North American Prodromal Synucleinopathy (NAPS)
&
The National Centralized Repository for Alzheimer’s Disease and Related Dementias (NCRAD)

Biofluids Collection Training Slides
Contact Information

• Questions?

Please contact NCRAD Coordinators at:

• Phone: 1-800-526-2839 or 317-278-1228
• E-mail: alzstudy@iu.edu or mipetkov@iu.edu
• Website: www.ncrad.org
Training Overview

• GUIDs
• Specimen Collection Schedule
• Kit Request Module
• Specimen Labels
• Handling/Processing Study Specimens
• Sample Shipping
• NCRAD Website
• Questions
Globally Unique Identifier (GUID)

• The GUID is a subject 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.
Globally Unique Identifier (GUID)

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 all of the following information
   • Complete legal given (first)name of participant at birth
   • The participant’s middle name, if applicable
   • Complete legal family (last) name of subject at birth
   • Day of birth
   • Month of birth
   • Year of birth
   • Name of city/municipality in which subject was born
   • Country of birth
## Specimen Collection Schedule

<table>
<thead>
<tr>
<th>Visit</th>
<th>Collection Container</th>
<th>Specimen Type</th>
<th>Container Received</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>10.0 ml EDTA (Lavender-Top) Blood Collection Tube</td>
<td>Plasma</td>
<td>2.0 ml cryovials</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Buffy Coat</td>
<td>2.0 ml cryovial</td>
</tr>
<tr>
<td></td>
<td>Sterile Containers</td>
<td>CSF</td>
<td>2.0ml cryovials</td>
</tr>
<tr>
<td>Visit 2</td>
<td>10.0 ml EDTA (Lavender-Top) Blood Collection Tube</td>
<td>Plasma</td>
<td>2.0 ml cryovials</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Buffy Coat</td>
<td>2.0 ml cryovial</td>
</tr>
<tr>
<td></td>
<td>Sterile Containers</td>
<td>CSF</td>
<td>2.0ml cryovials</td>
</tr>
</tbody>
</table>
Kit Request Module

http://kits.iu.edu/naps
Kit Request Module

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

• Kits and individual supplies available to order:
  • Blood Collection Kit - Visit 1
  • Blood Collection Kit - Visit 2
  • CSF Kit
  • LP 22 Gauge Kit
  • LP 24 Gauge Kit
  • Blood Supplemental Kit
  • CSF Supplemental Kit
  • Frozen Shipping Kit
  • Individual Supplies
Kit Request Module

1. Choose your site from the drop down list.

2. The coordinator name and contact information will populate.

3. Verify that this information is correct.

<table>
<thead>
<tr>
<th>Study Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Washington University</td>
</tr>
<tr>
<td>Washington University Sleep Medicine Center</td>
</tr>
<tr>
<td>Attn: Jennifer McLeland</td>
</tr>
<tr>
<td>1600 S. Brentwood Blvd., Suite 600</td>
</tr>
<tr>
<td>St. Louis, MO 63144</td>
</tr>
<tr>
<td>Phone: (314)747-3819</td>
</tr>
<tr>
<td>Email: <a href="mailto:mclelandj@wustl.edu">mclelandj@wustl.edu</a></td>
</tr>
</tbody>
</table>

**Is the contact name above correct?**
- Yes
- No

**Is the shipping address above correct?**
- Yes
- No

**Is the e-mail address above correct?**
- Yes
- No
Kit Request Module: Kit Selection

• Indicate the quantity needed of each kit

• Once selected, kit components of the chosen kit will appear at the bottom of the screen

• **Note: You can order more than one type of kit in a single kit request**
Kit Request Module: Kit Selection

• If individual supplies are needed, select yes, select the supplies needed, and specify quantities below.
• Click “Submit” to turn in your request.
• The IU staff will notify you that your request has been received and address any issues.
Kit Request Module

- Each site is responsible for ordering kits and maintaining supplies on site for their scheduled participants.

- To order kits, sites will use the Indiana University online kit ordering module: http://www.kits.iu.edu/naps

- Allow around 2 weeks for your order to be processed and delivered.
Specimen Labels
Specimen Labels

• Label type summary:
  • Kit Number Labels
  • NAPS ID Labels
  • Collection and Aliquot Tube Labels
    • Differ by specimen type

• All labels are provided in the kits
Specimen Labels: Kit Number Labels

- Used to track patient samples and provide quality assurance
- Will be placed on:
  - Biological Sample and Shipment Notification Form
  - Outside of cryobox(es) that houses aliquot tubes during storage and shipment
  - CSF Sample and Shipment Notification Form
    - CSF samples will have a different kit number than blood samples
Specimen Labels: NAPS ID Labels

• Subjects will be identified by their NAPS ID
• Sites will be responsible for handwriting the IDs on the provided labels
  • Fill in labels prior to adhering to tubes
  • Must use fine-point marker
• Labels will be placed on all collection tubes:
  • EDTA Lavender Top Tube (10 ml)
Specimen Labels: Collection & Aliquot Tube Labels

- Specimen Number (Assigned by NCRAD)
- Study Name
- Sample Type (Plasma, Buffy Coat, or CSF)
- Kit # (Assigned by NCRAD and unique to the subject and visit)
Specimen Labels: Blood Collection Tubes

- All EDTA collection tubes will have two labels:
  - Collection Tube Label
  - Site and NAPS ID Label

**Label 1:**

```
0000200128
NAPS
PLASMA
Kit #: 250001
```

**Label 2:**

```
NAPS ID:
```

Collection Tube Label
*place barcode near top

Site and NAPS ID Label
Specimen Labels: Aliquot Tube Labels (Plasma, Buffy Coat, and CSF)

- Only use the Collection and Aliquot Tube label
- Place barcode near the cap
Specimen Labels: Labeling Biologic Samples

• Label all collection and aliquot tubes *before* cooling, collecting, processing or freezing samples.

• Label only 1 subject’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
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
## Blood Collection & Processing: Sample Collection Tube

<table>
<thead>
<tr>
<th>Tube Type</th>
<th>Number of Tubes Drawn (per visit)</th>
<th>Tube Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDTA (Lavender-Top) Tube (10 ml)</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>
Blood Collection & Processing: Aliquot
Cryovials & Cap Colors

<table>
<thead>
<tr>
<th>Cap Color</th>
<th>Sample Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lavender Cap</td>
<td>Plasma</td>
</tr>
<tr>
<td>Clear Cap</td>
<td>Buffy Coat</td>
</tr>
<tr>
<td>Blue Cap</td>
<td>Residual</td>
</tr>
<tr>
<td>Orange Cap</td>
<td>CSF</td>
</tr>
<tr>
<td>Yellow Cap</td>
<td>CSF to Local Lab</td>
</tr>
</tbody>
</table>
**Plasma and Buffy Coat Preparation (10ml Lavender Top Tube x 4)**

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

**Step Two**
- Collect blood in EDTA Tubes 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**
- Centrifuge samples at 2000 xg for 10 minutes at 4°C.
- EDTA tubes need to be spun, aliquoted, and in the freezer within 2 hours from the time of collection.

**Step Five**
- Pool all plasma from the 4 EDTA tubes into a 50ml conical tube and invert gently 3 times to mix the plasma.

**Step Six**
- Label cryovial tubes with preprinted labels.
- Aliquot 1.5 ml into each cryovial tube.
- If residual aliquot is created, use blue cap to indicate volume difference and document Specimen Number on Biological Sample and Shipment Notification Form.
- Store plasma aliquots at -80°C until shipment.

**Step Seven**
- Label cryovials tube with preprinted label.
- Using a clean transfer pipette, collect the buffy coats (may have residual plasma and some RBCs included).
- Transfer the buffy coats into the cryovial tubes.
- Store buffy coats aliquot at -80°C until shipment.
EDTA Tube – Plasma Collection

- Plasma
- BUFFY COAT
- Red Blood Cells

Up to 14 cryovials possible:
13x 1.5 ml in lavender cap cryovials
1x <1.5 ml blue cap cryovial
EDTA Tube – Buffy Coat Collection

*Sites have the option of storing 1-2 buffy coats per participant per visit locally.
***Important Note***
CSF samples should be collected in the morning before breakfast and after an overnight fast. Only water is permitted past midnight, until lumbar puncture is completed.
CSF Preparation (20-30 ml)

**Step One**
- Label tubes with pre-printed subject labels prior to collection.
- Pre-chill all cryovials on wet ice.

**Step Two**
- Collect initial 1-2 ml (if bloody, collect CSF until cleared of blood) into 50 ml conical tube.
  - If not bloody, transfer 1-2 ml into the yellow-cap cryovial.
  - Send to local lab for testing.

**Step Three**
- Collect another 20-30 ml CSF into a new 50 ml sterile conical tube.

**Step Four**
- Place sample upright on wet ice until centrifugation begins.
  - Aliquot 1.5 ml into the orange-cap cryovials.
  - If a residual aliquot is created, aliquot into blue-cap cryovial.
  - Document specimen number and volume on CSF Sample Notification Form.
  - Within 15 minutes of collection, centrifuge sample at 4°C for 10 minutes at 2000xg.
  - Store CSF aliquots at -80°C until shipment.

**Step Five**
- x20 1.5 ml aliquots
  - Residual aliquot
CSF Collection and Processing

CSF Aliquot tube for local lab (label not provided)
Sample Shipping
Frozen Shipping: Guidelines

• Ship Monday-Wednesday Only

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

• Batch Samples together
  • Up to 8 Cryoboxes
  • Batch shipping should be performed every 3 months or as a full shipment of specimens accumulates, whichever is sooner.
# Sample Shipment Summary

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Processing/Aliquoting</th>
<th>Tubes to NCRAD</th>
<th>Ship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood (Lavender-Top EDTA tube) for isolation of plasma and buffy coat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma: 1.5 ml plasma aliquots per 2.0 ml cryovials</td>
<td>Up to 14</td>
<td>Frozen (Monday-Wednesday)</td>
<td></td>
</tr>
<tr>
<td>Buffy Coat: 0.75 ml buffy coat aliquot per 2.0 ml cryovial</td>
<td>4</td>
<td>Frozen (Monday-Wednesday)</td>
<td></td>
</tr>
<tr>
<td>CSF</td>
<td>1.5 ml CSF aliquots per 2.0 ml cryovials</td>
<td>Up to 20</td>
<td>Frozen (Monday-Wednesday)</td>
</tr>
</tbody>
</table>
Frozen Shipping: Cryoboxes

Place CSF aliquots in one cryobox and plasma/buffy coat aliquots in a second cryobox. Be sure to adhere a Kit Number Label on the lid of each cryobox.

Place cryobox in one Biohazard Bag.
Frozen Shipping: Dry Ice Requirements

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

• Each Styrofoam shipper can hold 8 cryoboxes

• Each Styrofoam shipper should contain about 45 lbs (20 kg) of dry ice.
**Frozen Shipping: Dry Ice Requirements**

Class 9 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

Your name & address

Repository name & address:
NCRAD  
IU School of Medicine  
351 W. 10th St  
TK-342  
Indianapolis, IN 46202
Shipping Frozen Samples

• Schedule FedEx

• Send Biological Sample and Shipment Notification Form and CSF Shipment and Notification Form to IU *ahead of shipment*
  
  • Email: alzstudy@iu.edu or
  
  • Fax: 317-321-2003
Shipping Regulations and Training

PLEASE NOTE:

• All study personnel responsible for shipping should be certified in biospecimen shipping.

• It is the responsibility of each site to ensure that the appropriate training has been provided and conducted in regards to IATA shipping.

Please see following slides for resources.
Federal Regulations/Training

• Sites are responsible for ensuring proper training is obtained.
• Current federal and international regulations require anyone directly involved with the shipment of potentially infectious materials and other regulated biological materials (including biological specimens and cultures) **be properly trained on pertinent shipping requirements.**

**International Air Transport Association (IATA) Training**

<table>
<thead>
<tr>
<th>DGi Training Center</th>
<th>IATA Training Schools</th>
</tr>
</thead>
<tbody>
<tr>
<td>800-338-2291</td>
<td>North America 1(514)390-6726</td>
</tr>
<tr>
<td>DGIt raining.com</td>
<td>Europe, Africa &amp; Middle East 41 (22) 799 2751</td>
</tr>
<tr>
<td>Provides IATA Certified Air Seminars and online courses</td>
<td>Asia, Australia &amp; the Pacific 65 239 7232</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.iata.org">www.iata.org</a></td>
</tr>
<tr>
<td>SaT Pak Inc.</td>
<td>Training schools located in 30 countries</td>
</tr>
<tr>
<td><a href="http://www.saftpak.com">www.saftpak.com</a></td>
<td></td>
</tr>
<tr>
<td>Provides dangerous goods training via CD or on-site instruction for North America and Europe</td>
<td></td>
</tr>
</tbody>
</table>
UN3373 Biological Substance, Category B Training

- Biological Substance, Category B are specimens being transported for “investigational purposes”
- Recommend: investigator sites document training of category B/dangerous goods
- We recommend establishing a record of your staff’s training and date of instruction
- The training records must be made available upon request by the appropriate national authority
  - Additional information from the Department of Transportation (DOT) can be found on their website http://hazmat.dot.gov
Frozen Shipping: FedEx Airbill

- Airbill must be completed or the shipping carrier will reject/return your package!

Sample shipments to NCRAD will be paid via the NAPS grant at Washington University.

[Image of FedEx Airbill]

- Dangerous goods info for dry ice shipments
- Net weight of dry ice in kg
- FedEx Account Number (will be prefilled)

Your name, address, and phone
Biological Sample and Shipment Notification Forms

• 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

• Fax: 317-321-2003
Biological Sample and Shipment Notification Form: Blood

- Blood Collection for:
  - Plasma
  - Buffy Coat

- Send by E-mail or fax prior to shipment, and include a copy in each shipment.
Biological Sample and Shipment Notification
Form: CSF

Send by E-mail or Fax prior to shipment, and include a copy in each shipment

---

### CSF Sample and Shipment Notification Form

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

To: Kelley Faber  Email: aflstudy@ui.edu  FAX: 317-321-2230  Phone: 1 800-526-2839

<table>
<thead>
<tr>
<th>General Information:</th>
<th>FedEx tracking #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>From:</td>
<td>Date:</td>
</tr>
<tr>
<td>Phone:</td>
<td>Email:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study: NAPS</th>
<th>Kit #:</th>
<th>KIT BARCODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit:</td>
<td>Visit 1</td>
<td>Visit 2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NAPS ID:</th>
<th>GUID:</th>
<th>Gauge needle used for LP:</th>
<th>22G</th>
<th>24G</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Sex:</th>
<th>M</th>
<th>F</th>
<th>Year of Birth:</th>
<th>CSF Collected?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

#### CSF Collection:

1. Date of collection: [MMDDYY]
2. Time of collection: [HHMM]
3. Last date subject ate: [MMDDYY]
4. Last time subject ate: [HHMM]
5. Collection process: Gravity Method | Aspiration

#### CSF Processing:

<table>
<thead>
<tr>
<th>Time spin started:</th>
<th>[HHMM]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of centrifuge:</td>
<td>Minutes</td>
</tr>
<tr>
<td>Temp of centrifuge:</td>
<td>°C</td>
</tr>
<tr>
<td>Rate of centrifuge:</td>
<td>x g</td>
</tr>
<tr>
<td>Total amount of CSF collected:</td>
<td>ml</td>
</tr>
<tr>
<td>Time aliquoted:</td>
<td>[HHMM]</td>
</tr>
<tr>
<td>Number of 1.5 ml CSF aliquots created (orange cap):</td>
<td>x 1.5 ml</td>
</tr>
<tr>
<td>If applicable, volume of residual CSF aliquot (less than 1.5 ml in blue cap):</td>
<td>ml</td>
</tr>
<tr>
<td>If applicable, specimen number of residual CSF aliquot:</td>
<td></td>
</tr>
<tr>
<td>Time frozen:</td>
<td>[HHMM]</td>
</tr>
<tr>
<td>Storage temperature of freezer:</td>
<td>°C</td>
</tr>
</tbody>
</table>

**Notes:**
NCRAD Website

• Helpful Pages:
  • [https://ncrad.org/holiday_closures.html](https://ncrad.org/holiday_closures.html)

---

<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>6th 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>
NCRAD Website: NAPS Active Study Page

Training videos, manual of procedures, and sample forms are available for reference on the NAPS Active Study Page.

https://ncrad.org/resource_naps.html
Contact Information

• Questions?

Please contact NCRAD Coordinators at:
  • Phone: 1-800-526-2839 or 317-278-1228
  • E-mail: alzstudy@iu.edu or mipetkov@iu.edu
  • Website: www.ncrad.org