WBLD?

☐ Yes
☐ No

Time WBLD was placed in freezer

(Use 24 Hour clock)

WBLD storage temperature

(degrees Celsius)

WHOLE BLOOD notes

CSF Processing

Was CSF collected?

- ☐ Yes
☐ No

Date of CSF collection

Time of CSF collection

(Use 24 Hour clock)

Time of CSF centrifugation

(Use 24 Hour clock)

Duration of CSF centrifugation

(minutes)

Rate of CSF centrifugation

(x g)

Was CSF centrifuged at room temperature?

- ☐ Yes
☐ No
(degrees Celsius)

Temperature of CSF centrifugation

(degrees Celsius)

Total volume of CSF collected

(mL)

Number of CSF aliquots created

(Each aliquot should be 1.5 mL)

Time CSF aliquots were placed in freezer

(Use 24 Hour clock)

CSF storage temperature

(degrees Celsius)

CSF notes

PHD3 Frozen Shipping Manifest

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the Frozen Shipping Manifest will be emailed to you for Subject [subj_id].

Please print a copy of that document and include it in the shipping container.

Study Site: ☐ University of Iowa

GUID: _____

Visit: ☐ 301
☐ 303

Kit Number: _____

Date of blood collection: _____

Date of CSF collection: _____

RNA

Number of PAXGene™ tubes shipped: _____

PLASMA EDTA

Number of PLASMA EDTA aliquots shipped: _____

Number of BUFFY COAT aliquots shipped: _____

WHOLE BLOOD EDTA

Number of WHOLE BLOOD tubes shipped: _____

CSF

Number of CSF aliquots shipped: _____

Shipping Information - Please complete.

Frozen shipments should be sent Monday-Wednesday only. Please check for holiday closures prior to shipping. Contact us at biosend@iu.edu if you are unsure whether or not it is safe to ship.

Date of shipment: _____

Did/will you use the IU UPS interface to generate the shipping label? ☐ Yes ☐ No

Which shipping service did you use? ☐ UPS ☐ FedEx ☐ World Courier ☐ Other

What is the shipment tracking number? _____

Appendix K – Frozen Shipping Instructions

IMPORTANT!

**FROZEN SAMPLES MUST BE SHIPPED MONDAY THROUGH WEDNESDAY ONLY
USING PRIORITY OVERNIGHT DELIVERY**

Please be aware of holidays and inclement weather, and plan your shipments accordingly.

Specimens being shipped to BioSEND are Category B UN3373 specimens and as such must be triple packaged and compliant with IATA Packing Instructions. *See the latest eEdition of the IATA regulations for complete documentation.*

Triple packaging consists of a primary receptacle(s), a secondary packaging, and a rigid outer packaging. The primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging. Secondary packaging must be secured in outer packaging with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

IATA Packing and Labeling Guidelines

- The primary receptacle (cryovials or blood collection tubes) must be leak proof and must not contain more than 1 L total.
- The secondary packaging (plastic canister or biohazard bag) must be leak proof and if multiple blood tubes are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent direct contact with adjacent blood tubes.
- Absorbent material must be placed between the primary receptacle (cryovials or blood collection tubes) and the secondary packaging. The absorbent material must be of sufficient quantity to absorb the entire contents of the specimens being shipped. Examples of absorbent material are paper towels, absorbent pads, cotton balls, or cellulose wadding.
- A shipping manifest listing the specimens being shipped must be included between the secondary and outer packaging.
- The outer shipping container must display the following labels:
 - ✓ Sender's name and address
 - ✓ Recipient's name and address
 - ✓ Responsible persons (shipper and recipient)
 - ✓ The words "Biological Substance, Category B"
 - ✓ UN3373
 - ✓ Class 9 label including UN 1845, and net weight of dry ice contained

BioSEND Packaging and Shipment Instructions – Frozen Shipments

1. Contact courier to confirm service is available and schedule package to be picked up.
2. **Record the courier tracking number onto the Sample Record and Shipment Notification form (Appendix I).**
3. Make a copy of the Sample Record and Shipment Notification form.
4. Place all frozen plasma, buffy coat, and CSF in the cryobox. Only include specimens from one subject in each cryobox.
5. Place the cryobox in the clear plastic biohazard bag. Leave the absorbent sheet in the biohazard bag and seal according to the instructions on the biohazard bag. Affix a Case Label to the outside of the biohazard bag.
6. Insert frozen 6ml EDTA whole blood tube into the bubble wrap tube sleeve and seal the top.
7. Place the tube sleeve with EDTA into the 2nd biohazard bag. Leave the absorbent sheet in the biohazard bag and seal according to the instructions on the biohazard bag. Affix a Case Label to the outside of the biohazard bag.

8. Place approximately 2-3 inches of dry ice in the bottom of the Styrofoam shipping container.
9. Place the biohazard bag containing the cryobox into the provided Styrofoam® shipping container on top of the dry ice. Please ensure that the cryobox is placed so that the cryovials are upright in the shipping container (as pictured).



10. Fully cover the cryobox with approximately 2 inches of dry ice.
11. Place the biohazard bag containing the 6ml EDTA on top of the 2nd layer of dry ice and cover with another 2-3 inches of dry ice.
12. The inner Styrofoam shipping container must contain approximately 10 lbs (or 4.5 kg) of dry ice. The dry ice should entirely fill the inner box and be placed on top of the canisters to ensure the frozen state of the specimens.
13. Replace the lid on the Styrofoam® container. Place the completed Sample Record and Shipment Notification form in the package on top of the Styrofoam lid for each patient specimen, and close and seal the outer cardboard shipping carton with packing tape.



14. Affix the airbill to the outside of the package. Please see Appendix Q for further instructions on generating airbills.

15. Complete the Class 9 UN 1845 Dry Ice Label with the following information:

- Your name and return address
- Net weight of dry ice in kg (this amount must match the amount recorded on the airbill)
- Consignee name and address:

BioSEND
IU School of Medicine
351 W. 10th Street ,TK-217
Indianapolis, IN 46202

- Do not cover any part of this label with other stickers, including pre-printed address labels.

IMPORTANT!

Complete the required fields on tClass 9 Dry Ice labels, or courier may reject or return your package.

16. Apply all provided warning labels (UN3373, Dry Ice Label and Fragile Label), taking care not to overlap labels or airbill.

17. Hold packaged samples in -80°C freezer until time of Fcourier pick-up/drop-off.

18. Specimens should be sent to the address below.Frozen shipments should be sent Monday through Wednesday only to avoid shipping delays on Thursday or Friday. Couriers do not replenish dry ice if shipments are delayed or held over during the weekend.

BioSEND
IU School of Medicine
351 W. 10th Street
TK-217 Indianapolis,
IN 46202

19. **Notify BioSEND by email (biosend@iu.edu) that a shipment has been sent and attach the Sample Record and Shipment Notification form to your email. Do not ship until you've contacted and notified BioSEND staff about the shipment in advance.**

20. Use the tracking number to ensure the delivery occurs as scheduled and is received by BioSEND.

In addition to tracking and reconciliation of samples, the condition and amount of samples received are tracked by BioSEND for each sample type. Investigators and clinical coordinators for each project are responsible for ensuring that the requested amounts of each fluid are collected to the best of their ability and that samples are packed with sufficient amounts of dry ice to avoid thawing in the shipment process.

Appendix O – Low Fat Diet Menu Suggestions, Foods to Avoid

Foods to avoid prior to blood collection:

Avoid: *All fats and nuts such as:*

- Butter
- Cream
- Bacon fat
- Lard
- All oils
- All margarine
- All nuts
- Peanut butter
- Coconut
- Whole seeds such as pumpkin and sunflower

Avoid: *All milk and dairy products such as:*

- All whole milk products
- All cheese
- All products containing cheese
- Sour cream
- All ice cream
- Milk chocolate

Avoid: *High fat prepared foods and foods naturally high in fat:*

All red meats or meats containing fat
such as pork and:

- Fatty meats such as:
 - Luncheon meats
 - Organ meats
 - Bacon
- Fatty fish such as:
 - Salmon
 - Mackerel

• Salad dressing and mayonnaise	• Buttered, au gratin, creamed, or fried vegetables
• Fried foods	• Gravies and sauces
• Fried snacks such as: <ul style="list-style-type: none"> ➢ Chips ➢ Crackers ➢ French Fries 	• Baked goods and frosting

Appendix Q - UPS ShipExec™ Thin Client Instructions

*** The shipment label in ShipExec should not be created until the day of shipment ***

- 1) Log in to the UPS ShipExec™ Thin Client website: <https://kits.iu.edu/UPS> or <https://kits.iu.edu/ups>.
 - a. To request an account, complete the following survey:
<https://redcap.uits.iu.edu/surveys/?s=88TTWY3KAF>
- 2) Find the “Shipping” dropdown menu in the top left corner of the screen and click on “Shipping and Rating”.
- 3) Once the Indiana University page loads, look for the “Study Group” dropdown menu under “Shipment Information” on the right side of the screen. Choose your study from the dropdown menu.
- 4) After selecting your study, click on the magnifying glass icon on the left side of the screen under “Ship From”.
- 5) An address book and filters will populate the screen. On the right side of the screen, a list of all the site addresses within the study you selected should populate.
 - a. Filter the list down more by looking to the left side of the screen and searching for their address by filling in the “Company”, “Contact”, or “Address 1” fields. Click on the Search button when ready.
 - b. Once you have found your site address, click on the “Select” button to the left of the address.
- 6) Make sure your address populated in the fields under “Ship From” on the main page.
 - a. If you accidentally selected the wrong address, click on the “Reset” button on the bottom right of the screen. After the page reloads and clears the information, select your study again from the “Study Group” menu and click on the magnifying glass icon again to search for your correct address.
 - b. To change the address for your site and study group, please complete the following survey:
<https://redcap.uits.iu.edu/surveys/?s=88TTWY3KAF>
- 7) Enter the total weight of your package in the “Weight” field on the right side of screen under the name of your study.
 - a. Leave the “Dry Ice Weight” field empty or enter “0” if shipping an ambient sample.
- 8) Enter the weight of the dry ice for frozen shipments in the “Dry Ice Weight” field.
 - a. The “Dry Ice Weight” field can never be higher than the “Weight” field.
 - b. **(Steps 9-10 can be skipped if you do not need to schedule a pickup)**
- 9) After entering the weights, click on the blue “Pickup Request” button.
- 10) When the Create Pickup Request box pops up, enter information into all the fields provided.
 - a. Enter the “Earliest Time Ready” and “Latest Time Ready” in 24-hour format.
 - i. Schedule pickup at a minimum 1 hour before the “Earliest Time Ready”
 - b. Choose a name and phone number that is the best contact if the UPS driver has question related to picking up your package
 - c. Entering the “Room Number” and “Floor” will help the UPS driver locate your package
 - i. The “Floor” field only allows numerical characters while the “Room Number” field is free text.
 - d. Click “Save” when done.
- 11) Once you are certain that all the correct information has been entered, click the “Ship” button in the bottom right corner of the screen.
- 12) If no red error messages pop up at the top of your screen after clicking on “Ship”, then you should have 2 downloaded PDF files: Shipment Receipt & UPS Package Label

- a. Shipment Receipt will list a “Pickup No.” that references your specific package if there is ever an issue with UPS picking up your package
- 13) Print out the UPS airway bill to any printer at your location.
 - a. Fold the UPS airway bill and slide it inside the plastic UPS sleeve.
 - b. Peel the back off the plastic UPS sleeve and stick the sleeve to your package, making sure it is laying as flat as possible along the surface of the package.
- 14) Place your package in the spot designated in your pickup request, or wherever your daily UPS pickups occur.
- 15) If you need to reprint your airway bill or void your shipment, click on “History” at the top of the main screen.
 - a. If your shipment does not automatically pop up, enter the date of shipment and then click “Search”.
 - b. To reprint your airway bill, click on the printer icon to the far left under “Action”
 - c. To void your shipment, click on the “X” icon to the far left under “Action”
 - i. If you created an airway bill that you no longer need, you must void the shipment to ensure your study will not be charged for the shipment.