ADRC Consortium for Clarity in ADRD Research Through Imaging (CLARiTI)



Collection and Shipment Training



Training Overview: CLARiTI

- * Kit Review & Kit Request Module
- Specimen Labeling Instruction
- Sample Collection and Processing
- Shipping and Packaging Sample Shipments
- Creating Airbills and Scheduling UPS Pickup
- Sample Form
- Common Nonconformance Issues
- ❖ NCRAD Resources and Contact Information



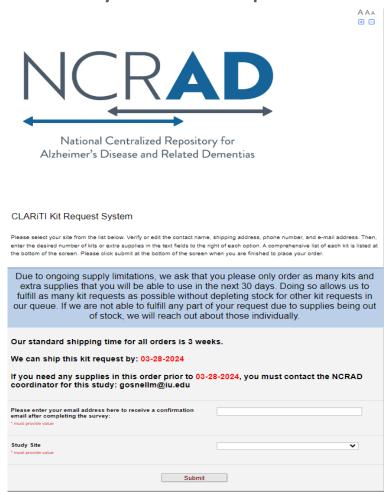
Kit Request Module

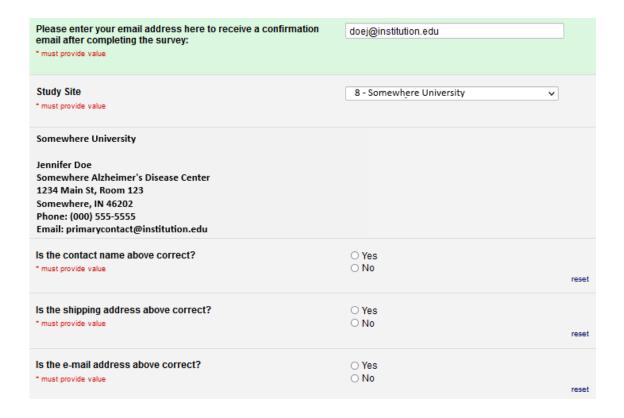
HTTPS://KITS.IU.EDU/CLARITI



CLARITI Kit Request Module

- Enter Email
- Choose your site from drop-down list

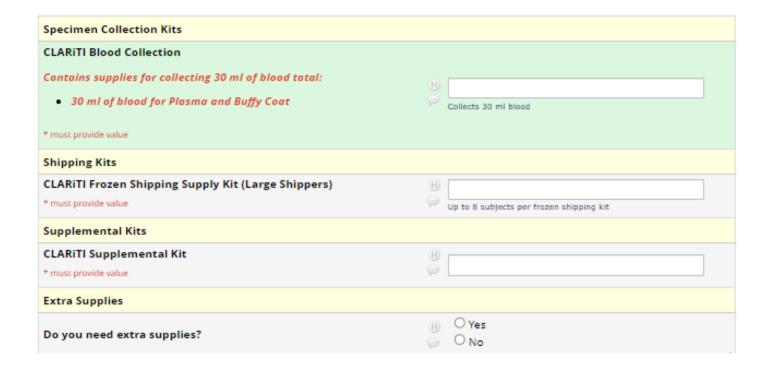




- The coordinator name and contact information will appear.
- Verify that this information is accurate and correct if necessary.



CLARiTI Kit Request Module



- > Can place an order for:
 - Blood collection kit
 - Frozen shipping kit
 - Supplement kit (*one per year*)
 - Individual supplies
- Finter kit order amounts
- Please do not order in bulk. Kit contents expire.
- ➤ Click "Submit" to complete your request

*Allow for 3 weeks for kits to arrive when placing order

CLARITI Kit Types

CLARITI Blood Kit



CLARITI Supplemental Kit



CLARITI Frozen Shipping Supply Kit (Large Shippers)



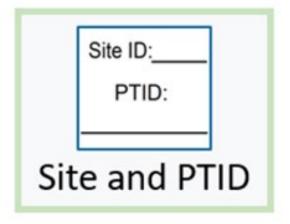


Specimen Labels



Three Label Types







Kit Number Labels



- Ties all biospecimens and kit contents together for each participant at each visit
- Provides quality assurance
- Will be placed on the following locations:
 - 1. Blood Sample and Shipment Notification Forms
 - 2. Cryoboxes that house aliquots during shipping
 - 3. One extra label provided



Site and PTID Labels

Site ID:

PTID:

- Participants will be identified by their Site and PTID and sites will be responsible for handwriting this onto the provided labels
 - Must use fine point permanent marker
- Placed on blood collection EDTA tubes



Collection Tube and Aliquot Labels





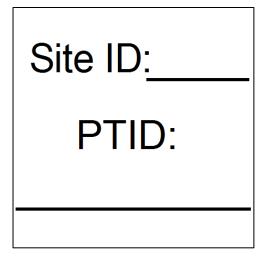


- Collection Tube/Aliquot labels are specific to the type of biospecimen
- Have 4 components:
 - Study name
 - 10-digit unique specimen barcode
 - Collection Group
 - Kit number
- Place on EDTA tubes and processed cryovials
- EDTA tubes will receive label that says "COLLECT" and processed cryovials will receive labels that say "ALIQUOT"



Blood Collection Tubes

Label 1: Site and PTID label



Label 2: Collection Tube label

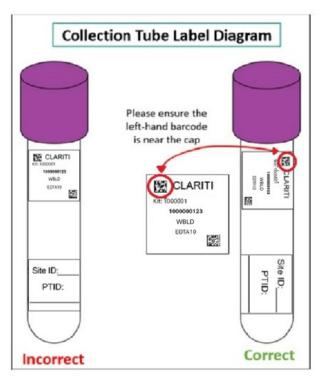


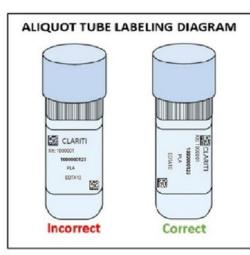
All collection tubes will have two labels:

- Handwritten Site and PTID label
- Collection tube label



Labeling Biologic Samples





- ➤ Write site ID and participant ID with finepoint marker prior to label placement
- Label all collection and aliquot tubes <u>before</u> cooling, collecting, processing or freezing samples
- Label only <u>one</u> participant's tubes at a time to avoid mix-ups
- ➤ Wrap the label around the tube <u>horizontally</u>. Label position is important for <u>all</u> tube types
- Make sure the label is completely adhered by rolling between your fingers



Handling/Processing Study Specimens

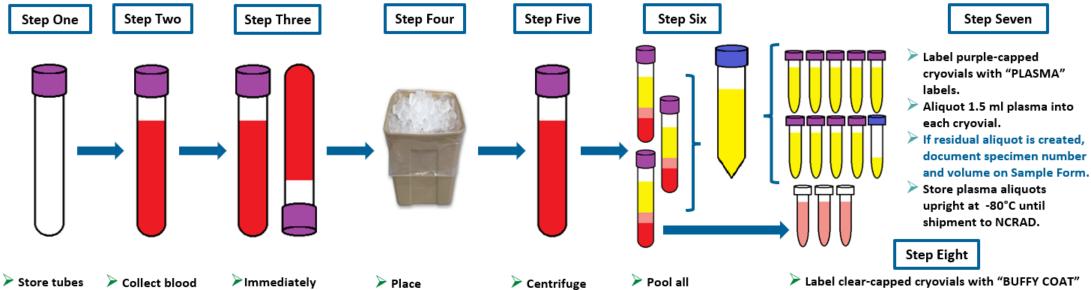


Specimen Collection and Processing: Specimen Tube Types

| Type | Tube Photo | Size | Size Purpose | |
|--------------|-------------------|---|--|---------|
| EDTA Tube | | 10 ml | Whole blood collection | 3 |
| Conical Tube | | 50 ml | Pooling plasma from EDTA tubes | 1 |
| Cryovial | 2 m | | 1.5 ml aliquots of plasma from conical tube | Up to 9 |
| Cryovial | | 2 ml Aliquot residual plasma <1.5 ml after filling purple top cryovials | | 1 |
| Cryovial | | 2 ml | ~1.0 ml aliquots of buffy coat from EDTA tubes | 3 |



Plasma/Buffy Coat Collection and Processing: 30 ml



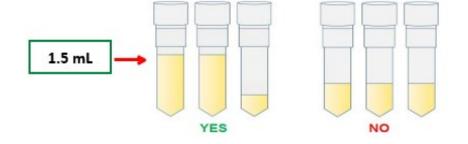
- at room temp.
- Each tube should be labeled with Collection Tube and Site and PTID Labels.
- into each EDTA Tube. allowing blood to flow for 10 seconds and ensuring blood flow has stopped.
- after blood draw, invert tubes 8-10 times to mix samples.
- thoroughly mixed tube on wet ice until centrifugation begins.
- samples at 2000 x g for 10 minutes at 4°C.
- plasma from the 3 EDTA tubes into a 50 ml conical tube and invert gently 3 times to mix the plasma.
- labels.
- Using a clean transfer pipette, collect the buffy coat (may have residual plasma and some RBCs included).
- Transfer the buffy coat from each EDTA tube into its own cryovial.
- Store buffy coat aliquots upright at -80°C until shipment to NCRAD.
- Spin, aliquot, and freeze all plasma and buffy coat aliquots within 2 hours of collection.



Plasma Collection

- Processed plasma creates up to nine 1.5ml aliquots in purple cap cryovials
- Residual plasma is placed in blue cap cryovial





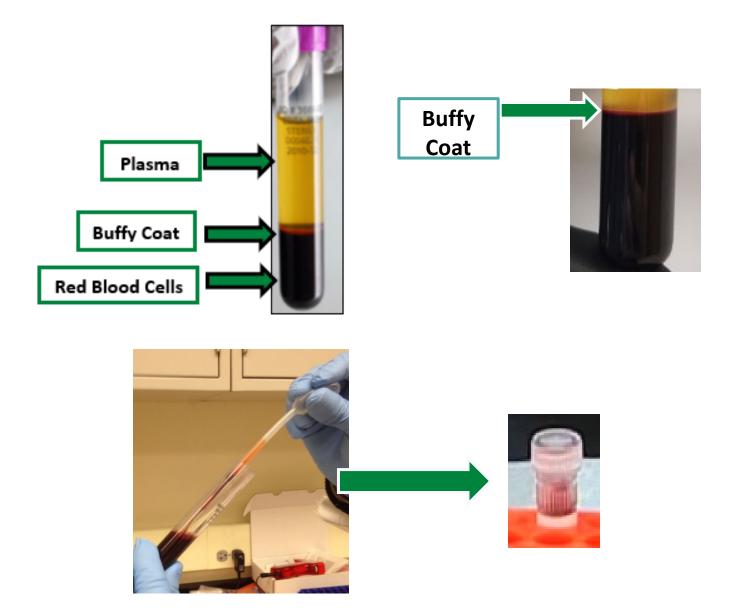
10 mL EDTA tube after centrifuge





Buffy CoatCollection

- Expected to have a reddish color from the RBCs.
- Be sure to only place the buffy coat from one EDTA tube into each cryovial
- Create up to 3 buffy coats





Packaging Sample Shipments



Frozen Shipment Packaging



All samples shipped frozen to NCRAD Monday-Wednesday ONLY



Hold packaged samples in a -80°C freezer until pickup



Include copy of Blood Sample and Shipment Notification Form in shipper



Sites provide pelleted dry ice for shipments

~45 lbs. per batch shipment (8 cryoboxes per large shipper)



Frozen Shipment Packaging

- Use the biohazard bag to package the frozen 25slot cryobox
- Confirm the kit number label has been placed on the outside of the cryobox





Frozen Shipment Packaging

- Place 2-3 inches of pelleted dry ice in the bottom of the Styrofoam shipping container, then insert the cryoboxes laying <u>upright</u>
- Fill shipper to the top with pelleted dry ice
- Each Styrofoam shipper must contain about 45 lbs (20 kg) of pelleted dry ice
- Each large frozen shipper holds up to 8 cryoboxes
- Put lid on and then place sample forms on top before box is sealed





Frozen Shipping – Dry Ice Requirements

Dry Ice label should not be covered with other stickers and must be completed, or the shipping carrier will reject/return your package!





Creating Airbills/Scheduling Pickups



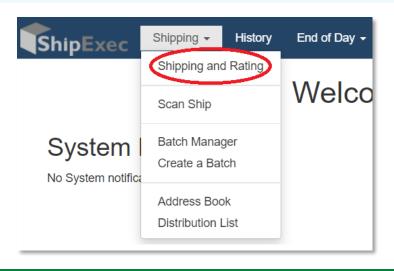
UPS ShipExecTM Thin Client Website



Log into the ShipExec Thin Client: https://kits.iu.edu/UPS



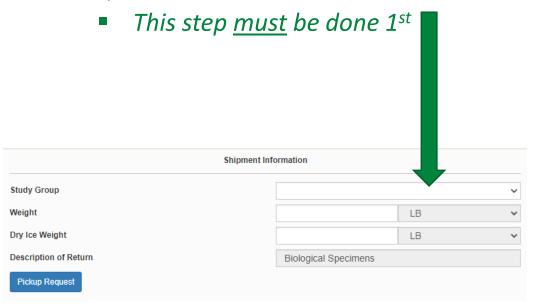
Click on the "Shipping" dropdown and click on "Shipping and Rating"



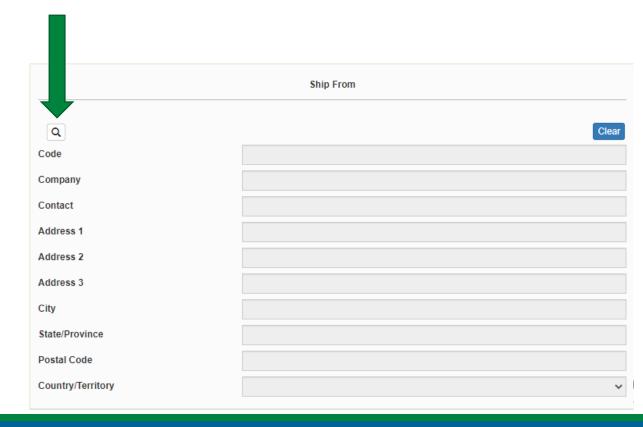


Finding Your Contact Information

 On the right side of the screen, choose the name of your study from the "Study Group" drop down menu

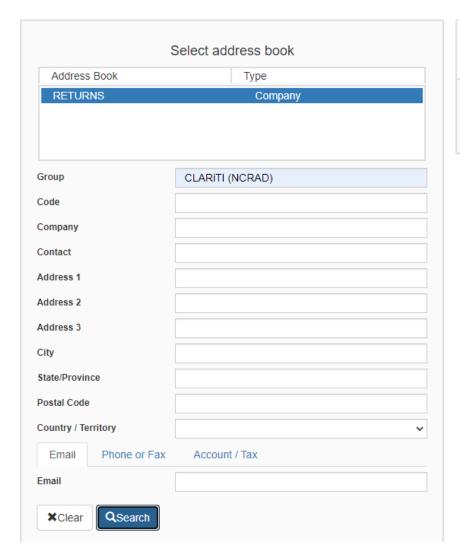


 On the left side of the screen, Click on the magnifying glass icon



Finding Your Contact Information

- On the right side of the screen, a list of all the site addresses within the study you selected should populate
- User can filter the search for their address further by filling in the "Company", "Contact", or "Address 1" fields
- Hit "Search" when ready.
- Once you have found your site address, click on the "Select" button to the left of the address
- If any information needs to be updated, please reach out to the NCRAD Coordinator of your study



| Action | Code \$ | Company \$ | Contact |
|--------|-------------------|---|-------------------|
| Select | CLARITI Boston | Boston University Medical Center | Eric Steinberg |



Verify Information

| Ship From | | Shipment Information | | | |
|---------------------|----------------------------------|-----------------------|----------------------|------|--|
| | | Study Group | CLARITI (NCRAD) | | |
| Q | Clear | Weight | | LB 🕶 | |
| Code | CLARITI Boston | Dry Ice Weight | | LB v | |
| Company | Boston University Medical Center | Description of Return | Biological Specimens | | |
| Contact | Eric Steinberg | Pickup Request | <u> </u> | | |
| Address 1 | 72 East Concord Street | Fluidy Request | | | |
| Address 2 | GCRU | | | | |
| Address 3 | Evans Building, 8th Floor | | | | |
| City | Boston | | | | |
| State/Province | MA | | | | |
| Postal Code | 02118 | | | | |
| Country / Territory | United States V | | | | |

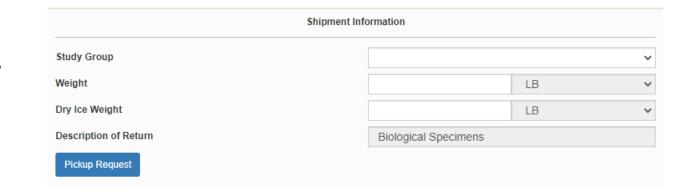
Please double check that both the shipping information AND study reference are correct for this shipment



Entering Shipment Information

Frozen shipments

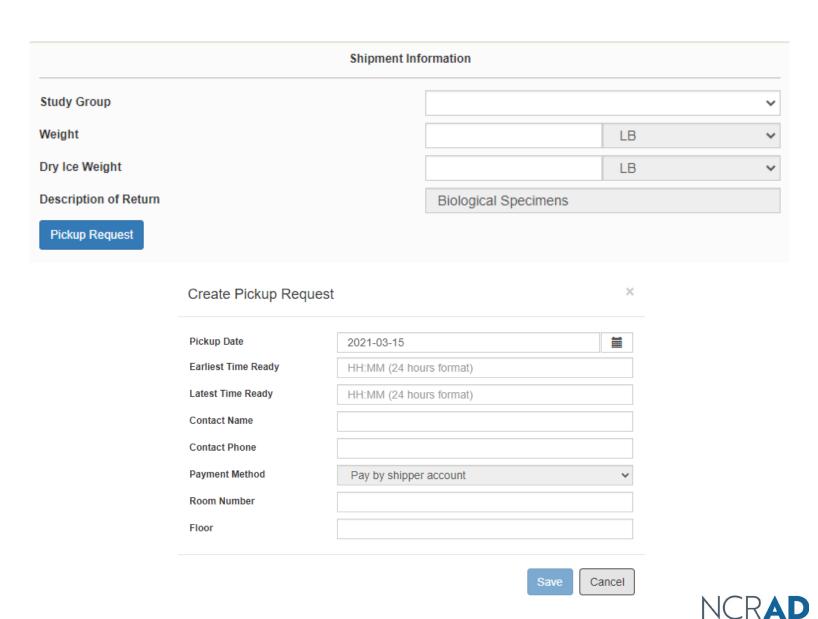
- Enter the total weight of your package in the "Weight" field
- Enter the dry ice weight in the "Dry Ice Weight" field
 - The "Dry Ice Weight" field cannot be higher than the "Weight" field (will receive an error message)





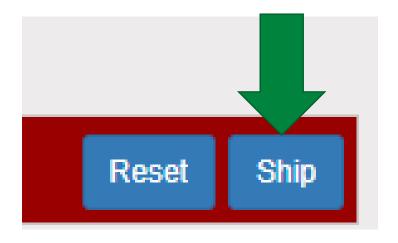
Need to request UPS Pickup?

- Click on the "Pickup Request" button
- Fill out all fields for the pickup request
- Enter in the "Earliest Time Ready" and "Latest Time Ready" in 24-hour format
 - Users must schedule pickup minimum 1 hour before "Earliest Time Ready"
- Choose a name and number that is the best to contact if the UPS driver has questions related to picking up your package
- Entering the Room Number and Floor will help the UPS driver locate your package
 - Room number field is free text.
 - Floor field is numerical only
- Hit "Save" when done



Shipping Packages

 If all fields in "Ship From" and "Shipment Information" fields are completed (and if necessary, pickup request is completed), click Ship in the bottom right corner of the page





Accessing Airbill

- Two documents will be created
- Save the Shipment Receipt and the UPS Waybill
- The "Pickup No:" is the reference number to your specific pickup request in case there are any issues with your package being picked up by UPS
- Check "Pickup Status" by going to UPS.com, click on the Shipping, select Schedule a Pickup, and look on the right side of screen to click on "Pickup Request Status". Enter in the Pickup No. listed on receipt into PRN field and submit

Shipment Receipt



Airbill





Accessing Airbill

- Print out the UPS air waybill
- Fold the UPS air waybill and slide it inside the plastic UPS sleeve (NCRAD will provide these in kit requests)
- Peel the back off the plastic UPS sleeve and stick the sleeve to your package, making sure it is laying as flat as possible along the surface of the package.

JOHN SMITH 317-555-1234 INDIANA UNVERSITY 980 W. WALNUT STREET INDIANAPOLIS IN 46202

20 LBS

1 OF 1

RS

SHIP TO: IUGB 317-278-6158 IU SCHOOL OF MEDICINE TK 217 351 W 10TH ST

INDIANAPOLIS IN 46202



UPS NEXT DAY AIR

TRACKING #: 1Z 976 R8W 84 3084 1976

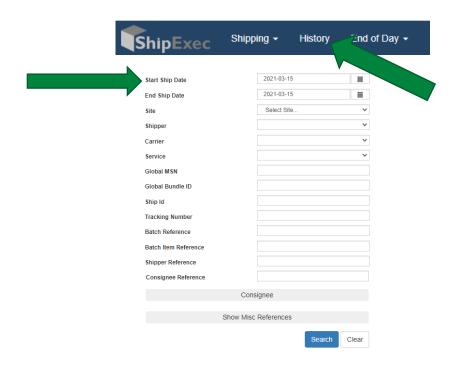


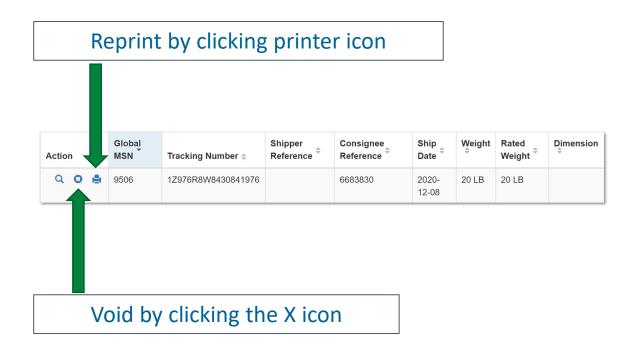
BILLING: P/P
DESC: Biological Specimens
RETURN SERVICE
UN1845, DRY ICE, CLASS 9, 1 x 4.5 KG
AUDIT REQUIRED

Reference No.1: 6683830



Creating Airbills & Scheduling Pick Ups: Reprinting/Voiding Airbills





- To reprint airbill or void a shipment, click "History" at the top of the ShipExec Thin Client portal
- If your shipment doesn't automatically pop up, enter in the date of shipment and then click "Search"



Blood Sample and Shipment Notification Form





Biospecimen Collection, Processing, and Shipment Manual

Appendix B: Blood Sample and Shipment Notification Form Please email the form on or prior to the date of shipment.

| | To: Kelley Fa | ber Email: alzstudy@ | Piu.edu Ph | none: 1-800-526-2839 | | |
|--|---|----------------------|-------------------------------|---|---------|------|
| From: | From: UPS tracking #: <u>1Z976R8W84</u> | | | | | |
| Phone: | Phone: Email: | | | | | |
| Study: CLARITI Sex: M F Year of Birth: | | | | | | |
| Site ID: PT ID: KIT BARCODE | | | | | | |
| NACC ID:_ | NACC ID:Visit: Baseline Follow Up | | | | | |
| Blood Col | lection: | | | | | |
| Date of Draw: | | [MMDDYY] | [MMDDYY] Time of Draw: | | [HHMM] | |
| | Date participant last ate: | | /] Time participant last ate: | | _[ННММ] | |
| Blood Pro | cessing: | Plasma & Buffy | Coat (EDTA | Tube) | | |
| EDTA #1 specimen number (Last four digits): | | | Original blo | od volume of EDTA #1: | mL | |
| EDTA #2 specimen number (Last four digits): | | DN/A | Original blo | od volume of EDTA #2: | mL | □N/A |
| | EDTA #3 specimen number (Last four digits): | N/A | Original blo | od volume of EDTA #3: | mL | □N/A |
| | Time spin started: | (HHMM] | | Duration of centrifuge: | mir | 15 |
| | Temp of centrifuge: | °c | | Rate of centrifuge: | x g | |
| | Time aliquoted: | [HHMM] | Number of | 1.5 mL plasma aliquots created (purple cap): | | |
| . . | e of residual plasma aliquot ss than 1.5 mL in blue cap): | mL _N/A | | nen number of residual | | □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 | y coat #3 specimen number (Last four digits): | | | Buffy coat #3 volume: | mL | N/A |
| | Time aliquots frozen: | [HHMM] | Storage t | emperature of freezer: | °c | |
| Notes: | Notes: | | | | | |

Blood Sample and Shipment Notification Form



A copy of the sample form *must* be emailed or faxed to NCRAD prior to the date of sample arrival.



Please include sample forms in all shipments of frozen samples.



Email: alzstudy@iu.edu



Noncomformance Issues



Non-Conformance

Solution

| Low volume aliquots | Put cryovials in a row, aliquoting in order until sample is |
|---------------------|---|
| | depleted |

Tubes received frozen at an angle/inverted Carefully place tubes upright in freezer and in shipper

Refer to training or MOP for correct label placement.
Save all labels until samples are packed for shipping.

All frozen samples for one participant are not sent within one shipment box

Aliquots are not labeled or labeled incorrectly

Keep plasma and buffy coat for individual participants together. Use one cryobox per participant

Complete Blood Sample and Shipment Form during

Fields on Blood Sample and Shipment Form left blank or incorrect data is given

participant's study visit while samples are processed

Make copy of participants completed form after visit and

Blood Sample and Shipment Forms are not e-mailed or faxed to NCRAD before shipment arrives

Make copy of participants completed form after visit and save until shipment.

NCRAD Website



NCRAD Website: Helpful Pages/Tutorials

https://ncrad.org/contact/holiday-closures

| 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 |
| December 26-31 | Winter Break |

https://ncrad.org/contact/shipping-resources

Shipping Address

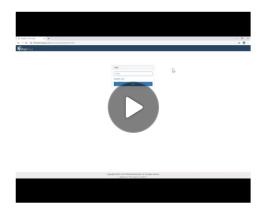
Indiana University School of Medicine 351 W. 10th St TK-217 Indianapolis, IN 46202

UPS Shipping Resources

To generate air waybills and schedule UPS pickups for shipments to NCRAD, please visit the UPS ShipExec™ Thin Client website.

For instructions on how to use the UPS ShipExec™ Thin Client website, please refer to the NCRAD UPS ShipExec™ Thin Client Guide.

Navigating UPS ShipExec™





Contact Information

Mica Gosnell

- Phone: (317) 274-7423
- E-mail: gosnellm@iu.edu

General NCRAD Contact

- Phone: (800) 526-2839
- E-mail: alzstudy@iu.edu
- Website: www.ncrad.org

