

#### **BBBSR Protocol Update: V03.2021**

| Section | Change   |  |  |  |
|---------|--|--|--|--|
| 8.1.1   | Renamed "NCRAD Packaging Instructions—Frozen Shipments". Removed |  |  |  |
|         | shipping information   |  |  |  |
| 8.2     | Frozen Shipping Instructions added to include new UPS steps      |  |  |  |



# Blood Based Biomarker Shared Resource

in collaboration with the

# National Centralized Repository for Alzheimer's Disease and Related Dementias



Biospecimen Collection, Processing, and Shipment Manual of Procedures

**Version 03.2021** 



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#### 1.0 ABBREVIATIONS

AD Alzheimer's Disease

BBBSR Blood Based Biomarker Shared Resource

DNA Deoxyribonucleic Acid

EDTA Ethylene Diamine Tetra-acetic Acid

GUID Globally Unique Identifier

IATA International Air Transport Association
NACC National Alzheimer's Coordinating Center

NCRAD National Centralized Repository for Alzheimer's Disease and Related Dementias

PHI Protected Health Information

RBC Red Blood Cells

RCF Relative Centrifugal Force RPM Revolutions Per Minute



#### 2.0 PURPOSE

The collection of biofluids is an important part of the Blood Based Biomarker Shared Resource (BBBSR) Study. The purpose of this manual is to provide study staff (PIs, study coordinators, phlebotomists) at the various study sites with instructions for collection and submission of biological samples for BBBSR study visits. It includes instructions for biofluid submission to NCRAD located in Indianapolis at Indiana University.

The following samples will be sent to NCRAD:

- Plasma
- Buffy Coat (DNA Extraction)

This manual includes instructions for collection of blood, fractionation of blood from collection tubes, aliquoting, labeling, storage prior to shipping, and shipping to NCRAD.

These procedures are relevant to all study personnel responsible for processing specimens provided to NCRAD for the BBBSR protocol.



#### 3.0 NCRAD Information

#### 3.1 NCRAD Contacts

#### Tatiana Foroud, PhD, Core Leader

Phone: 317-274-2218

#### Kelley Faber, MS, CCRC, Project Manager

Phone: 317-274-7360 Email: kelfaber@iu.edu

#### Kaci Lacy, MPH, CCRP, Clinical Research Coordinator

Phone: 317-278-1170 Email: lacy@iu.edu

#### **General NCRAD Contact Information**

Phone: 1-800-526-2839 Fax: 317-321-2003 Email: alzstudy@iu.edu Website: www.ncrad.org

#### **Sample Shipment Mailing Address**

BBBSR at NCRAD Indiana University School of Medicine 351 W. 10th St. TK-342 Indianapolis, IN 46202 Phone: 1-800-526-2839

#### 3.2 NCRAD Hours of Operation

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

Ambient samples must be shipped Monday-Thursday only.

Frozen samples must be shipped Monday-Wednesday only.

For packing and shipment details of samples, please refer to <u>Section 8.0</u> of this protocol.

Check the weather report to make sure impending weather events (blizzards, hurricanes, etc.) will not impact the shipping or delivery of the samples.



#### 3.3 NCRAD Holiday Observations

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

Please note that between December 24<sup>th</sup> and January 2<sup>nd</sup>, Indiana University will be open Monday through Friday for essential operations **ONLY** and will re-open for normal operations on January 2<sup>nd</sup>. If possible, biological specimens for submission to Indiana University should **NOT** be collected and shipped to Indiana University after the second week in December. 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 20<sup>th</sup> by e-mailing <a href="mailto:alzstudy@iu.edu">alzstudy@iu.edu</a>, so that they can arrange to have staff available to process incoming samples. **Please see:** <a href="https://ncrad.org/holiday\_closures.html">https://ncrad.org/holiday\_closures.html</a> for additional information.

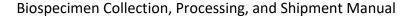
- Please note that courier services may observe a different set of holidays.
- Please be sure to verify shipping dates with your courier prior to any holiday.
- Weekend/holiday delivery must be arranged in advance with NCRAD staff.

#### 4.0 GLOBALLY UNIQUE IDENTIFIER (GUID)

The GUID is a subject ID that allows researchers to share data specific to a study participant, without exposing personally identifiable information. A GUID is made up of random alpha-numeric characters and does not include any PHI in the identifier. By using GUIDs in your research data, the system can associate a single research participant's genetic, imaging, and clinical assessment data even if the data was collected at different locations or throughout different studies. No PHI will be sent to NCRAD, only the GUID.

To create a GUID follow these steps:

1. Create an account: https://bricsguid.nia.nih.gov/portal/jsp/login.jsp





- 2. Once you have an account, go to the GUID Tool Create GUID
- 3. To open the 'Launch GUID Tool' you will need to have Java installed on your device
- 4. In order to generate a GUID, the following PHI is required (Appendix A):
  - Complete legal given (first) name of subject at birth
  - If the subject has a middle name
  - Complete legal family (last) name of subject at birth
  - > Day of birth
  - Month of birth
  - > Year of birth
  - Name of city/municipality in which subject was born
  - Country of birth

#### 5.0 BBBSR Laboratory Collection

#### 5.1 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
- > Tourniquet
- Alcohol Prep Pad
- Gauze Pad
- Bandage
- > Butterfly needles and hub
- ➤ Microcentrifuge tube rack
- Sharps bin and lid
- ➤ Wet Ice Bucket
- Wet ice
- > Dry ice

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 ≥ 2000 x g with refrigeration to 4°C
- > -80°C Freezer

In order to ship specimens, you must provide:

Dry ice (approximately 45 lbs per shipment)



#### 5.2 Biospecimens Sent to NCRAD

Samples are to be submitted according to the shipping methods outlined in <u>Section 8.0</u>. Guidelines for the processing, storage location, and timing of sample collection are listed in the tables below.

#### 5.2.1 Biofluid Collection Schedule

#### **Biospecimen Collection Table**

| Biospecimen      | All Visits |  |
|------------------|------------|--|
| Plasma           | X          |  |
| Buffy Coat (DNA) | Х          |  |

Whole blood is collected in two collection tubes (two 10 ml purple-top EDTA tubes) for shipment to NCRAD. The 10 ml EDTA tubes are processed locally into plasma, and buffy coat fractions; they are then aliquoted, frozen at the study site, and shipped to NCRAD.

Consent forms must specify that any biological samples and de-identified clinical data may be shared with academic and/or industry collaborators through NCRAD. Recommended consent language can be found on the NCRAD website at: <a href="https://ncrad.org/recommended">https://ncrad.org/recommended</a> consent language.html. A copy of the consent form for each participant should be kept on file by the site investigator.

#### 5.2.2 Biofluid Collection Charts

| Collection Tube           | Drawn At | Specimen<br>Type | Aliquot<br>Volume           | Total Number of Aliquots | Shipping<br>Temperature |
|---------------------------|----------|------------------|-----------------------------|--------------------------|-------------------------|
| 2 EDTA (Purple-Top) Blood | Visit 1  | Plasma           | 1.5 ml plasma<br>aliquots   | Up to 7                  | Frozen                  |
| Collection Tubes (10 ml)  | Visit 1  | Buffy Coat       | ~1.0 ml buffy coat aliquots | 2                        | Frozen                  |

#### 6.0 Specimen Collection Kits, Shipping Kits, and Supplies

NCRAD will provide: 1) Blood sample collection kits for research specimens to be stored at NCRAD, the Blood Supplemental Supply Kit, the Frozen Shipment Kit and Ambient Shipping Kit and 2) clinical lab supplies (with the exception of dry ice and equipment supplies listed in <a href="Section 5.1">Section 5.1</a>). The provided materials include blood tubes, pipettes, boxes for plasma/buffy coat aliquots, as well as partially completed shipping labels to send materials to NCRAD. Kit number labels, site and PTID labels, collection tube labels, and cryovial labels will all be provided by NCRAD. Details regarding the blood kits are found in this Manual of Procedures. Collection tube and cryovial labels will be



preprinted with study information specific to the type of sample being drawn. Ensure that all tubes are properly labeled during processing and at the time of shipment according to Section 7.1.

#### 6.1 NCRAD Specimen Collection Kit Contents

Collection kits contain the following (for each subject) and 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 NCRAD Study team to do so. <u>Please store all kits</u> at room temperature until use.

#### **BBBSR Kit**

| Quantity | BBBSR Kit Components                                  |
|----------|---|
| 2        | EDTA (purple-top) blood collection tube (10 ml)       |
| 1        | 15 ml conical polypropylene tube-individually wrapped |
| 6        | Cryovial (2.0 ml) with purple cap                     |
| 1        | Cryovial (2.0 ml) with blue cap                       |
| 2        | Cryovial (2.0 ml) with gray cap                       |
| 2        | Preprinted Collection Tube Labels                     |
| 9        | Preprinted Cryovial Label                             |
| 3        | Preprinted Kit Number Label                           |
| 3        | Label for handwritten Site and PTID                   |
| 1        | Cryovial box (holds up to 25 cryovials)               |
| 4        | Disposable graduated transfer pipettes                |

#### **BBBSR Supplemental Supply Kit**

| Quantity | BBBSR Supplemental Supply Kit Components              |
|----------|---|
| 10       | EDTA (purple-top) blood collection tube (10 ml)       |
| 5        | 15 ml conical polypropylene tube-individually wrapped |
| 30       | Cryovial (2.0 ml) with purple cap                     |
| 5        | Cryovial (2.0 ml) with blue cap                       |
| 10       | Cryovial (2.0 ml) with gray cap                       |
| 15       | Label for handwritten Site and PTID                   |
| 5        | Cryovial box (holds up to 25 cryovials)               |
| 10       | Disposable graduated transfer pipettes                |

#### **NCRAD Frozen Shipping Supply Kit**

| Quantity | Frozen Shipping Kit Components for Blood-Based Biomarkers |
|----------|---|
| 8        | Plastic Biohazard bag with absorbent sheet (small)        |
| 1        | UPS return airbill and pouch                              |
| 1        | Shipping box/Styrofoam container                          |
| 1        | Warning label packet with dry ice sticker                 |



#### **Individual Supplies**

| Quantities | Items Available upon request within the NCRAD kit module             |
|------------|--|
| By Request | Cryovial box (holds up to 25 cryovials)                              |
| By Request | Cryovial (2.0 ml) with purple cap                                    |
| By Request | Cryovial (2.0 ml) with blue cap                                      |
| By Request | Cryovial (2.0 ml) with gray cap                                      |
| By Request | UPS return airbill   |
| By Request | UPS Laboratory Pak   |
| By Request | Shipping container for dry ice shipment (shipping and Styrofoam box) |
| By Request | Styrofoam shipping containers (11"x 9"x 8", 1 1/2" wall)             |
| By Request | Plastic biohazard bag with absorbent sheet (small)                   |
| By Request | Disposable graduated transfer pipette                                |
| By Request | EDTA (Purple-Top) Blood Collection Tube (10 ml)                      |
| By Request | Warning label packet   |
| By Request | UN3373 label   |
| By Request | Biohazard label  |
| By Request | Dry ice shipping label   |
| By Request | Fine Point Permanent Markers   |
| By Request | Site and PTID Labels   |

#### 6.2 Kit Supply to Study Sites

Each site will be responsible for ordering and maintaining a steady supply of kits from NCRAD. We advise sites to keep a supply of each kit type available. Be sure to check your supplies and order additional materials before you run out or supplies expire so you are prepared for study visits. Please go to: <a href="http://kits.iu.edu/BBBSR">http://kits.iu.edu/BBBSR</a> to request additional kits and follow the prompts to request the desired supplies.

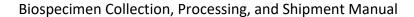
Please allow TWO weeks for kit orders to be processed and delivered.

#### 7.0 BLOOD COLLECTION AND PROCESSING PROCEDURES

#### 7.1 Labeling Samples

#### \*\*\*Important Note\*\*\*

In order to ensure the highest quality samples are collected, it is essential to follow the specific collection and shipment procedures detailed in the following pages. Please read the following instructions first before collecting any specimens. Have all your supplies and equipment out and prepared prior to drawing blood.





- \*\*Label Type Summary\*\*
- 1. Kit Number Label
- 2. Site and PTID Label
- 3. Collection Tube Label
- 4. Cryovial Label

Kit Number

**Kit Number Labels** tie together all specimens collected from one subject at one visit. They should be placed on each cryobox, and in the designated location on the Blood and CSF Sample and Shipment Notification Forms (Blood and CSF kits will have different Kit Numbers).

Site ID:\_\_ PTID:

**Site and PTID Labels** are used to document the individual's unique Site and PTID. Place one label on each blood collection tube.

0001234567

BBBSR

PLASMA

Kit #: 123456

Place one **Collection Tube Label** on each blood collection tube.

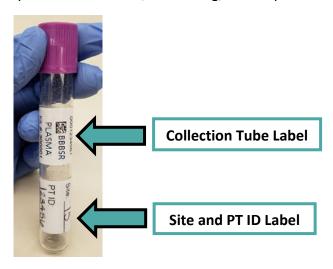
BBBSR PLASMA Kit #123456

Place one Cryovial Label on each cryovial.

#### \*\*Important Note\*\*

**Each collection tube will contain two labels**: the collection tube label and the Site and PTID Label. Be sure to place labels in the same configuration consistently among tubes, with the barcoded label near the top of the tube and the handwritten Site and PTID label.



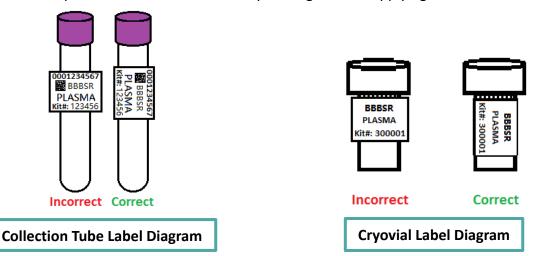


Labeled EDTA (Purple-Top) Blood Collection Tube

In order to ensure the label adheres properly and remains on the tube, <u>please</u> <u>follow these instructions:</u>

- ➤ Place cryovial labels on <u>ALL</u> cryovials <u>BEFORE</u> sample collection. This should help to ensure the label properly adheres to the tube before exposure to moisture or different temperatures.
- Using a fine point permanent marker, fill-in and place the site and PTID labels on the EDTA (purple-top) tubes <u>BEFORE</u> sample collection. These labels are placed on collection tubes in addition to the collection tube label.
- The collection tube labels contain a 2D barcode on the left hand side of the label. Place this barcode toward the tube cap.
- Place label <u>horizontally</u> on the tube (wrapped around sideways if the tube is upright).

Take a moment to ensure the label is **completely adhered** to each tube. It may be helpful to roll the tube between your fingers after applying the label.





## 7.2 Whole Blood Collection with 10 ml EDTA (Purple-Top) Tube for Plasma and Buffy Coat

- 1. Store empty EDTA tubes at room temperature,  $64^{\circ}F$   $77^{\circ}F$  ( $18^{\circ}C$   $25^{\circ}C$ ) before use.
- 2. Set centrifuge to 4°C to pre-chill before use.
- 3. Place completed site and PTID Label and preprinted **PLASMA** collection tube label on the purple-top EDTA tube. Place preprinted **PLASMA** cryovial labels on the six 2 ml cryovial tubes with purple caps and one 2 ml cryovial tube with blue cap (if necessary, for residual). Place preprinted **BUFFY COAT** cryovial label on the 2 ml cryovials with gray caps.
- 4. Using a blood collection set and a holder, collect blood into the **EDTA** (Purple-Top) Blood Collection Tube (10 ml) using your institution's recommended procedure for standard venipuncture technique.

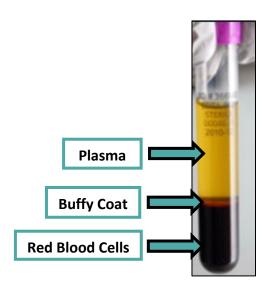
#### The following techniques shall be used to prevent possible backflow:

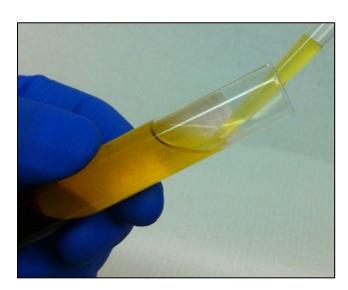
- a. Place participant's arm in a downward position.
- b. Hold tube in a vertical position, below the participant's arm during blood collection.
- c. Release tourniquet as soon as blood starts to flow into tube.
- d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.
- 5. 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 with its vacuum is designed to draw 10 ml of blood into the tube.
  - a. If complications arise during the blood draw, please note the difficulties on the 'Biological Sample and Shipment Notification Form'. Do not attempt to draw an additional EDTA tube at this time. Process blood obtained in existing EDTA tube.
- 6. Immediately after blood collection, gently invert/mix (180 degree turns) the EDTA tube 8-10 times.
- 7. Immediately after inverting the EDTA tube, place it on wet ice until centrifugation begins.
- 8. Centrifuge balanced tubes for 10 minutes at 2000 x g at 4°C. It is critical that the tubes be centrifuged at the appropriate speed and temperature to



ensure proper plasma separation (see worksheet in <u>Appendix B</u> to calculate RPM.)

- a. Equivalent rpm for spin at 2000 x g
- b. While centrifuging, remember to record all times, temperatures and spin rates on the Biological Sample and Shipment Notification Form.
- c. Record original volume drawn for each tube in spaces provided on the Biological Sample Shipment and Notification Form.
- d. Plasma samples need to be spun, aliquoted, and placed in the freezer within 1 hour from the time of collection.
- e. Record time aliquoted on the Biological Sample Shipment and Notification Form.
- 9. Remove the plasma by tilting the tube and placing the pipette tip along the lower side of the wall being careful not to agitate the packed red blood cells at the bottom of the collection tube.
- 10. Each EDTA tube should yield, on average, 4-5 ml of plasma. Transfer plasma from both EDTA tubes into the 15 ml conical tube and gently invert 3 times. Aliquot 1.5 ml plasma per cryovial. Be sure to only place plasma in cryovials with purple caps and labeled with PLASMA labels. Place residual plasma (<1.5 ml) in the blue-capped cryovial. If a residual aliquot (<1.5 ml) is created, document the specimen number and volume on the Biological Sample and Shipment Notification Form.

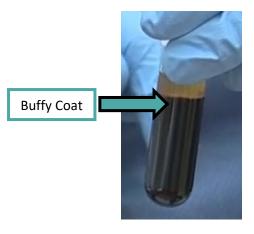


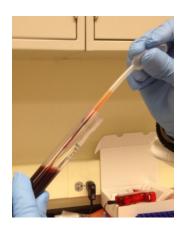


NOTE: When pipetting plasma from the EDTA tube into the 15 ml conical tube, be very careful to pipette the plasma top layer only, leaving the buffy coat and the red blood cell layers untouched.



- 11. Place the labeled cryovials in the 25 cell cryobox and place on dry ice.
  Transfer to -80°C Freezer when possible. Store all samples at -80°C until shipped to NCRAD on dry ice. Record time aliquots placed in freezer and storage temperature of freezer on Biological Sample Shipment and Notification Form.
- 12. After plasma has been removed from the EDTA (Purple-Top) Blood Collection Tubes (10 ml), aliquot the buffy coat layer (in the top layer of cells, the buffy coat is mixed with RBCs-see figure) from one EDTA tube into a labeled, gray-capped cryovial using a micropipette. The buffy coat aliquot is expected to have a reddish color from the RBCs. Be sure to only place the buffy coat from one EDTA tube into each cryovial. Repeat this step for the second EDTA tube, placing this buffy coat into the second gray-capped cryovial.







Buffy Coat Aliquot (gray-capped cryovial)

- 13. Dispose of collection tube with red blood cell pellet according to your site's guidelines for disposing of biomedical waste.
- 14. Record the specimen number and volumes of the EDTA tubes and corresponding buffy coat samples on the Biological Sample Shipment and Notification Form.
- 15. Place the labeled cryovials in the 25 cell cryobox and place on dry ice.

  Transfer to -80°C Freezer when possible. Store all samples at -80°C until shipped to NCRAD on dry ice. Record time aliquots placed in freezer and storage temperature of freezer on Biological Sample and Shipment Notification Form.



Plasma Aliquots (up to 7 possible) and Buffy Coats (2)

Spin, aliquot, and freeze all plasma and buffy

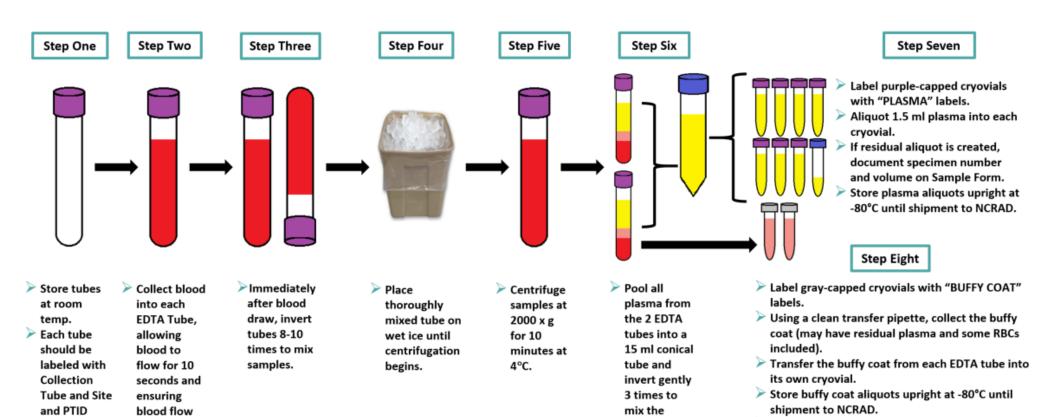
coat aliquots within 1 hour of collection.



Labels.

has stopped.

### Plasma and Buffy Coat Preparation EDTA Purple-Top Tube (10 ml)



Version (03.2021) 17

plasma.



#### 8.0 PACKAGING & SHIPPING INSTRUCTIONS

**ALL** study personnel responsible for shipping should be certified in biospecimen shipping. If you have difficulty finding biospecimen shipping training, please notify a NCRAD coordinator.

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

#### 8.1 Frozen Packaging Instructions

The most important issue for shipping is to maintain the temperature of the samples. The frozen samples must never thaw; not even the outside of the tubes should be allowed to defrost. This is best accomplished by making sure the Styrofoam container is filled completely with pelleted dry ice.

# \*\*\*Important Note\*\*\* FROZEN SAMPLES <u>MUST</u> BE SHIPPED MONDAY-WEDNESDAY ONLY!

Specimens being shipped to NCRAD should be considered as Category B UN3373 specimens and as such must be tripled packaged and compliant with IATA Packing Instructions 650. See the Latest Edition 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.



#### \*\*\* Packing and Labeling Guidelines \*\*\*

- > The primary receptacle (cryovial) must be leak proof and must not contain more than 1L total.
- The secondary packaging (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 and the secondary packaging. The absorbent material should be of sufficient quantity in order 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 of 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 Person
  - ✓ The words "Biological Substance, Category B"
  - ✓ UN3373
  - ✓ UPS Dry Ice label and net weight of dry ice contained





#### 8.1.1 NCRAD Packaging Instructions – Frozen Shipments

- 1. Contact UPS to confirm service is available and schedule package to be picked up.
- 2. Notify NCRAD of shipment by emailing NCRAD coordinators at <a href="mailto:alzstudy@iu.edu">alzstudy@iu.edu</a>. Attach the following to the email:
  - a. Completed Sample Form (<u>Appendix C</u>) to the email notification (email NCRAD coordinator prior to shipment to receive sample form).
  - b. If email is unavailable please call NCRAD at 1-800-526-2839 and do not ship until you've contacted and notified NCRAD coordinators about the shipment in advance.
- 3. Place the cryovial boxes containing frozen samples into a biohazard bag.





4. As the cryovial box is placed in the plastic biohazard bag, do NOT remove the absorbent material found in the bag. Seal according to the instructions on the bag.



- 5. Place approximately 2-3 inches of dry ice in the bottom of the Styrofoam shipping container.
- 6. Place the biohazard bags into the provided Styrofoam-lined shipping container on top of the dry ice. Please ensure that cryovial boxes are placed so the cryovials are upright in the shipping container.
- 7. Fully cover the biohazard bags containing the cryovial boxes tubes with approximately 2 inches of dry ice.
- 8. After the samples have been placed into the shipping container, fill the inner Styrofoam with plenty of dry ice pellets to ensure the frozen state of the specimens during transit.
- 9. Replace the lid on the Styrofoam carton. Place the completed Blood Sample 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.
- 10. Complete the UPS Dry Ice Label with the following information:
  - a. Net weight of dry ice in kg (must match amount on the airbill)



- b. Do not cover any part of this label with other stickers, including preprinted address labels.
- 11. Apply all provided warning labels and the preprinted UPS return airbill to the outside of package, taking care not to overlap labels.

#### \*\*\*Important Note\*\*\*

Complete the required fields on the UPS Dry Ice label or UPS may reject or return your package.

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



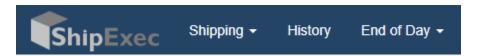
13. Specimens should be sent to the below address via UPS Next Day Air. Frozen shipments should be sent Monday through Wednesday to avoid shipping delays on Thursday or Friday.

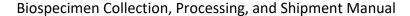
BBBSR at NCRAD
Indiana University School of Medicine
351 W. 10th St. TK-342
Indianapolis, IN 46202

14. Use UPS tracking to ensure the delivery occurs as scheduled and is received by NCRAD. Please notify NCRAD by email (<a href="mailto:alzstudy@iu.edu">alzstudy@iu.edu</a>) that a shipment has been sent and include the UPS tracking number in your email.

#### 8.2 Frozen Shipping Instructions

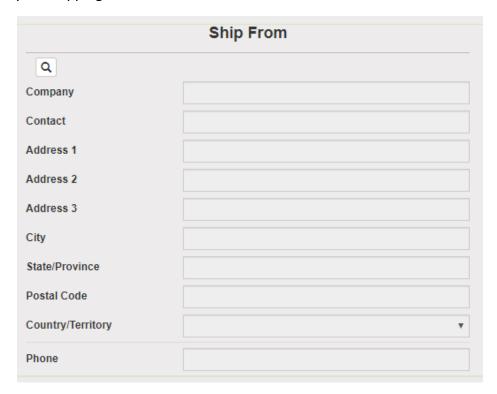
- 1. Log into the ShipExec Thin Client at kits.iu.edu/UPS.
  - a. If a new user or contact needs access, please reach out to your study contact for access.
- 2. Click "Shipping" at the top of the page and select "Shipping and Rating".







- 3. Select your study from the "Study Group" drop down on the right side of the main screen. Choosing your study will automatically filter the address book to only addresses within this study.
- 4. Click on the magnifying glass icon in the "Ship From" section to search for your shipping address.



- a. Search by Company (site), Contact (name), or Address 1 (first line of your site's street address). Click Search.
- b. Click Select to the left of the correct contact information.
- 5. Verify that both the shipping information AND study reference are correct for this shipment.
  - a. If wrong study contact or study reference, click Reset in the bottom right of the screen to research for the correct information.
- 6. Enter Package Information
  - a. Ambient shipments
    - Enter the total weight of your package in the "Weight" field and leave the "Dry Ice Weight" field empty.
  - b. Frozen shipments
    - i. Enter the total weight of your package in the "Weight" field.
    - ii. Enter the dry ice weight in the "Dry Ice Weight" field.



- iii. If the "Dry Ice Weight" field is higher than the "Weight" field, you will receive an error message after clicking Ship and need to reenter these values.
- c. Click Ship in the bottom right of the page when complete.
- 7. If your site does not already have a daily UPS pickup, you can schedule one here.
  - a. Click the blue Pickup Request button. Enter the earliest pickup time and latest pickup time in 24-hr format.
  - b. Give a name & phone number of someone who the UPS driver can call if having issues finding the package
  - c. Give the Floor and Room Number (if needed) to be as descriptive as possible where this package needs to be picked up from. Click Save.
- 8. Print the airbill that is automatically downloaded.
  - a. To reprint airbill, click History at the top left of the page.
    - Shipments created from the user that day will automatically populate. If shipments from a previous day need to be located, search by ship date.
    - ii. Locate the correct shipment, and click on the printer icon to the left of the tracking number under "Action" to reprint the airbill
    - iii. Click print icon on right side of the tracking number line.
- 9. Fold airbill, and place inside plastic UPS sleeve.

Peel the back off of the UPS sleeve, and stick the sleeve to the package.

#### 9.0 Data Queries and Reconciliation

Sample and Shipment Notification forms must be completed on the day that samples are collected (for ambient samples), or before sample shipment (for batch frozen samples) because they include information that will be used to reconcile sample collection and receipt, as well as information essential to future analyses.

NCRAD will collaborate with the data team at NACC to reconcile information captured in the NACC database compared to samples received and logged at NCRAD. Additional discrepancies may be sent directly to the Center staff to reconcile.

Data queries or discrepancies with samples shipped and received at NCRAD may result from:



- Incorrect samples collected and shipped
- Damaged or incorrectly prepared samples
- Unlabeled samples, samples labeled with incomplete information, or mislabeled samples
- Discrepant information documented on the Blood Sample and Shipment Notification Form and logged at NCRAD compared to information entered into the NACC database.

#### **10.0** APPENDICES

Appendix A: GUID Demographics Form

Appendix B: Rate of Centrifuge Worksheet

Appendix C: Blood Sample and Shipment Notification Form



#### **Appendix A: GUID Demographics Form**

Please be certain to collect the following demographic information to generate a Global Unique Identifier. **Do NOT** return this information to NCRAD. Only send the GUID to NCRAD.

| 1. Compete legal given (first) name of subject at birth:  |
|---|
| 2. Complete additional (middle) name or names at birth:   |
| 3. Complete legal family (last) name of subject at birth: |
| 4. Suffix:  |
| 5. Date of Birth:   |
| 6. Name of city/municipality in which subject was born:   |
| 7. Country of birth:                                      |





#### **Appendix B: Rate of Centrifuge Worksheet**

Please complete and return this form by fax or email to the NCRAD Project Manager if you have any questions regarding sample processing. The correct RPM will be sent back to you.

| Submitter Information Name: Submitter e-mail:  | Site:  |
|--|--|
| Centrifuge Information   |  |
| Please answer the following questions about  | your centrifuge.   |
| Centrifuge Type  |  |
| Fixed Angle Rotor:   Swing Buck  | eet Rotor:   |
| Radius of Rotation (mm):   |  |
| _  | (in mm) by measuring distance from the center of evice when inserted into the rotor (if measuring a the bucket). |
| Calculating RPM from G-Force:  | $\Rightarrow RPM = \sqrt{\frac{RCF}{r \times 1.118}} \times 1,000$   |
| RCF = Relative Centrifugal Force (G-Force) RPM = Rotational Speed (revolutions per min | ute)   |

Comments:

centrifuge

Please send this form to NCRAD Study Coordinator

R= Centrifugal radius in mm = distance from the center of the turning axis to the bottom of

317-321-2003 (Fax) <u>alzstudy@iu.edu</u>



#### **Appendix C: Blood Sample and Shipment Notification Form**

Please email or fax the form on or prior to the date of shipment.

| To: Kelley Faber Email: alzstudy@iu.edu Fax: 317-321-2003 Phone: 1-800-526-2839 |   |   |             |  |  |
|---|---|---|-------------|--|--|
| From: UPS tracking #:   |   |   |             |  |  |
| Phone: Email:   |   |   |             |  |  |
| Study: BBBSR BIFB ADC   | Study: BBBSR BIFB ADCFB: NACC Visit Sex: M F Year of Birth: |   |             |  |  |
| PT ID:  |   |   | KIT BARCODE |  |  |
| BIFB ID: BIFB   |   | <u> </u>  | '           |  |  |
| Blood Collection:   |   |   |             |  |  |
| Date of Draw:   | [MMDDYY]  | Time of Draw:   | [HHMM]      |  |  |
| Date subject last ate:  | -   | Time subject last ate:  |             |  |  |
|   |   | -   |             |  |  |
| Blood Processing:   |   |   |             |  |  |
|   | Plasma & Buffy Co   | oat (EDTA Tube)   |             |  |  |
| EDTA #1 specimen number   | i idoma di bani, de   |   |             |  |  |
| (Last four digits):   |   | Original blood volume of EDTA #1:                               | mL          |  |  |
| EDTA #2 specimen number   |   | 0:: 111 1 1 (5557) #2   |             |  |  |
| (Last four digits):   |   | Original blood volume of EDTA #2:                               | mL          |  |  |
| Time spin started:  | [HHMM]  | Duration of centrifuge:   | mins        |  |  |
| Temp of centrifuge:   | °C  | Rate of centrifuge:   | x g         |  |  |
| Time aliquoted:   | [HHMM]  | Number of 1.5 mL plasma aliquots created (purple cap, up to 6): |             |  |  |
| If applicable, volume of residual   |   | If applicable, specimen number of                               |             |  |  |
| plasma aliquot (less than 1.5 mL  |   | residual plasma aliquot   |             |  |  |
| in blue cap):   | mL  | (Last four digits):   | \_\_\N/A    |  |  |
| Buffy coat #1 specimen number   |   | Duffice and #4 columns  | 1           |  |  |
| (Last four digits): Buffy coat #2 specimen number                               |   | Buffy coat #1 volume:   | mL          |  |  |
| (Last four digits):   |   | Buffy coat #2 volume:   | mL          |  |  |
| Time aliquots placed in freezer:  | [HHMM]  | Storage temperature of freezer:                                 | °C          |  |  |
| Notes:  |   |   |             |  |  |