

MCS-R01 Protocol Update: V04.09.2024

| Section | Change | |
|------------------|---|--|
| Section 7.1.1 | Specified to included Blood Sample and Shipment Notification Form on outside | |
| Step 10 | of Styrofoam container. | |
| Section 7.1.1 | Specified maximum number of cryoboxes for shipping container. | |
| Step 7 | | |
| Section 3.1 | Added new URL for PACT study webpage on NCRAD website. | |
| Section 6.1 | Updated labels to reflect new format. | |
| Throughout | Applied new template including change in colors, formats, and logo | |
| | throughout. | |
| Throughout | Alternate text applied to images and tables throughout. | |
| Throughout | Applied new template including change in colors, formats, and logo | |
| | throughout. | |
| Throughout | Alternate text applied to images and tables throughout. | |
| Throughout | Replaced "dry ice" language with "pelleted dry ice" throughout. | |
| Throughout | Replaced "subject" and "patient" language with "participant". | |
| Section 3.1, | Included alternate phone number in addition to NCRAD contact information. | |
| Appendix B, and | | |
| Section 7.1.1 | | |
| Section 6.2 | Updated Step C to clarify "Release tourniquet as soon as blood starts to flow | |
| Step 4c | into last collection tube" | |
| Section 5.1 | Removed "Biohazard Label" from individual supplies. | |
| Section 6.2 | Included unused cryovials to disposal instruction. | |
| Step 13 | | |
| Section 6.2 Step | Language corrected from one-hour to two-hour window time | |
| 8.C. | | |



Multicultural Community Dementia Screening

in collaboration with the

National Centralized Repository for Alzheimer's Disease and Related Dementias



Biospecimen Collection, Processing, and Shipment Manual of Procedures

Version 04.09.2024



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1.0 Abbreviations

| AD | Alzheimer's Disease |
|-------|---|
| MCS | Multicultural Community Dementia Screening |
| 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 Multicultural Community Dementia Screening (MCS) Study. The purpose of this manual is to provide study staff with instructions for collection and submission of biological samples for MCS 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 MCS 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: <u>kelfaber@iu.edu</u>

Erin Delaney, AS, CCRP, Clinical Research Coordinator Phone: 317-278-1221 Email: <u>eridelan@iu.edu</u>

General NCRAD Contact Information

Phone: 1-800-526-2839/317-278-8413 Fax: 317-321-2003 Email: <u>alzstudy@iu.edu</u> Website: <u>www.ncrad.org</u> MCS Study Webpage: <u>https://ncrad.org/coordinate-studies/MCS</u>

Sample Shipment Mailing Address

MCS at NCRAD Indiana University School of Medicine 351 W. 10th St. TK-342 Indianapolis, IN 46202 Phone: 1-800-526-2839/317-278-8413

3.2 NCRAD 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 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 rd Monday in January | Martin Luther King, Jr Day |
| 4 th Monday in May | Memorial Day |
| June 19 | Juneteenth |
| July 4 | Independence Day |
| 1 st Monday in September | Labor Day |
| 4 th Thursday in November | Thanksgiving |
| 4 th Friday in November | Friday after Thanksgiving |
| December 25 | Christmas Day |

Please note that between December 24th and January 2nd, Indiana University will be open Monday through Friday for essential operations **ONLY** and will re-open for normal operations on January 2nd. 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 20th by e-mailing <u>alzstudy@iu.edu</u>, so that they can arrange to have staff available to process incoming samples. **Please see:** <u>https://ncrad.org/holiday_closures.html</u> 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 MCS LABORATORY COLLECTION

4.1 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
- > Pelleted dry ice

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

- ≻ Centrifuge capable of \ge 2000 x g with refrigeration to 4°C
- -80°C Freezer

In order to ship specimens, you must provide:

> Pelleted dry ice (approximately 45 lbs per shipment)

4.2 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 | Х |
| 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: <u>https://ncrad.org/recommended_consent_language.html</u>. A copy of the consent form for each participant should be kept on file by the site investigator.



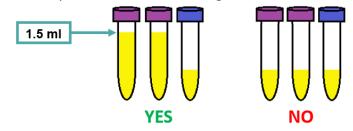
4.2.2 Biofluid Collection Charts

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

4.3 Filling Cryovials

In order to ensure that NCRAD 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 after processing is completed (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 sample.

Aliquot the remaining biologic material as the residual volume and ship to NCRAD. Ship *all* material to NCRAD. Fill as many aliquot tubes as possible. For example, if 2.7 ml of a plasma sample is obtained, fill 1 cryovial with 1.5 ml, and one additional cryovial with the remaining 1.2 ml.



Please note: It is critical for the integrity of future studies using these samples that study staff note if an aliquot tube contains a residual volume (anything under 1.5 ml). Please highlight that the aliquot contains a small volume by utilizing the blue cryovial cap provided in each kit. Please record the last four digits of the residual aliquot on the Biological Sample and Notification Form. If there are any unused cryovials, please do not send the empty cryovials to NCRAD. These unused cryovials (ensure labels are removed) can be saved as part of a supplemental supply at your site or the cryovials can be disposed of per your site's requirements.

To assist in the preparation and aliquoting of samples, colored caps are used for the aliquot tubes. The chart below summarizes the association between cap color and type of aliquot.



| Cap Color | Sample Type |
|-----------|------------------------|
| Lavender | Plasma |
| Clear | Buffy Coat |
| Blue | Residual sample plasma |

5.0 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 2) clinical lab supplies (with the exception of pelleted dry ice and equipment supplies listed in <u>Section 5.1</u>). 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 aliquot labels will all be provided by NCRAD. Details regarding the blood kits are found in this Manual of Procedures. Collection tube and aliquot 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 <u>Section 7.1</u>.

5.1 NCRAD Specimen Collection Kit Contents

Collection kits contain the following (for each participant) and provide the necessary supplies to collect samples from a given participant. 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</u> <u>store all kits at room temperature until use.</u>

| Quantity | MCS Kit Components |
|----------|---|
| 2 | EDTA (purple-top) blood collection tube (10 ml) |
| 1 | Centrifuge Tube, 15 ml |
| 6 | Cryovial (2.0 ml) with purple cap |
| 1 | Cryovial (2.0 ml) with blue cap |
| 2 | Cryovial (2.0 ml) with clear cap |
| 9 | Preprinted Cryovial Labels |
| 5 | Preprinted Kit Number Label |
| 3 | Label for handwritten Participant ID |
| 1 | Cryovial box (holds up to 25 cryovials) |
| 3 | Disposable graduated transfer pipettes (3 ml) |
| 1 | Resealable Bag |
| 1 | Resealable small poly bag (4" x 6") |

MCS Blood Kit



MCS Supplemental Supply Kit

| Quantity | MCS Supplemental Supply Kit Components |
|----------|---|
| 4 | EDTA (purple-top) blood collection tube (10 ml) |
| 12 | Cryovial (2.0 ml) with purple cap |
| 2 | Cryovial (2.0 ml) with blue cap |
| 4 | Cryovial (2.0 ml) with clear cap |
| 2 | Conical tubes (50.0 ml) |
| 5 | Label for handwritten Participant ID |
| 2 | Cryovial box (holds up to 25 cryovials) |
| 6 | Disposable graduated transfer pipettes (3 ml) |
| 1 | Resealable bag |
| 6 | Resealable small poly bag (4" x 6") |

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 (UN3373, Fragile, Dry Ice) | |
| 1 | Resealable bag | |

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 clear 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 (3 ml) | |
| By Request | EDTA (Purple-Top) Blood Collection Tube (10 ml) | |
| By Request | Warning label packet (UN3373, Fragile, Biohazard, Dry Ice) | |
| By Request | UN3373 label | |
| By Request | Dry ice shipping label | |
| By Request | Fine Point Permanent Markers | |
| By Request | Participant ID Labels | |



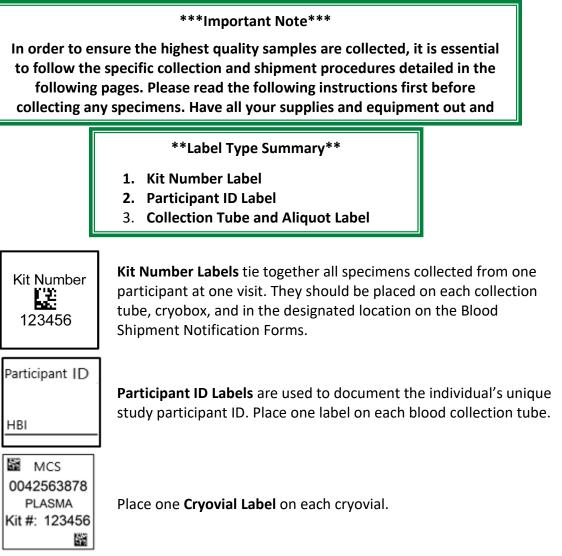
5.2 Kit Supply to Study Site

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: http://kits.iu.edu/MCS to request additional kits and follow the prompts to request the desired supplies.

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

6.0 BLOOD COLLECTION AND PROCESSING PROCEDURES

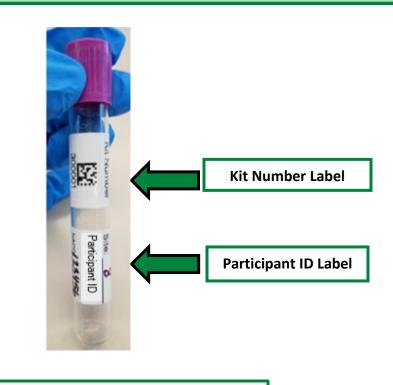
6.1 Labeling Samples





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 toward the bottom.



Labeled EDTA (Purple-Top) Blood Collection Tube

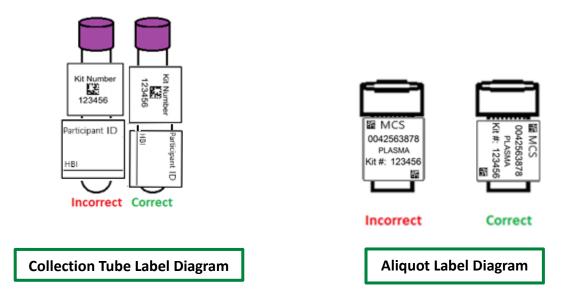
In order to ensure the label adheres properly and remains on the tube, <u>please</u> <u>follow these instructions:</u>

- 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 participant ID 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 <u>completely adhered</u> to each tube. It may be helpful to roll the tube between your fingers after applying the label.



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

- Store empty EDTA tubes at room temperature, 64°F 77°F (18 °C 25 °C) before use. Verify all supplies have not expired before use.
- 2. Set centrifuge to 4°C to pre-chill before use.
- 3. Place completed Participant ID Label and preprinted **PLASMA** Collection Tube Label on the purple-top EDTA tube. Place preprinted **PLASMA** Aliquot 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 Clear caps.
- 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:

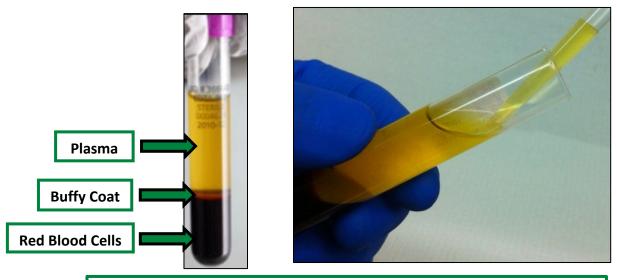
a. Place participant's arm in a downward position.



- 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 last collection 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 equivalent RPM for spin at 2000 x g).
 - a. While centrifuging, remember to record all times, temperatures and spin rates on the Biological Sample and Shipment Notification Form.
 - b. Record original volume drawn for each tube in spaces provided on the Biological Sample Shipment and Notification Form.
 - c. Plasma samples need to be spun, aliquoted, and placed in the freezer within 2 hour from the time of collection.
 - d. 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)</p>



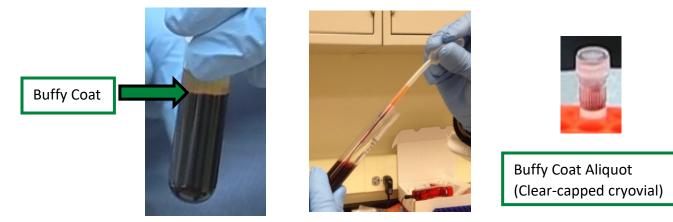
Biospecimen Collection, Processing, and Shipment Manual ml) in the blue-capped cryovial. If a residual aliquot (<1.5 ml) is created, document the specimen number and volume on the Biological Sample and Shipment Notification Form.



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 pelleted dry ice. Transfer to -80°C Freezer when possible. Store all samples at -80°C until shipped to NCRAD on pelleted 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 from one EDTA tube into a labeled, Clear-capped cryovial using a pipette. 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 Clear-capped cryovial.





- 13. Dispose of collection tube with red blood cell pellet and unused cryovials 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 pelleted dry ice. **Transfer to -80°C Freezer when possible.** Store all samples at -80°C until shipped to NCRAD on pelleted dry ice. Record time aliquots placed in freezer and storage temperature of freezer on Biological Sample and Shipment Notification Form.

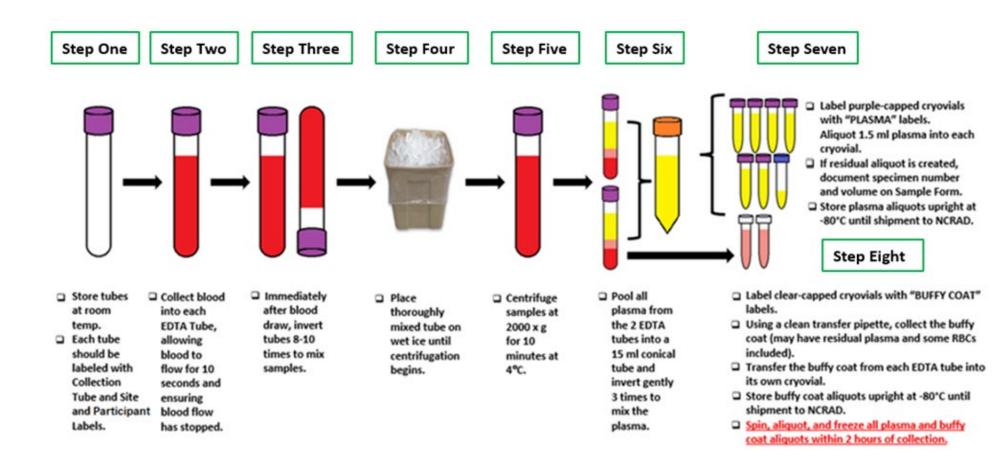


Plasma Aliquots (up to 7 possible) and Buffy Coats (2)

NCRAD

Biospecimen Collection, Processing, and Shipment Manual

Plasma and Buffy Coat Preparation EDTA Purple-Top Tube (2 x 10 ml)





7.0 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 pelleted dry ice to avoid thawing in the shipment process.

7.1 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



7.1.1 NCRAD Packaging Instructions - Frozen Shipments

- If possible, hold packaged samples in -80°C freezer until time of UPS pick-up/drop-off. If storage in a -80°C freezer until UPS pick-up is not possible, package samples no more than 4 hours before the expected pick-up time.
- 2. Contact UPS to confirm service is available and schedule package to be picked up.
- 3. Notify NCRAD of shipment by emailing NCRAD coordinators at <u>alzstudy@iu.edu.</u> Attach the following to the email:
 - 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 1-800-526-2839/317-278-8413 and do not ship until you've contacted and notified NCRAD coordinators about the shipment in advance.



- 4. Place the cryovial boxes containing frozen samples into a biohazard bag.
- 5. 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.



- 6. Place approximately 2-3 inches of pelleted dry ice in the bottom of the Styrofoam shipping container.
- 7. Place the biohazard bags into the provided Styrofoam-lined shipping container on top of the pelleted dry ice. The large shipping container holds up to 8 cryoboxes. Please ensure that cryovial boxes are placed so the cryovials are upright in the shipping container.
- 8. Fully cover the biohazard bags containing the cryovial boxes tubes with approximately 2 inches of pelleted dry ice.
- 9. After the samples have been placed into the shipping container, completely fill the inner Styrofoam with pelleted dry ice pellets to ensure the frozen state of the specimens during transit.
- 10. Replace the lid on the Styrofoam carton. Place the completed Blood Sample and Shipment Notification Form in the package on top of the outside of Styrofoam lid for each participant specimen, and close and seal the outer cardboard shipping carton with packing tape.



- 11. Complete the UPS Dry Ice Label with the following information:
 - a. Net weight of pelleted 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.
- 12. 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.

- 13. If possible, hold packaged samples in -80°C freezer until time of UPS pick-up/drop-off. If storage in a -80°C freezer until UPS pick-up is not possible, package samples no more than 4 hours before the expected pick-up time.
- 14. Specimens should be sent to the below address via UPS Next Day Air. Frozen shipments should be sent **Monday through Wednesday ONLY** to avoid shipping delays on Thursday or Friday.

MCS at NCRAD Indiana University School of Medicine 351 W. 10th St. TK-217 Indianapolis, IN 46202

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

7.2 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.

| | Ship From |
|-------------------|-----------|
| Q | |
| Company | |
| Contact | |
| Address 1 | |
| Address 2 | |
| Address 3 | |
| City | |
| State/Province | |
| Postal Code | |
| Country/Territory | • |
| Phone | |

- 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. 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.
 - b. 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 top of the package. Do NOT overlap other labels or package seams.



8.0 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.

9.0 APPENDICES

Appendix A: Rate of Centrifuge Worksheet Appendix B: Blood Sample and Shipment Notification Form



Biospecimen Collection, Processing, and Shipment Manual Appendix A: 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 Bucket Rotor: \Box

Radius of Rotation (mm):

Determine the centrifuge's radius of rotation (in mm) by measuring distance from the center of the centrifuge spindle to the bottom of the device when inserted into the rotor (if measuring a swing bucket rotor, measure to the middle of the bucket).

Calculating RPM from G-Force:

$$\mathsf{RCF} = \left(\frac{\mathsf{RPM}}{1,000}\right)^2 \times \mathsf{r} \times 1.118 \quad \Rightarrow \quad \mathsf{RPM} = \sqrt{\frac{\mathsf{RCF}}{\mathsf{r} \times 1.118}} \times 1,000$$

RCF = Relative Centrifugal Force (G-Force)

RPM = Rotational Speed (revolutions per minute)

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

Comments:

Please send this form to NCRAD Study Coordinator

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



Appendix B: 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 Phone: 1-800-526-2839/317-278-8413 | | | | |
|--|----------|-----------------------------------|--------|--|
| From: <u>Mahesh Joshi, PhD</u> UPS tracking #: <u>1Z976R8W84</u> | | | | |
| Phone: 561-869-6827 Email: maj145@med.miami.edu | | | | |
| Study: Multicultural Community Dementia Screening | | | | |
| Visit: Baseline 1-Year 2-Year 3-Year 4-Year 5-Year | | | | |
| | | | | |
| Sex: M F Year of Birth: _ | | KIT BARCODE | | |
| Participant ID: <u>HBI</u> | | | | |
| Blood Collection: | | | | |
| Date of Draw: | [MMDDYY] | Time of Draw: | [HHMM] | |
| Date participant last ate: | [MMDDYY] | Time participant last ate: | [HHMM] | |
| | | | | |
| Blood Processing: | | | | |
| Plasma & Buffy Coat (EDTA Tube) | | | | |
| | | | | |
| Original blood volume of EDTA #1: | | Original blood volume of EDTA #2: | mL | |
| | | | | |
| Time spin started: | [HHMM] | Duration of centrifuge: | mins | |
| Temp of centrifuge: | °C | Rate of centrifuge: | x g | |
| | | Number of 1.5 mL plasma aliquots | | |
| Time aliquoted: | [HHMM] | created (purple cap, up to 6): | | |
| If applicable, volume of | | If applicable, specimen number of | | |
| residual plasma aliquot | | residual plasma aliquot | | |
| (less than 1.5 mL in blue cap): | mL 🗌 N/A | (Last four digits): | N/A | |
| Buffy coat #1 specimen number | | | | |
| (Last four digits): | | Buffy coat #1 volume: | mL | |
| Buffy coat #2 specimen number | | | | |
| (Last four digits): | | Buffy coat #2 volume: | mL | |
| Time aliquots placed in freezer: | [ННММ] | Storage temperature of freezer: | °C | |
| | | | | |
| Notes: | | | | |