Asian Cohort for Alzheimer’s Disease

in collaboration with

The National Centralized Repository for Alzheimer’s Disease and Related Dementias (NCRAD)
Contact Information

• Questions?

Please contact NCRAD Coordinators at:
  • Phone: 1-800-526-2839 or 317-274-7546
  • E-mail: alzstudy@iu.edu or wilmesk@iu.edu
  • Website: www.ncrad.org
Training Overview

• Blood Collection
  • Blood Collection Schedule
  • Kit Request Module
  • Specimen Labels
  • Handling/Processing Study Specimens
  • Sample Shipping

**If not able to collect blood samples for a participant, Saliva can be collected for DNA extraction**

• Saliva Collection
  • Saliva Collection Schedule
  • Specimen Labels
  • Handling/Processing Study Specimens
  • Sample Shipping

• NCRAD Website
• Questions?
## ACAD Blood-Based Biomarker Collection Schedule

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Tube Type</th>
<th>Number of Tubes Supplied in Kit</th>
<th>Aliquot Volume</th>
<th>Tubes to NCRAD</th>
<th>Ship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood for isolation of plasma &amp; buffy coat</td>
<td>EDTA (Purple-Top) Blood Collection Tube (10 ml)</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>PLASMA: 2.0 ml cryovials with purple cap (residual volume placed in 2.0 ml cryovial with blue cap)</td>
<td>4</td>
<td>1.5 ml plasma aliquot per 2.0 ml cryovial (purple cap)</td>
<td>Up to 4</td>
<td>Frozen</td>
</tr>
<tr>
<td></td>
<td>BUFFY COAT: 2.0 ml cryovial</td>
<td>1</td>
<td>1.0 ml buffy coat aliquot per 2.0 ml cryovial (gray cap)</td>
<td>1</td>
<td>Frozen</td>
</tr>
</tbody>
</table>
Kit Request Module

https://kits.iu.edu/acad
Kit Request Module

• An initial stock of kits will be delivered prior to the designated site-specific start date.

• Kits and individual supplies are available to order:
  • ACAD Blood-Based Kit
  • ACAD Blood-Based Supplemental Supply Kit
  • ACAD Frozen Blood Shipping Supply Kit
  • ACAD Saliva Collection Kit
  • ACAD Saliva Shipping Supply Kit
NCRAD Kit Request Module

1. Choose your site from the drop-down list

2. The coordinator name and contact information will appear

3. Verify that this information is accurate, correct if necessary
## Study Visit Kits

- Indicate the quantity needed of each kit.
- Once selected, kit components of the chosen kit will appear at the bottom of the screen (Pictured).
- Click “Submit” to turn in your request.
- The IU staff will notify you that your request has been received and address any issues.
- **Note: You can order more than one type of kit in a single kit request.**

### ACAD Blood-Based Kit Qty

<table>
<thead>
<tr>
<th>ACAD Blood-Based Kit Qty</th>
<th>1</th>
</tr>
</thead>
</table>

### ACAD Frozen Blood Shipping Supply Kit Qty

<table>
<thead>
<tr>
<th>ACAD Frozen Blood Shipping Supply Kit Qty</th>
<th></th>
<th></th>
</tr>
</thead>
</table>

### ACAD Saliva Collection Kit Qty

<table>
<thead>
<tr>
<th>ACAD Saliva Collection Kit Qty</th>
<th></th>
<th></th>
</tr>
</thead>
</table>

### ACAD Saliva Shipping Supply Kit Qty

<table>
<thead>
<tr>
<th>ACAD Saliva Shipping Supply Kit Qty</th>
<th></th>
<th></th>
</tr>
</thead>
</table>

### Do you need Extra Supplies?

- Yes
- No

### Comments

<table>
<thead>
<tr>
<th>Comments</th>
</tr>
</thead>
</table>

### Each ACAD Blood-Based Kit Contains:

1. EDTA (Purple-Top) Blood Collection Tube (10 ml)
2. Cryovial tube (2.0 ml) with purple cap
3. Cryovial tube (2.0 ml) with blue cap
4. Cryovial tube (2.0 ml) with gray cap
5. Disposable graduated transfer pipette
6. Pre-printed Collection Tube Label
7. Pre-printed Cryovial Label
8. Pre-printed Kit Number Label
9. Label for handwritten PTID Label
10. Resealable bag
11. Cryovial box (holds up to 25 cryovials)
NCRAD Kit Request Module: When It Must be Used

• Each site will be responsible for ordering kits (labels included) and maintaining supplies on site for scheduled participants

• To order, sites will use the Indiana University online kit ordering module: https://kits.iu.edu/acad

• Allow a minimum of 2 weeks for your order to be processed and delivered.
Blood Specimen Labels
Label Type Summary

1. Kit Number Label
2. PTID Label
3. Collection Tube Label
4. Cryovial Label
Kit Number Labels

- Used to track patient samples and provide quality assurance
- Will be placed on the following locations:
  1. Biological Sample and Shipment Notification Form
  2. Outside cryobox that houses aliquot tubes during storage and shipment

Provided by NCRAD in the kits
PTID Label

• Subjects will be identified by their PTID.
• The PTID may only be available shortly before the visit
• Sites will be responsible for handwriting this onto the provided labels
  • Must use fine point permanent marker
  • Each site will receive 4 markers in initial kit supply
• Write information on label prior to adhering to tube
• Label will be placed on all collection tubes
  • EDTA (Lavender-Top) Blood Collection Tube (10 ml) for DNA and Plasma
• Kits will include one extra label
Collection Tube Labels

Specimen Number (assigned by NCRAD)
Study Name
Sample Type
Kit # (assigned by NCRAD) unique to the subject and visit

Placed on all collection tubes
Cryovial Label

- Only one label to be placed on each cryovial
  - Plasma
    - From EDTA tube
  - Buffy Coat
    - From EDTA tube
Blood Collection Tube

Label 1: Collection Tube Label

- 0001234567
- ACAD
- PLASMA
- Kit #:300001

Label 2: PTID Label

PTID: ____________

All collection tubes will have 2 labels:
- The handwritten PTID label
- The Collection Tube Label

EDTA (Purple-Top) Blood Collection Tube (10 ml)
Labeling NCRAD Cryovials

Please...

• Label all collection and aliquot tubes \textit{before} cooling, collecting, processing or freezing samples.

• Label only \text{1} subject’s tubes at a time to avoid mix-ups.

• Wrap the label around the tube \textit{horizontally}. Label position is important for \textit{all} tube types.

• Make sure the label is completely adhered by rolling between your fingers.
Handling/Processing Study Blood Specimens
# Site Required Equipment

## Blood Collection/Safety Equipment

1. **Personal Protective Equipment (PPE)**
   - Lab Coat, Safety Glasses
2. Tourniquet
3. Alcohol Prep Pad
4. Gauze Pad
5. Butterfly Needles
6. Bandage
7. Sharps Bin and Lid

## Processing/Storage Equipment

1. Centrifuge capable of ≥2000 rcf with refrigeration to 4°C
2. -80°C Freezer
3. Wet Ice Bucket
# Sample Collection - Blood

<table>
<thead>
<tr>
<th>Tube Type</th>
<th>Number of Tubes Drawn</th>
<th>Tube Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDTA (Lavender-Top) Blood Collection Tube (10 ml) for Plasma</td>
<td>x1</td>
<td>![Image of EDTA tube]</td>
</tr>
</tbody>
</table>
# NCRAD Cryovial Cap Colors

<table>
<thead>
<tr>
<th>Cap Color</th>
<th>Sample Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purple Cap</td>
<td>Plasma</td>
</tr>
<tr>
<td>Blue Cap</td>
<td>Residual</td>
</tr>
<tr>
<td>Gray Cap</td>
<td>Buffy Coat</td>
</tr>
</tbody>
</table>

![Image of cryovial caps]

- Purple cap
- Blue cap
- Gray cap
Plasma Collection

Plasma Aliquots (up to 4 possible) and Buffy Coat (1)
Buffy Coat Collection

Create 1 buffy coat
Plasma and Buffy Coat Preparation (10ml Purple Top Tube)

**Step One**
- Store tubes at room temp.
- Label tube with pre-printed labels prior to blood draw.

**Step Two**
- Collect blood in Plasma Tube allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

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

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

**Step Five**
- Centrifuge sample at 2000 x g for 10 minutes at 4°C.
- Sample needs to be spun, aliquoted, and in the freezer within 2 hours of collection.

**Step Six**
- Adhere pre-printed labels to the purple cap cryovials.
- Aliquot 1.5 ml plasma into each cryovial.
- If residual aliquot is created, document specimen number and volume on Sample Notification Form.
- Store plasma aliquots upright at -80°C until shipment to NCRAD.

**Step Seven**
- Adhere pre-printed “BUFFY COAT” label to the gray cap cryovial.
- Using a clean transfer pipette, collect the buffy coat (may have residual plasma and some RBCs included).
- Transfer the buffy coat into the cryovial tube.
- Store buffy coat aliquot upright at -80°C until shipment to NCRAD.
- **All plasma and buffy coat aliquots need to be spun, aliquoted and in the freezer within 2 hours of collection.**
Blood Sample Shipping
## Blood Sample Shipment Summary

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>ACAD</th>
<th>Processing/Aliquoting</th>
<th>Tubes to NCRAD</th>
<th>Ship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood (Purple-Top EDTA) for isolation of plasma &amp; buffy coat</td>
<td>Yes</td>
<td>1.5 ml plasma aliquots</td>
<td>Up to 4</td>
<td>Frozen</td>
</tr>
<tr>
<td>for DNA extraction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Whole blood (Purple-Top EDTA) for isolation of plasma &amp; buffy coat (for DNA extraction)</em></td>
<td>Yes</td>
<td>1.0 ml buffy coat aliquot</td>
<td>1</td>
<td>Frozen</td>
</tr>
</tbody>
</table>
Frozen Sample Shipping

• **Ship Monday-Wednesday Only**
  
  • Plasma and Buffy Coat
    
    • Hold packaged samples in a -80°C freezer until pickup.
  
  • Batch Samples together
    
    • 8 Cryoboxes
    
    • Batch shipping should be performed every 3 months or as a full shipment of specimens accumulates, whichever is sooner.
Frozen Blood Shipping - Cryoboxes

One cryobox to contain Plasma and Buffy Coat Aliquots

Place kit number label on each cryobox
Frozen Shipping – Dry Ice Requirements

• Fully cover the cryoboxes with about 2 inches of dry ice in the provided shipper.

• Each Styrofoam shipper must contain about 45 lbs (20 kg) of dry ice.
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 20.4 kg of Dry Ice
Shipping Frozen Samples

• Schedule UPS pickup

• *Send Biological Sample and Shipment Notification Form to IU* ahead of shipment
  • *Email: alzstudy@iu.edu*
Blood Sample and Shipment Notification Forms

• A copy of the sample form must be emailed to NCRAD prior to the date of sample arrival.

• Please include sample forms in all shipments of frozen and ambient samples.

• Email: alzstudy@iu.edu
Blood Sample and Shipment Notification Form

Blood collected for:
- Plasma
- DNA
Saliva Sample Collection

**If not able to collect blood samples for a participant, Saliva can be collected for DNA extraction**
## ACAD Saliva-Based Biomarker Collection Schedule

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Tube Type</th>
<th>Number of Tubes Supplied in Kit</th>
<th>Tubes to NCRAD</th>
<th>Volume</th>
<th>Ship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saliva for DNA extraction</td>
<td>Saliva Kit (DNA Genotek) OGR-500</td>
<td>1</td>
<td>1</td>
<td>2.0 ml of Saliva collected in each 4.0 ml tube</td>
<td>Ambient</td>
</tr>
</tbody>
</table>
Saliva Specimen Labels
Label Type Summary

1. PTID Label
2. Specimen Label
PTID Label

• Subjects will be identified by their PTID.
• The PTID may only be available shortly before the visit
• Sites will be responsible for handwriting this onto the provided labels
  • Must use fine point permanent marker
  • Each site will receive 4 markers in initial kit supply
• Write information on label prior to adhering to tube
• Label will be placed on all collection tubes
  • Saliva Collection Tube
• Kits will include one extra label
One Specimen Label for each saliva collection tube. The second, matching Specimen Label should be affixed to the participant’s corresponding Biological Sample and Shipment Notification Form.
Saliva Collection Tube

- Place barcode toward the tube cap AND below the “Fill To” line.
- Place labels before sample collection
Saliva Sample Collection
NCRAD Saliva Collection Instructions

Preparation for saliva collection:

• **Remember**: Do NOT remove plastic film from the lid.

• **Subject should not eat, drink, smoke, chew gum or brush teeth for 30 minutes prior to giving sample.**

• Subject does NOT need to rinse their mouth prior to giving the sample.

• Before spitting, subject should relax and rub their cheeks gently for 30 seconds to create saliva.

• Most people take between 2 and 5 minutes to deliver a saliva sample.
NCRAD Saliva Collection Instructions

Collection:

1. Do NOT remove the plastic film from the lid of the container. Spit directly into the funnel at the top of the tube until the amount of liquid saliva (not including bubbles) reaches the fill line shown. The saliva tube has a false bottom, so you will only need to provide 2 ml of saliva to reach the fill line. Do NOT fill above the line.

2. After collection, hold the tube upright.

3. Unscrew the funnel from the tube.

4. Pick up the small cap for the tube. Use the small cap to close the tube tightly. Discard the funnel.

5. Shake the capped tube for 5 seconds. Complete the Biological Sample and Shipment Notification Form. Place sample into the provided biohazard bag. Peel the protective wrapping off to seal the bag. Roll packaging around the tube.

Place sample into the provided Bulk Saliva Shipping Box.
Video of Saliva Collection Procedure:

To review a video of the saliva collection procedure, please visit:

http://www.dnagenotek.com/ROW/support/ciOG500.html
Saliva Sample Shipping
Saliva Sample Shipping

Collect saliva, ensure properly closed and place in biohazard bag.

Place the sealed biohazard bag, with the saliva tube sealed separately inside, into the bulk shipping box (contains 36 saliva samples)

UPS ClinPak
Saliva Sample Shipping (cont’d)

• Ensure all ambient, labeled saliva samples are appropriately packaged.

• Place the completed Saliva Sample and Shipment Notification Forms in the UPS ClinPak.

• Apply all provided warning labels and the printed UPS return label to the outside of the package, taking care not to overlap labels.

• Use UPS tracking to ensure delivery occurs.
Saliva Sample and Shipment Notification Forms

• A copy of the sample forms *must* be emailed or faxed to NCRAD prior to the date of sample arrival.
• Please include all sample forms within UPS ClinPak
• A web-based version will be an option soon.
• Email: alzstudy@iu.edu
Saliva Sample and Shipment Notification Form

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site ID</td>
<td></td>
</tr>
<tr>
<td>Participant ID</td>
<td></td>
</tr>
<tr>
<td>To:</td>
<td>Kelley Faber</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:abstudy@nki.edu">abstudy@nki.edu</a></td>
</tr>
<tr>
<td>UPS tracking #:</td>
<td></td>
</tr>
<tr>
<td>From:</td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td></td>
</tr>
<tr>
<td>Sex:</td>
<td></td>
</tr>
<tr>
<td>Year of Birth:</td>
<td></td>
</tr>
<tr>
<td>Study: ACAD GUID:</td>
<td></td>
</tr>
<tr>
<td>Visit (circle one): V01 V02</td>
<td></td>
</tr>
<tr>
<td>Specimen Label:</td>
<td></td>
</tr>
<tr>
<td>Saliva Collection:</td>
<td></td>
</tr>
<tr>
<td>Date collected:</td>
<td></td>
</tr>
<tr>
<td>Time of collection:</td>
<td></td>
</tr>
<tr>
<td>Last date subject ate:</td>
<td></td>
</tr>
<tr>
<td>Last time subject ate:</td>
<td></td>
</tr>
<tr>
<td>Notes:</td>
<td></td>
</tr>
<tr>
<td>Saliva Volume:</td>
<td></td>
</tr>
</tbody>
</table>

Send by E-mail prior to shipment, and include a copy in each shipment.
# 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>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/holiday_closures.html
Contact Information

• Questions?

Please contact NCRAD Coordinators at:

  • Phone: 1-800-526-2839 or 317-274-7546
  • E-mail: alzstudy@iu.edu; wilmesk@iu.edu
  • Website: www.ncrad.org