Adult Changes in Thought Study

in collaboration with the

National Centralized Repository for Alzheimer's Disease and Related Dementias

Biospecimen Collection, Processing, and Shipment Manual of Procedures

Version 05.2024

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1.0 Abbreviations

ACT	Adult Changes in Thought
AD	Alzheimer's Disease
DNA	Deoxyribonucleic Acid
EDTA	Ethylene Diamine Tetra-acetic Acid
IATA	International Air Transport Association
IUGB	Indiana University Genetics Biobank
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
UPS	United Parcel Service

2.0 Purpose

The collection of blood-based biofluids is an important part of the Adult Changes in Thought (ACT) 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 blood-based biological samples for ACT study visits. It includes instructions for blood-based biospecimen 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 blood specimens being provided to NCRAD for the ACT protocol.

3.0 NCRAD Information

3.1 NCRAD Contacts

Tatiana Foroud, PhD, NCRAD Principal Investigator
Phone: 317-274-2218

Kelley Faber, MS, CCRC, Project Manager
Phone: 317-274-7360
Email: kelfaber@iu.edu

Mica Gosnell, MS, Clinical Research Coordinator
Phone: 317-274-7423
Email: gosnellm@iu.edu

General NCRAD Contact Information
Phone: 1-800-526-2839 or 317-278-8413
Email: alzstudy@iu.edu
Website: www.ncrad.org
ACT Study Specific Webpage: NCRAD - The ACT Active Study Page

3.2 Sample Shipment Mailing Address

NCRAD
Indiana University School of Medicine
351 West 10th Street
TK-217
Indianapolis, IN 46202
alzstudy@iu.edu

3.3 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 Section 9.0 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.

3.4 NCRAD Holiday Observations

Date	Holiday
January 1	New Year's Day
3rd Monday in January	Martin Luther King, Jr Day
4th Monday in May	Memorial Day
June 19	Juneteenth (observed)
July 4	Independence Day (observed)
1st Monday in September	Labor Day
4th Thursday in November	Thanksgiving
4th 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 alzstudy@iu.edu, so that they can arrange to have staff available to process incoming samples. **Please see: https://ncrad.org/contact/holiday-closures 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 NCRAD 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
- Pelleted 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:

- 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 Section 9.0. Guidelines for the processing, storage location, and timing of sample collection are listed in the following tables.

4.2.1 Biofluid Collection Schedule

Sample Type	ACT U19 Biomarker Cohort 1
Plasma	X
Buffy Coat	X

Whole blood is collected in one type of tube (purple top 10 mL EDTA tube) for shipment to NCRAD. **Three** 10mL 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: https://ncrad.org/bank-samples/sample-management/recommended-consent-language. A copy of the consent form for each participant should be kept on file by the site investigator.

4.3 Biospecimen Collection Chart

4.3.1 Blood Collection

Sample Type	Tube Type	Number of Tubes Supplied in Kit	Aliquot Volume	Tubes to NCRAD	Ship
Whole blood for isolation of plasma & buffy coat (for DNA extraction)	EDTA (Purple-Top) Blood Collection Tube (3 x 10 mL)	3	N/A	N/A	**N/A**
	PLASMA: 2.0 mL cryovials with purple cap (residual volume placed in 2.0 mL cryovial with blue cap)	10	1.5 mL plasma aliquot per 2.0 mL cryovial (purple/blue cap)	Up to 10	**Frozen**
	BUFFY COAT: 2.0 mL cryovial	3	1.0 mL buffy coat aliquot per 2.0 mL cryovial (clear cap)	3	**Frozen**

If a sample is not obtained at a particular visit, this should be recorded in the notes section of the **Biological Sample and Shipment Notification Form (see Appendix B).** Submit a copy to NCRAD with a reason provided for the omission.

5.0 Specimen Collection Kits, Shipping Kits, and Supplies

NCRAD will provide: 1) Blood based sample collection kits for research specimens to be stored at NCRAD, the Blood Supplemental Supply Kit, the Frozen Blood Shipment Supply Kit and 2) clinical lab supplies (with the exception of pelleted dry ice and equipment supplies listed in Section 5.1). The provided materials include blood tubes, pipettes, boxes for plasma/buffy coat aliquots, as well as airbill sleeves to send materials to NCRAD. Kit Number Labels, PTID Labels, Collection Tube and Cryovial Labels will all be provided by NCRAD. Collection Tube and Cryovial Labels will be pre- printed 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.

5.1 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. *Please store all kits at room temperature until use.*

ACT Blood Kit

Quantity	ACT Blood Kit Components
3	EDTA (Purple-Top) Blood Collection Tube (10 mL)
9	Cryovial (2.0 mL) with purple cap for plasma
1	Cryovial (2.0 mL) with blue cap for remaining plasma (if any)
3	Cryovial (2.0 mL) with clear cap for buffy coat
1	50 mL conical
4	Disposable graduated transfer pipette (3.0 mL)
16	Pre-printed Collection Tube and Cryovial Tube Label
3	Pre-printed Kit Number Label
4	Label for handwritten PTID
1	Large resealable kit bag
1	Small resealable bag for labels
1	Cardboard cryobox, 25 slot

ACT Frozen Blood Shipping Kit

Quantity	ACT Frozen Blood Shipping Kit Components
1	UPS Blue Dry Ice Sticker
1	UN3373 sticker
1	Fragile label
1	Shipping box/Styrofoam container (large)
8	Biohazard bag w/ absorbent sheet
1	UPS Airbill Sleeve
1	Resealable bag

ACT Blood Supplemental Kit

Quantity	ACT Blood Supplemental Kit Components
6	EDTA (Purple-Top) Blood Collection Tube (10 mL)
2	Cardboard cryobox, 25 slot
8	Disposable pipet (3ml)
2	50 mL conical tube
18	Cryovial (2.0 mL) with purple cap for plasma
2	Cryovial (2.0 mL) with blue cap for remaining plasma (if any)
6	Cryovial (2.0 mL) with clear cap for buffy coat
8	Label for handwritten PTID
1	Large resealable bag
2	Small resealable bag (4" x 6")

Individual Supplies

Quantities	Items Available upon request within the NCRAD kit module.
By Request	EDTA (Purple-Top) Blood Collection Tube (10 mL)
By Request	Cryovial (2.0 mL) with purple cap for plasma
By Request	Cryovial (2.0 mL) with blue cap for remaining plasma (if any)
By Request	Cryovial (2.0 mL) with clear cap for buffy coat
By Request	50 ml conical polypropylene tube (blue cap)
By Request	Disposable graduated transfer pipette (3.0 mL)
By Request	Label for handwritten PTID
By Request	Cryovial box (holds up to 25 cryovials)
By Request	Shipping container for dry ice shipment (shipping and Styrofoam box)- large shipper
By Request	Plastic biohazard bag with absorbent sheet (small)
By Request	Fragile Label
By Request	UPS Blue Dry Ice Sticker
By Request	UN3373 label
By Request	Fine point permanent markers
By Request	UPS Airbill Sleeve

5.2 Kit Supply to Study Sites

Each individual 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/ACT to request additional kits and follow the prompts to request the desired supplies. Options include ordering a specific number of kits; we are also including the option of simply ordering the desired amount of extra supplies.

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

Due to ongoing supply limitations, we ask that you please only order as many kits and extra supplies that you will be able to use in the next 30 days. Doing so allows us to fulfill as many kit requests as possible without depleting stock for other kit requests in our queue. If we are not able to fulfill any part of your request due to supplies being out of stock, we will reach out about those individually.

6.0 Blood Collection and Processing Procedures

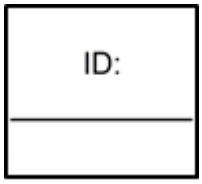
6.1 Labeling Samples

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.

6.1.1 Label Type Summary

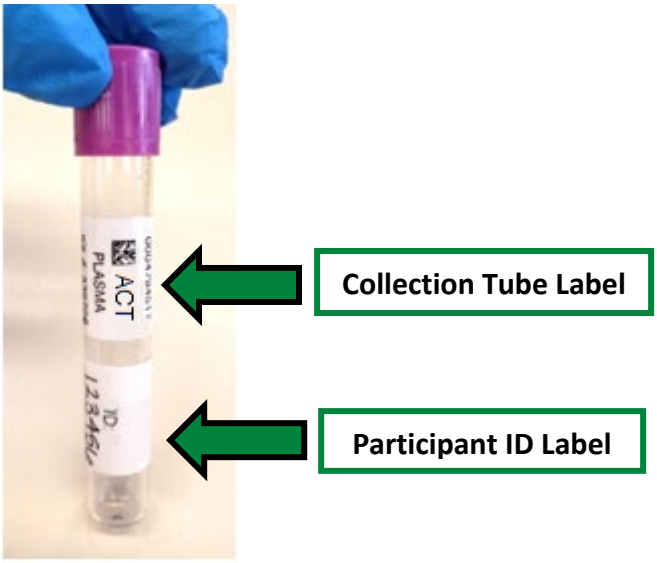
1. Kit Number Label
2. Participant ID Label
3. Collection Tube and Aliquot Label

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 Sample and Shipment Notification Forms.



Participant ID Labels are used to document the individual's unique Participant ID. Place one label on each blood collection tube.

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



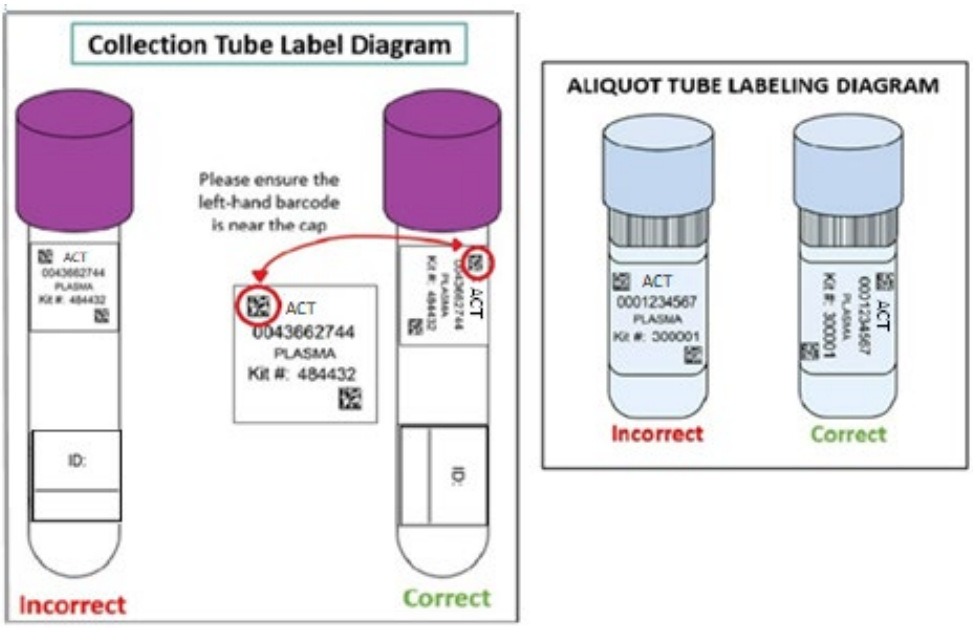
Labeled EDTA (Purple-Top) Blood Collection Tube

Each collection tube will contain two labels: the collection tube label and the Participant ID 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 Participant ID label near the bottom of the tube.

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

- Place Collection Tube and Aliquot Labels on **ALL** collection tubes and cryovials **BEFORE** 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 **BEFORE** 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 **horizontally** on the tube (wrapped around sideways if the tube is upright).

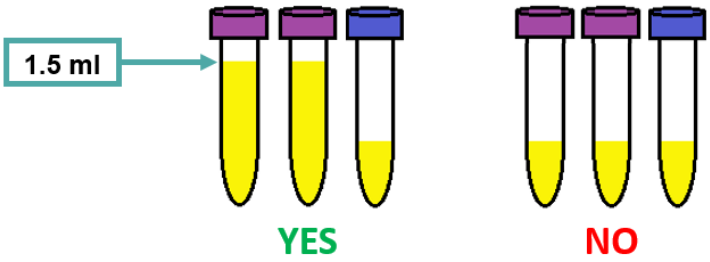
Take a moment to ensure the label is **completely adhered** to each tube. It may be helpful to roll the tube between your fingers after applying the label. **If there are any unused cryovials, please do not send the empty cryovials to NCRAD. These unused cryovials (ensure labels are removed) can be saved as part of a supplemental supply at your site or the cryovials can be disposed of per your site's requirements.**



6.2 Filling Aliquot Tubes (Plasma)

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 3.7 ml of a plasma sample is obtained, fill 2 cryovials with 1.5 ml, and one additional cryovial with the remaining 0.7 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
Purple	Plasma
Clear	Buffy Coat
Blue	Residual sample

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

1. Store empty EDTA tubes at room temperature, 64°F - 77°F (18 °C – 25 °C) 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 tubes. Place preprinted **PLASMA** Aliquot Labels on the 2 ml cryovials with purple caps and 2 ml cryovial with blue cap (if necessary, for residual). Place preprinted **BUFFY COAT** Aliquot Label on the 2 ml cryovials with clear 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 horizontal position below the participant's arm during blood collection and invert several times immediately after filling.
   c. Release tourniquet mid to end of the last collection tube.
   d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

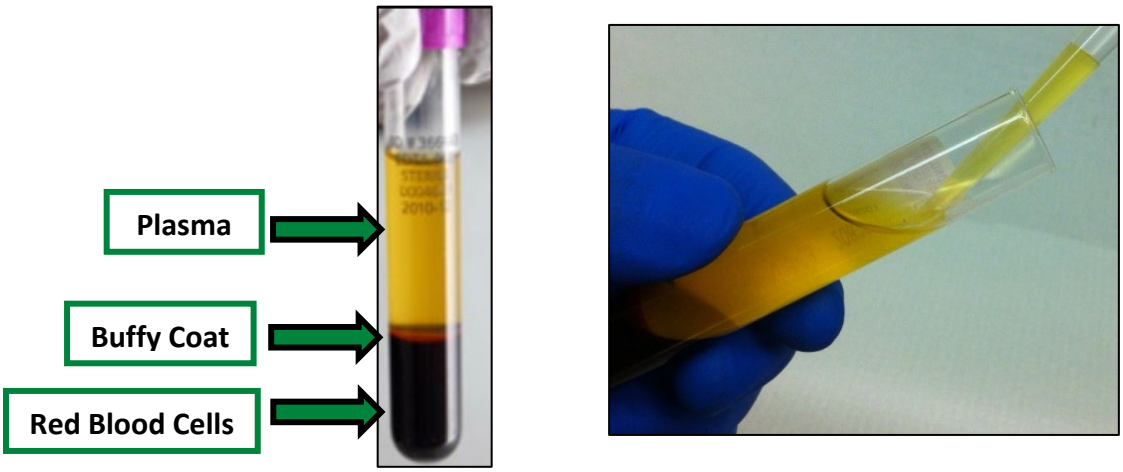
5. Allow at least 10 seconds for a complete blood draw to take place in each tube. **Ensure that the blood has stopped flowing into the tube before removing the tube from the holder.** The tube with its vacuum is designed to draw 10 ml of blood into the tube.
    a. If complications arise during the 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. 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 Appendix A 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 hours from the time of collection.
    d. Record time aliquoted on the Biological Sample Shipment and Notification Form.

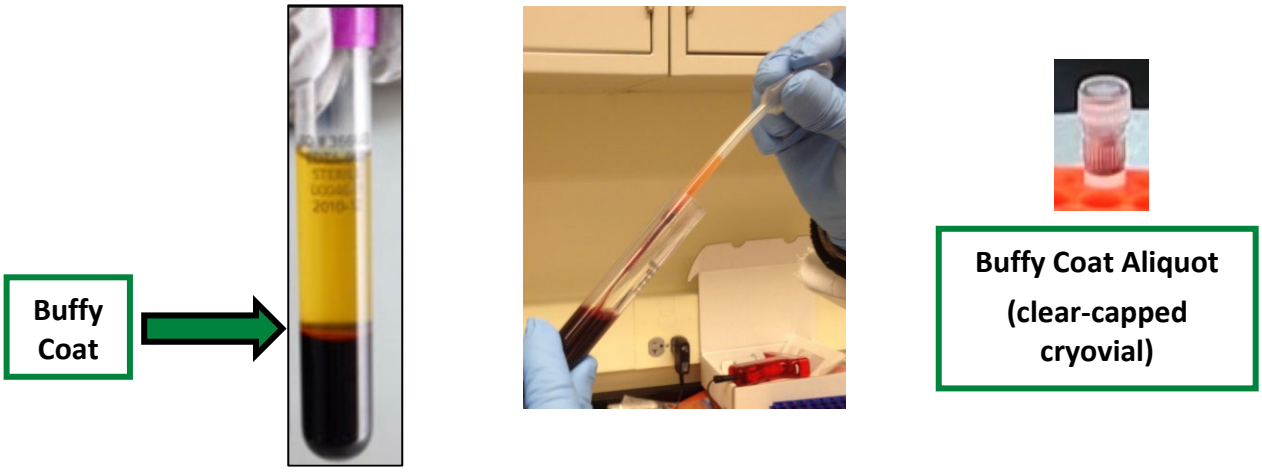
8. Remove the plasma by tilting the tube and placing the pipette tip along the lower side of the wall being careful not to agitate the packed red blood cells at the bottom of the collection tube.

9. Each EDTA tube should yield, on average, 4-5 ml of plasma. Transfer plasma from all EDTA tubes into the 50 ml conical tube and gently invert 3 times. Aliquot 1.5 ml plasma per cryovial. When pipetting plasma from the EDTA tube into the 50 ml conical tube, be very careful to pipette the plasma top layer only, leaving the buffy coat and the red blood cell layers untouched. 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.**



10. 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 frozen and storage temperature of freezer on Biological Sample Shipment and Notification Form (Appendix B).

11. 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, clear-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 and third EDTA tubes (if collecting 30ml total), placing these buffy coats into the second and third clear-capped cryovials.



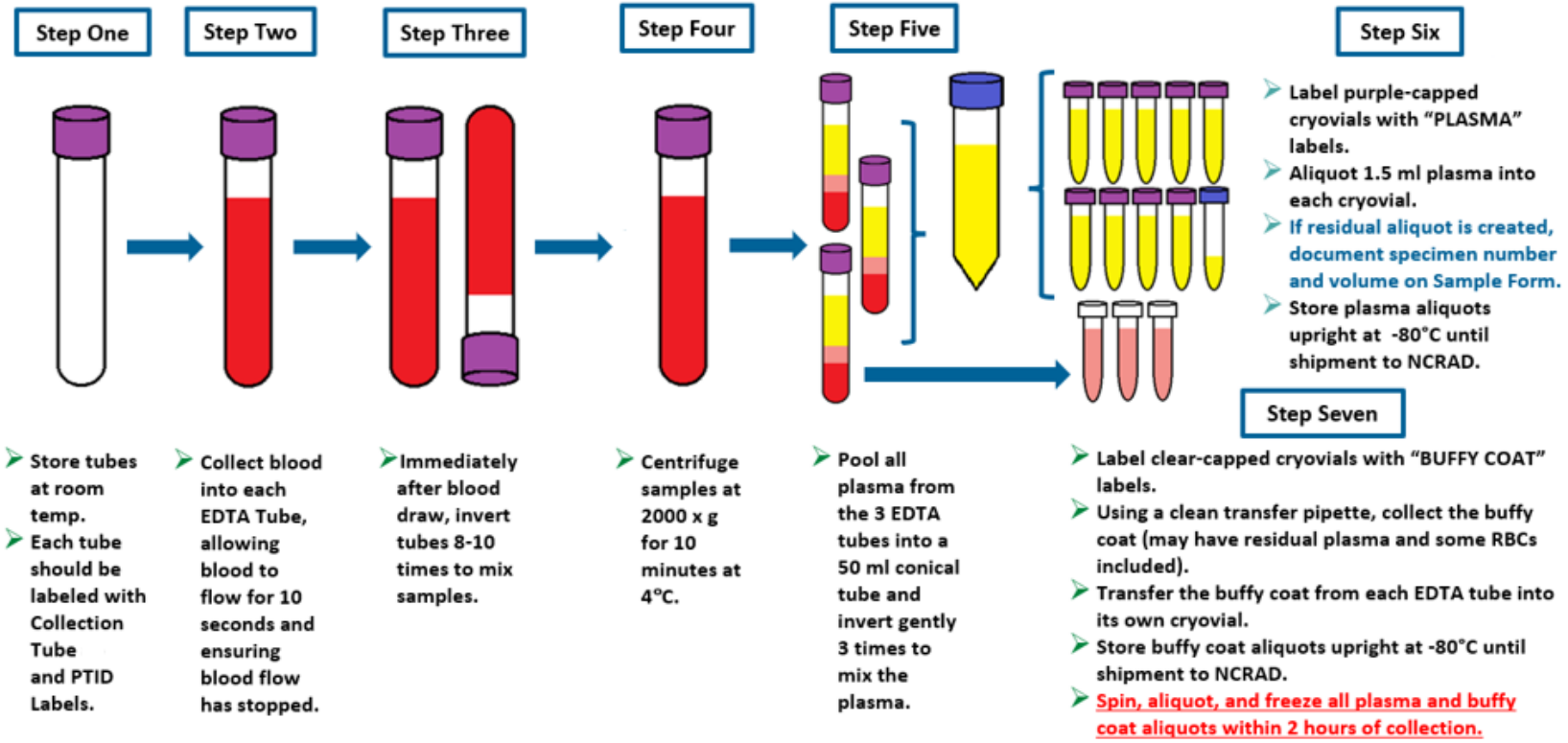
12. Dispose of collection tube with red blood cell pellet according to your site's guidelines for disposing of biomedical waste.

13. Record the specimen number and volumes of the EDTA tubes and corresponding buffy coat samples on the Biological Sample Shipment and Notification Form.

14. 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 frozen and storage temperature of freezer on Biological Sample and Shipment Notification Form.

Plasma Aliquots (up to 10 possible) and Buffy Coats (3)

Plasma and Buffy Coat Preparation EDTA Purple-Top Tube (3 x 10 ml)



Note: Be sure to check expiration date of tubes/supplies before collection to be sure they are not expired.

7.0 Incomplete or Difficult Blood Draws

Situations may arise that prevent study coordinators from obtaining the total amount scheduled for biospecimens. In these situations, please follow the below steps:

1. *If the biospecimens at a scheduled visit **are partially** collected:*
    a. Attempt to process and submit any samples that were able to be collected during the visit
    b. Document difficulties on the 'Biological Sample and Shipment Notification Form' prior to submission to NCRAD
        i. Indicate blood draw difficulties at the bottom of the 'Biological Sample and Shipment Notification Form' within the "Notes" section.
        ii. Complete the 'Biological Sample and Shipment Notification Form' with tube volume approximations and number of aliquots created.

8.0 Frozen Packaging and 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 number 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.

8.1 Frozen Packaging Instructions

FROZEN SAMPLES MUST BE SHIPPED MONDAY-WEDNESDAY ONLY!

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.

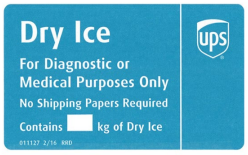
Specimens being shipped to NCRAD should be considered as Category B UN3373 specimens and as such must be tripled packaged and compliant with IATA Packing Instructions 650. *See the Latest Edition of the IATA Regulations for complete documentation.*

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
  - ✓ Fragile



8.1.1 NCRAD Packaging Instructions – Frozen Shipments

1. Notify NCRAD of shipment by emailing NCRAD coordinators at alzstudy@iu.edu. Attach the following to the email:
   a. Completed Sample Form (Appendix C) 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 or 317-278-3418 and do not ship until you've contacted and notified NCRAD coordinators about the shipment in advance.

2. Place the cryovial boxes containing frozen samples into a biohazard bag. You can ship up to 8 cryovial boxes per large shipper.

3. 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.

4. Place approximately 2-3 inches of pelleted dry ice in the bottom of the Styrofoam shipping container.

5. Place the biohazard bags into the provided Styrofoam-lined shipping container on top of the pelleted dry ice. Please ensure that cryovial boxes are placed so the cryovials are upright in the shipping container.

6. Fully cover the biohazard bags containing the cryovial boxes tubes and fill the shipper to the top with pelleted dry ice.

7. After the samples have been placed into the shipping container, completely fill the inner Styrofoam with dry ice pellets to ensure the frozen state of the specimens during transit.

8. 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.

9. 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.

10. Apply all provided warning labels and UPS return airbill to the outside of package, taking care not to overlap labels. **Complete the required fields on the UPS Dry Ice label or UPS may reject or return your package.**

11. 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

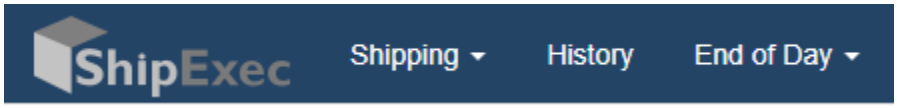
possible, package samples no more than 4 hours before the expected pick-up time.

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

8.2 Frozen Shipping Instructions

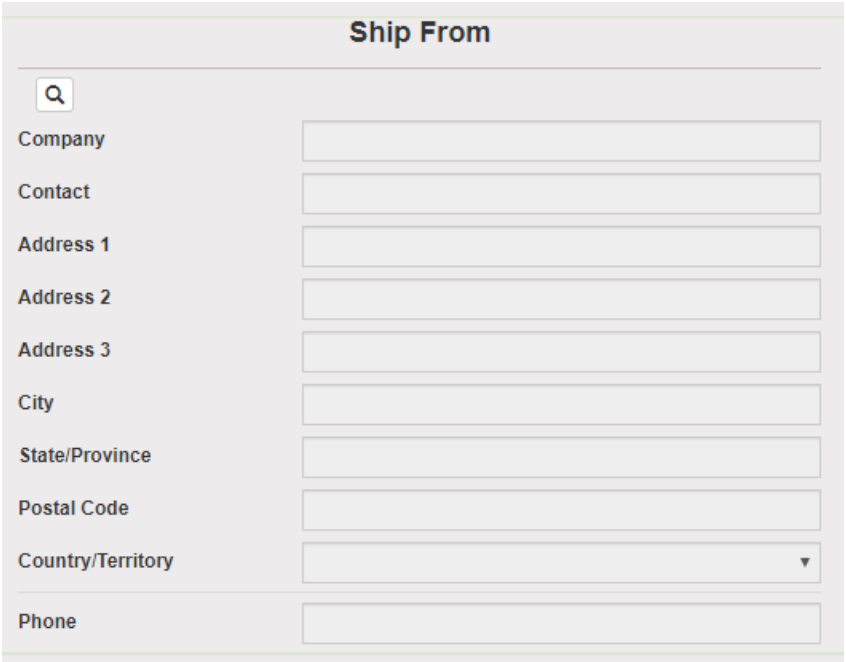
1. Log into the ShipExec Thin Client at kits.iu.edu/UPS.
    a. If a new user or contact needs access, please reach out to your study contact for access.

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. Frozen shipments
        i. Enter the total weight of your package in the “Weight” field.
        ii. Enter the pelleted 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.
        i. 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.

10. Peel the back off of the UPS sleeve and stick the sleeve to the package top. Ensure that sleeve does not cover any warning labels (e.g. dry ice label) or overlap taped seams.

9.0 Data Queries and Reconciliation

Sample and Shipment Notification forms must be completed on the day that samples are collected since they capture information related to the details of the sample collection and processing. These forms include information that will be used to reconcile sample collection and receipt, as well as information essential to future analyses.

When documenting the date and time the participant last ate, this refers to any food or drink apart from clear liquids, black coffee, or tea. Please note fasting is not a requirement.

NCRAD will collaborate with the data team to reconcile information captured in the 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 database.

10.0 Appendices List

Appendix A: Rate of Centrifuge Worksheet

Please complete and return this form by 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: **Site:**

Submitter e-mail:

Centrifuge Information

Please answer the following questions about your centrifuge.

Centrifuge Type

Fixed Angle Rotor: ☐ Swing Bucket Rotor: ☐

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:

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

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 at alzstudy@iu.edu

Appendix B: Blood Sample and Shipment Notification Form

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

To: Kelley Faber Email: alzstudy@iu.edu Phone: 1-800-526-2839

From:_____ **UPS tracking #:** **1Z976R8W84**

Phone:_____ **Email:**_____

Study: ACT **Sex:** ☐M ☐F **Year of Birth:** _____

KIT BARCODE

Participant ID: _____

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)**

EDTA #1 specimen number **(Last four digits):**	_____	Original blood volume of EDTA #1:	_____ mL
EDTA #2 specimen number **(Last four digits):**	_____ ☐N/A	Original blood volume of EDTA #2:	_____ mL ☐N/A
EDTA #3 specimen number **(Last four digits):**	_____ ☐N/A	Original blood volume of EDTA #3:	_____ mL ☐N/A
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):	_____
Volume of residual plasma aliquot (less than 1.5 mL in blue cap):	_____ mL ☐N/A	Specimen number of residual plasma aliquot **(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):**	_____ ☐N/A	Buffy coat #2 volume:	_____ mL ☐N/A
Buffy coat #3 specimen number **(Last four digits):**	_____ ☐N/A	Buffy coat #3 volume:	_____ mL ☐N/A
Time aliquots frozen:	_____ [HHMM]	Storage temperature of freezer:	_____ °C

Notes:_____