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

Collection and Shipment Training

NCRAD
National Centralized Repository for Alzheimer’s Disease and Related Dementias
Training Overview: CLARiTI

- GUIDs
- 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
Globally Unique Identifier (GUID)

The GUID is a participant 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.
GUID (Globally Unique Identifier)

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. When the GUID Tool is open, you will need the following information (CLARiTI MOP Appendix A):
   - Complete legal given (first) name of participant at birth
   - Participant’s middle name, if applicable
   - Complete legal family (last) name of participant at birth
   - Day of birth
   - Month of birth
   - Year of birth
   - Name of city/municipality in which participant was born
   - Country of birth
Kit Request Module

HTTPS://KITS.IU.EDU/CLARITI

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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

- Enter 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
489799

Site ID:
PTID:

Collection Tube and Aliquot
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
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
Blood Collection Tubes

Label 1: Site and PTID label

Site ID:_____  
PTID:  

Label 2: Collection Tube label

CLARITI  
0043821061  
PLASMA  
Kit #: 489799

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 fine-point marker prior to label placement.
- Label all collection and aliquot tubes *before* cooling, collecting, processing or freezing samples.
- Label only one participant’s tubes at a time to avoid mix-ups.
- Wrap the label around the tube *horizontally*. Label position is important for all tube types.
- Make sure the label is completely adhered by rolling between your fingers.
Handling/Processing Study Specimens

National Centralized Repository for Alzheimer’s Disease and Related Dementias
Specimen Collection and Processing: Specimen Tube Types

<table>
<thead>
<tr>
<th>Type</th>
<th>Tube Photo</th>
<th>Size</th>
<th>Purpose</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDTA Tube</td>
<td></td>
<td>10 ml</td>
<td>Whole blood collection</td>
<td>3</td>
</tr>
<tr>
<td>Conical Tube</td>
<td></td>
<td>50 ml</td>
<td>Pooling plasma from EDTA tubes</td>
<td>1</td>
</tr>
<tr>
<td>Cryovial</td>
<td></td>
<td>2 ml</td>
<td>1.5 ml aliquots of plasma from conical tube</td>
<td>Up to 9</td>
</tr>
<tr>
<td>Cryovial</td>
<td></td>
<td>2 ml</td>
<td>Aliquot residual plasma &lt;1.5 ml after filling purple top cryovials</td>
<td>1</td>
</tr>
<tr>
<td>Cryovial</td>
<td></td>
<td>2 ml</td>
<td>~1.0 ml aliquots of buffy coat from EDTA tubes</td>
<td>3</td>
</tr>
</tbody>
</table>
Plasma/Buffy Coat Collection and Processing: 30 ml

**Step One**
- Store tubes at room temp.
- Each tube should be labeled with Collection Tube and Site and PTID Labels.

**Step Two**
- Collect blood into each EDTA Tube, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

**Step Three**
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

**Step Four**
- Place thoroughly mixed tube on wet ice until centrifugation begins.

**Step Five**
- Centrifuge samples at 2000 x g for 10 minutes at 4°C.

**Step Six**
- Pool all plasma from the 3 EDTA tubes into a 50 ml conical tube and invert gently 3 times to mix the plasma.

**Step Seven**
- Label purple-capped cryovials with “PLASMA” labels.
- Aliquot 1.5 ml plasma into each cryovial.
- If residual aliquot is created, document specimen number and volume on Sample Form.
- Store plasma aliquots upright at -80°C until shipment to NCRAD.

**Step Eight**
- Label clear-capped cryovials with “BUFFY COAT” 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 Coat Collection

- 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
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 25-slot 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 upright.
- 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.
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!

Net weight of dry ice in kg

Contains 20 kg of Dry Ice
Creating Airbills/Scheduling Pickups

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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
  - *This step must be done 1st*

- 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
Verify Information

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
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.
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

National Centralized Repository for Alzheimer’s Disease and Related Dementias
Appendix C: Blood Sample and Shipment Notification Form

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

To: Kelley Faber  Email: k fab@fdu.edu  Phone: 1-800-526-2838

From:  UPS tracking #: 12976R8W884

Phone:  Email:

Study: CLARITY  Sex: □ M □ F  Year of Birth: 

Site ID:  PT ID:  

GUID:  Visit: □ Baseline □ 3 month

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**Blood Collection:**

<table>
<thead>
<tr>
<th>Date of Draw: [MM/DD/YY]</th>
<th>Time of Draw: [HH:MM]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date subject last site: [MM/DD/YY]</td>
<td>Time subject last site: [HH:MM]</td>
</tr>
</tbody>
</table>

---

**Blood Processing:**

<table>
<thead>
<tr>
<th>EDTA #1 specimen number (Last four digits):</th>
<th>Original blood volume of EDTA #1</th>
<th>ml.</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDTA #2 specimen number (Last four digits):</td>
<td>Original blood volume of EDTA #2</td>
<td>ml. N/A</td>
</tr>
<tr>
<td>EDTA #3 specimen number (Last four digits):</td>
<td>Original blood volume of EDTA #3</td>
<td>ml. N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time spin started: [HH:MM]</th>
<th>Duration of centrifuge: mins</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temp of centrifuge: °C</td>
<td>Rate of centrifuge: x g</td>
</tr>
<tr>
<td>Time aliquoted: [HH:MM]</td>
<td>Number of 1.5 ml plasma aliquots created (purple cap):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Volume of residual plasma aliquot (less than 1.5 ml in blue cap):</th>
<th>ml. N/A</th>
<th>Specimen number of residual plasma aliquot (last four digits):</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buffy coat #1 specimen number (Last four digits):</td>
<td>Buffy coat #1 volume:</td>
<td>ml.</td>
<td></td>
</tr>
<tr>
<td>Buffy coat #2 specimen number (Last four digits):</td>
<td>Buffy coat #2 volume:</td>
<td>ml. N/A</td>
<td></td>
</tr>
<tr>
<td>Buffy coat #3 specimen number (Last four digits):</td>
<td>Buffy coat #3 volume:</td>
<td>ml. N/A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time aliquots frozen: [HH:MM]</th>
<th>Storage temperature of freezer: °C</th>
</tr>
</thead>
</table>

**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

National Centralized Repository for Alzheimer's Disease and Related Dementias
<table>
<thead>
<tr>
<th>Non-Conformance</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low volume aliquots</td>
<td>Put cryovials in a row, aliquoting in order until sample is depleted</td>
</tr>
<tr>
<td>Tubes received frozen at an angle/inverted</td>
<td>Carefully place tubes upright in freezer and in shipper</td>
</tr>
<tr>
<td>Aliquots are not labeled or labeled incorrectly</td>
<td>Refer to training or MOP for correct label placement. Save all labels until samples are packed for shipping.</td>
</tr>
<tr>
<td>All frozen samples for one participant are not sent within one shipment box</td>
<td>Keep plasma and buffy coat for individual participants together. Use one cryobox per participant</td>
</tr>
<tr>
<td>Fields on Blood Sample and Shipment Form left blank or incorrect data is given</td>
<td>Complete Blood Sample and Shipment Form during participant’s study visit while samples are processed</td>
</tr>
<tr>
<td>Blood Sample and Shipment Forms are not e-mailed or faxed to NCRAD before shipment arrives</td>
<td>Make copy of participants completed form after visit and save until shipment.</td>
</tr>
</tbody>
</table>
NCRAD Website
NCRAD Website: Helpful Pages

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Holiday</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 1</td>
<td>New Year’s Day</td>
</tr>
<tr>
<td>3rd Monday in January</td>
<td>Martin Luther King, Jr. Day</td>
</tr>
<tr>
<td>4th Monday in May</td>
<td>Memorial Day</td>
</tr>
<tr>
<td>June 19</td>
<td>Juneteenth (observed)</td>
</tr>
<tr>
<td>July 4</td>
<td>Independence Day (observed)</td>
</tr>
<tr>
<td>1st Monday in September</td>
<td>Labor Day</td>
</tr>
<tr>
<td>4th Thursday in November</td>
<td>Thanksgiving</td>
</tr>
<tr>
<td>4th Friday in November</td>
<td>Friday after Thanksgiving</td>
</tr>
<tr>
<td>December 25</td>
<td>Christmas</td>
</tr>
</tbody>
</table>

https://ncrad.org/shipping_address.html

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UPS Shipping Resources

To guarantee airwaybill and schedule UPS pickups for shipments to NCRAD, please visit the UPS ShipExecute™ Thin Client website. For instructions on how to use the UPS ShipExecute™ Thin Client website, please refer to the NCRAD UPS ShipExecute™ Thin Client Guide.

Navigating UPS ShipExecute™

[Video Embedded]
Contact Information

Mica Gosnell
- Phone: (317) 274-7423
- E-mail: gosnello@iu.edu

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