Parkinson's Spectrum Disorders Center

UCSF Weill Institute for Neurosciences

PSDC New Coordinator Training: 10.2018

NCRAD
Training Overview: PSDC

- Study Overview
- Kit Review
- Sample Collection and Processing
- Sample Shipping
- Sample Form
- NCRAD Website
- Common Nonconformance Issues
- Questions?
### PSDC Study Specimens

<table>
<thead>
<tr>
<th>Specimen</th>
<th>PSDC Visit 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNA (Buffy Coat)</td>
<td>X</td>
</tr>
<tr>
<td>Plasma</td>
<td>X</td>
</tr>
<tr>
<td>PBMC</td>
<td>X</td>
</tr>
<tr>
<td>Serum</td>
<td>X</td>
</tr>
<tr>
<td>RNA</td>
<td>X</td>
</tr>
<tr>
<td>CSF</td>
<td>X*</td>
</tr>
</tbody>
</table>

*CSF in select population
Kit Request Module

kits.iu.edu/psdc

Please allow 2 weeks for your kit request to be processed and shipped.
The coordinator name and contact information will appear. Verify that this information is accurate, or correct it if necessary. Once you confirm the info is correct, the kit supplies will drop down.
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**
## PSDC Blood Kit

<table>
<thead>
<tr>
<th>Quantity</th>
<th>PSDC Blood Kit Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>EDTA (Lavender-Top) Blood Collection Tube (10 ml)</td>
</tr>
<tr>
<td>2</td>
<td>Sodium Heparin (Green-Top) Blood Collection Tube (10 ml)</td>
</tr>
<tr>
<td>1</td>
<td>Serum Determination (Red-Top) Blood Collection Tube (10 ml)</td>
</tr>
<tr>
<td>3</td>
<td>PAXgene™ Blood Collection Tube (2.5 ml)</td>
</tr>
<tr>
<td>1</td>
<td>15ml orange cap conical tube</td>
</tr>
<tr>
<td>10</td>
<td>Cryovial tube (2 ml) with lavender cap</td>
</tr>
<tr>
<td>3</td>
<td>Cryovial tube (2 ml) with red cap</td>
</tr>
<tr>
<td>3</td>
<td>Cryovial tube (2 ml) with clear cap</td>
</tr>
<tr>
<td>2</td>
<td>Cryovial tube (2 ml) with blue cap</td>
</tr>
<tr>
<td>27</td>
<td>Pre-printed labels for blood collection and aliquot tubes</td>
</tr>
<tr>
<td>5</td>
<td>Pre-printed labels with kit number</td>
</tr>
<tr>
<td>10</td>
<td>Labels for handwritten Site and PIDN</td>
</tr>
<tr>
<td>1</td>
<td>Cryovial tube box (holds up to 25 cryovials)</td>
</tr>
<tr>
<td>1</td>
<td>Shipping Supplies for ambient shipment of PBMCs: Plastic biohazard bag with absorbent sheet, Small IATA shipping box with insulated cooler, Small refrigerant pack, Aqui-Pak 6 tube absorbent pouch, UN3373 Biological Substance Category B label, List of contents card, FedEx return airbill and pouch, FedEx Clinic Pak</td>
</tr>
</tbody>
</table>
PSDC CSF Kit

<table>
<thead>
<tr>
<th>Quantity</th>
<th>NCRAD CSF Kit Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>Cryovial tube (2 ml) with orange cap</td>
</tr>
<tr>
<td>1</td>
<td>Cryovial tube (2 ml) with blue cap</td>
</tr>
<tr>
<td>1</td>
<td>Cryovial tube (2 ml) with yellow cap</td>
</tr>
<tr>
<td>1</td>
<td>Lumbar Puncture tray (24G)</td>
</tr>
<tr>
<td>2</td>
<td>Individually Packaged Sterile 50ml Conical Tube</td>
</tr>
<tr>
<td>1</td>
<td>Cryovial tube box (holds up to 25 cryovials)</td>
</tr>
<tr>
<td>17</td>
<td>Pre-printed labels for blood collection and aliquot tube</td>
</tr>
<tr>
<td>5</td>
<td>Pre-printed labels with kit number</td>
</tr>
</tbody>
</table>
## Frozen Shipping Kit

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Frozen Shipping Kit Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Plastic Biohazard bag with 250 mL absorbent sheets</td>
</tr>
<tr>
<td>1</td>
<td>FedEx return airbill and pouch</td>
</tr>
<tr>
<td>1</td>
<td>Shipping box/Styrofoam container</td>
</tr>
<tr>
<td>1</td>
<td>Warning label packet with dry ice sticker</td>
</tr>
<tr>
<td>12</td>
<td>Bubble wrap pouch</td>
</tr>
</tbody>
</table>
Redraw/Take Home Kits

• Redraw may include:
  – EDTA tube, or
  – Sodium Heparin tubes

• Sample redraw may occur in one of two ways:
  – Subject travels to site
  – Site staff sends participant kit
    • Drawn with local physician
    • Cost of draw should be covered by PSDC site by direct payment to physician OR reimbursement to participant
Redraw/Take Home Kit

DNA Redraw/Take Home Kit
• 1 EDTA tube

PBMC Redraw/Take Home Kit
• 2 PBMC tubes
Specimen Labels
Three Label Types

Kit Number

Site ID: 
PIDN:

Collection and Aliquot Tube

Kit Number

0004087175
PSDC
PLASMA
Kit #: 250001

0004133813
PSDC
BUFFY COAT
Kit #: 250001

0004134017
PSDC
PBMC
Kit #: 250001

0004133873
PSDC
SERUM
Kit #: 250001

0004133825
PSDC
RNA
Kit #: 250001
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. CSF Sample and Shipment Notification Form (IF COLLECTED)
  3. Cryobox that houses aliquots during shipping
  4. Outside of the biohazard bag that houses PAXgene™ tubes and aliquot tubes during shipping process

- CSF samples will have a different kit number label than the blood collection specimens

Provided by NCRAD in the kits
Site and PIDN Label

- Subjects will be identified by their site ID and PIDN
- The PIDN is generated at UCSF
- Coordinator will be responsible for handwriting this onto the provided labels
  - Must use Fine Point Sharpie Marker
  - Each site will receive 3 markers in initial kit supply
Collection Tubes - BLOOD

Label 1: collection tube label

- EDTA Tube
- Sodium Heparin Tube
- Serum Tube
- PAXgene™ Tube

Label 2

- Site ID: _____
- PIDN: ____________

- All collection tubes will have two labels
  - The collection tube labels
  - The handwritten Site and PIDN label
Collection Tubes - BLOOD

- EDTA Tube
- Sodium Heparin Tube
- Serum Determination Tube
- PAXgene™ Tube

Collection and Cryovial Tube Label
Site and PIDN ID Label
Aliquot Tube Labels – Plasma, Buffy Coat, Serum, and CSF

- Only one label to be placed on ALL aliquot tubes
  - **Plasma**
    - From EDTA tube
  - **Buffy Coat**
    - From EDTA tube
  - **Serum**
    - Serum Tube
  - **CSF**
    - Sterile Container
Aliquot Tube Labels – Plasma, Buffy Coat, Serum, and CSF

- Collection and Aliquot tube label only
- Please place barcode near cap
Collection and Aliquot Tube Labels - CSF

• Separate Kit Number for CSF collection
  – Kit number will differ from kit number used for the blood samples for the same subject at the same visit

• CSF label
  – Collection tubes
  – CSF aliquots
Labeling Biologic Samples

Please...

• 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
# Blood Draw Order

<table>
<thead>
<tr>
<th>Tube Type</th>
<th>Number of Tubes Drawn</th>
<th>Tube Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. EDTA (Lavender-Top) Tube (10 ml)</td>
<td>x3</td>
<td><img src="image" alt="EDTA Tube" /></td>
</tr>
<tr>
<td>2. Sodium Heparin (Green-Top) Tube (10 ml)</td>
<td>x2</td>
<td><img src="image" alt="Sodium Heparin Tube" /></td>
</tr>
<tr>
<td>3. Serum Determination (Red-Top) Tube (10 ml)</td>
<td>x1</td>
<td><img src="image" alt="Serum Determination Tube" /></td>
</tr>
<tr>
<td>4. PAXgene™ Tube (2.5 ml)</td>
<td>x3</td>
<td><img src="image" alt="PAXgene™ Tube" /></td>
</tr>
</tbody>
</table>
## Cryovial Cap Colors

<table>
<thead>
<tr>
<th>Cap Color</th>
<th>Sample Type</th>
<th>Cap Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lavender</td>
<td>Plasma</td>
<td><img src="image" alt="Lavender Cap Image" /></td>
</tr>
<tr>
<td>Clear</td>
<td>Buffy Coat</td>
<td><img src="image" alt="Clear Cap Image" /></td>
</tr>
<tr>
<td>Red</td>
<td>Serum</td>
<td><img src="image" alt="Red Cap Image" /></td>
</tr>
<tr>
<td>Orange</td>
<td>CSF Aliquot (1.5 ml)</td>
<td><img src="image" alt="Orange Cap Image" /></td>
</tr>
<tr>
<td>Yellow</td>
<td>CSF Aliquot to local lab</td>
<td><img src="image" alt="Yellow Cap Image" /></td>
</tr>
<tr>
<td>Blue</td>
<td>Residual Aliquot (Plasma, Serum, or CSF)</td>
<td><img src="image" alt="Blue Cap Image" /></td>
</tr>
</tbody>
</table>
Plasma Collection

Create up to 10 aliquots

Residual Aliquot with Blue Cap
Buffy Coat Collection

NCRAD Tutorials: http://kits.iu.edu/psdc/videos
**Plasma and Buffy Coat Preparation (10ml Purple Top Tube x 3)**

- **Step One**: Store tubes at room temperature.
- **Step Two**: Collect blood in 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**: Centrifuge samples at 1500 x g for 15 minutes at 4°C. EDTA tubes need to be spun, aliquoted, and stored in the freezer within 2 hours from the time of collection.
- **Step Five**: Pool all plasma from the 3 EDTA tubes into a 15ml conical tube.
- **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.
  - Label cryovial tube with preprinted label.
  - 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 at -80°C until shipment.

- Please allow at least 30 minutes for the centrifuge to cool down and reach 4°C.
- Samples must be stored in -80°C for at least 8 hours before shipment.
PBMC Collection

• Sodium heparin (green top) BD Vacutainer® (10 ml)
  – Not processed at site
  – *NOTE*: Must be shipped AMBIENT to NCRAD the day sample is drawn. No Friday Draws.
PBMC Preparation (10ml Sodium Heparin Tube x 2)

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

**Step Two**
- Collect blood in Sodium Heparin 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**
- Store tubes at room temperature until shipment.
- Ship ambient same day as blood draw.

*No Friday Draws*
Serum Determination Tube

Serum Determination Tube (Immediately after blood draw – pictured below)

** Please note: After standing at room temperature for 30 minutes, blood will be clotted and immobile**

Serum Determination Tube (unfilled)  
Serum Determination Tube (after centrifuge)
Serum Preparation (10ml Red Top Tube)

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

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

Step Three
- Immediately after blood draw, invert tubes 5 times to mix samples.

Step Four
- Allow blood to clot for 30 minutes.
- Centrifuge samples at 1500 x g for 15 minutes at 4°C.
- Serum samples need to be spun, aliquoted, and in the freezer within 2 hours from the time of collection.

Step Five
- 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 serum aliquots at -80°C until shipment.

- Serum tube must be drawn before the PAXgene tube.
- Samples must be stored in -80°C for at least 8 hours before shipment.
- Please allow at least 30 minutes for the centrifuge to cool down and reach 4°C.
RNA PAXgene™ Tubes for RNA

  Documented within MOP for site staff review
  Released by PreAnalytiX
RNA Preparation (2.5ml PAXgene™ Tube)

**Step One**
- Store tubes at room temperature.
- Label tubes with pre-printed Collection/Aliquot tube and Site/RAVE ID labels prior to blood draw.

**Step Two**
- Collect blood in PAXgene™ 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**
- Store tubes at -80°C in a wire rack until shipment.
CSF Collection and Processing
Pre-Ice CSF Cryovials

- Prelabel prior to adding cryovials in wet ice
- Pre-ice all cryovials included in kit
Step One

- Label tubes with pre-printed labels prior to collection.
- Pre-Chill all cryovials on wet ice.

Step Two

- Collect CSF into the 3mL luer lock syringe.
- Dispense 1-2mL in YELLOW cap cryovial.
- Send to local lab for testing.

Step Three

- Collect CSF into 6mL luer lock syringe.
- Collect 20-23 mL.
- Immediately after collection, transfer to 50 mL conical tube.
- Invert tube 3-4 times to mix sample.

Step Four

- Within 15 minutes of collection, centrifuge samples at RT at 2000 x g for 10 minutes.
- Using a clean transfer pipette, transfer all CSF into a second 50mL conical tube leaving the pellet in the bottom. Mix the second tube gently by inverting 3-4 times
- Aliquot 1.5 ml into the orange cap cryovials
- Document specimen number of residual aliquot on sample form
- Store CSF aliquots at -80°C until shipment
- 1-3 mL may stay at local lab for researcher, if 20 mL of CSF is submitted to NCRAD

Step Five

Step Six

- Samples must be stored in -80°C for at least 8 hours before shipment.
Sample Shipments
# 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) for isolation of plasma &amp; buffy coat (for DNA extraction)</td>
<td>1.5 ml plasma aliquots per 2 ml cryovials</td>
<td>8-10</td>
<td>Frozen</td>
</tr>
<tr>
<td></td>
<td>1 ml buffy coat aliquot per 2 ml cryovial</td>
<td>3</td>
<td>Frozen</td>
</tr>
<tr>
<td>Whole blood (Green-Top Sodium Heparin) for isolation of PBMCs</td>
<td>N/A</td>
<td>2</td>
<td>Ambient</td>
</tr>
<tr>
<td>Whole blood (Red-Top Serum) for isolation of serum</td>
<td>1.5 ml serum aliquots per 2 ml cryovials</td>
<td>4</td>
<td>Frozen</td>
</tr>
<tr>
<td>Whole blood (PAXgene™) for RNA extraction</td>
<td>N/A</td>
<td>3</td>
<td>Frozen</td>
</tr>
<tr>
<td>CSF</td>
<td>1.5 ml CSF aliquots per 2 ml cryovials</td>
<td>16</td>
<td>Frozen</td>
</tr>
</tbody>
</table>
Ambient Sample

• Sodium Heparin/PBMC

• Only Monday-Thursday collection and same day shipping. Plan ahead to schedule FedEx.

• Samples must be received at IU one day after collection.

• Do NOT draw or ship ambient samples on Friday

• Include copy of Biological Sample Shipment and Notification Form
• Place the ambient PBMC tubes in the absorbent slots and biohazard bag.
• Place the kit number label on the outside of the biohazard bag.
• Place the bag inside the small shipping box, and then set the refrigerant pack on top of it.
• Place small shipping box within a provided FedEx Clinical Pak, seal, and place FedEx label on outside of package.

*Gel packs must be put in a freezer at minimum the night before shipping.
Frozen Samples

• All other samples
  – Plasma, Buffy Coat, Serum, PAXgene™, and CSF
  – **Ship Monday-Wednesday Only**
• Store samples for at least 8 hours in a -80°C freezer. Keep the samples in the freezer until they are ready for pickup.
• Include copy of Biological Sample Shipment and Notification Form
• Batch samples together
  – 4 participant samples (Plasma, Buffy, Serum, RNA, CSF)
  – **Batch shipping should be performed every three months or as a full shipment of specimens accumulates, whichever is sooner.**
Shipping Frozen Samples

Place kit number label on cryobox.

Place kit number label on cryobox. The CSF kit number will differ from the blood kit number.
Frozen Shipping Packaging

- Use the large biohazard bag to accommodate the 2, 25-Slot Cryobox and PAXgene™ tubes.

- Insert PAXgene™ tubes into the bubble slots and place within the large biohazard bag.

- Place kit number on outside of biohazard bag.
Frozen Shipping Packaging

- Place 2-3 inches of dry ice in the bottom of the Styrofoam shipping container, then insert the cryoboxes laying upright.
- 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 Shipments

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!

- **Number of packages in shipment**
- **and dry ice in kg**
- **Net weight of dry ice in kg**
- **Your name & address**
- **Repository name & address**
Fedex Airbill

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

FedEx Account Number

Your name, address & phone

FedEx Priority Overnight must be selected

Dangerous goods info (for dry ice shipments only)

Net weight of dry ice in kg
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 and ambient samples.
• Email: alzstudy@iu.edu
• Fax: 317-278-1100
Biological Sample and Shipment Notification Form

Includes expanded blood processing section for both Plasma and Serum

Participants should have all aspects of form completed prior to shipping
# Biological Sample Notification Form - CSF

## Appendix C

### CSF Sample and Shipment Notification Form

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

### General information:

<table>
<thead>
<tr>
<th>To:</th>
<th>Kelley Faber</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email:</td>
<td><a href="mailto:jzstudy@iu.edu">jzstudy@iu.edu</a></td>
</tr>
<tr>
<td>FAX:</td>
<td>317-278-1100</td>
</tr>
<tr>
<td>Phone:</td>
<td>1-800-526-2839</td>
</tr>
</tbody>
</table>

| From: |  |
| Date: |  |
| Phone: |  |
| Email |  |

| Study: PSOC | PIDN: |  |
| Sex: M | F |  |
| Year of Birth: |  |
| FedEx tracking #: |  |

### CSF Collection:

1. Date of Collection: 
2. Time of Collection: 24 hour clock: 
3. Last date subject ate: 
4. Last time subject ate: 24 hour clock: 
5. Collection process: Gravity Method OR Aspiration

### CSF Processing:

- Time spin started: 24 hour clock: 
- Duration of centrifuge: minutes
- Temp of centrifuge: °C
- Rate of centrifuge: x g
- Total amount of CSF collected (ml): 
- Time aliquoted: 
- Number of 1.5 ml aliquots created [up to 16 total]: [Orange cap cryovials]: x 1.5 ml
- If applicable, volume of CSF residual aliquot (less than 1.5 ml): [Blue cap cryovial]: ml
- If applicable, specimen number of residual aliquot tube: (Last four digits): 
- Time frozen: 
- Storage temperature of freezer: °C

### Notes:

Version 10.2018
Redraw/Take Home Sample Form - PBMC

Appendix E
Green Top-Sodium Heparin Redraw/Take Home Sample Form

TO BLOOD DRAWING PERSONNEL

This blood sample is for a study sponsored by the National Institute of Health (NIH). Samples are housed at Indiana University School of Medicine. It will need to be shipped to the address below. Please use the enclosed pre-addressed FedEx Clinical Pak.

PSDC at NCRAD
Indiana University School of Medicine
351 W. 10th St. TK-342
Indianapolis, IN 46202
Phone: 1-800-526-2839

The kit provided contains vacutainer tubes with which to obtain blood from the individual for research purposes. Each kit contains 2 green-topped tubes and all necessary shipping supplies.

DO NOT REFRIGERATE; STORE AT ROOM TEMPERATURE.
DO NOT DRAW OR SHIP ON FRIDAY OR SATURDAY.
PLEASE SHIP SAME DAY AS BLOOD IS DRAWN.

Instructions for drawing and shipping blood samples:

1. Fill GREEN TUBES completely, if possible.
2. Invert (do not shake) tubes eight to ten times after drawing blood to thoroughly mix additive with sample.
3. Enclose this form in shipment with sample.
4. Ship samples by Federal Express immediately after drawing. Use the enclosed, pre-paid Federal Express mailer. There will be no cost to you or the patient for the shipping. Consult the enclosed information sheet for packing instructions.

KIT NUMBER (RECORDED ON LABEL): ________________________________
PIDN (RECORDED ON LABEL): ________________________________
STUDY SITE ID (RECORDED ON LABEL): ________________________________
DATE BLOOD WAS DRAWN: ________________________________________
DONOR YEAR OF BIRTH: ___________ DONOR SEX: _______________
Redraw/Take Home Sample Form - EDTA

Appendix F
Lavender Top-EDTA Redraw/Take Home Sample Form

TO BLOOD DRAWING PERSONNEL

This blood sample is for a study sponsored by the National Institute of Health (NIH). Samples are housed at Indiana University School of Medicine. It will need to be shipped to the address below. Please use the enclosed pre-addressed FedEx Clinical Pak.

PSDC at NCRAD
Indiana University School of Medicine
351 W. 10th St. TK-342
Indianapolis, IN 46202
Phone: 1-800-526-2839

The kit provided contains a vacutainer tube with which to obtain blood from the individual for research purposes. Each kit contains 1 lavender-tube and all necessary shipping supplies.

DO NOT REFRIGERATE: STORE AT ROOM TEMPERATURE.
DO NOT DRAW OR SHIP ON FRIDAY OR SATURDAY.
PLEASE SHIP SAME DAY AS BLOOD IS DRAWN.

Instructions for drawing and shipping blood samples:

1. Fill LAVENDER TUBE completely, if possible.
2. Invert (do not shake) tube eight to ten times after drawing blood to thoroughly mix additive with sample.
3. Enclose this form in shipment with sample.
4. Ship samples by Federal Express immediately after drawing. Use the enclosed, pre-paid Federal Express mailer. There will be no cost to you or the patient for the shipping. Consult the enclosed information sheet for packing instructions.

KIT NUMBER (RECORDED ON LABEL): ________________________________

PIDN (RECORDED ON LABEL): ________________________________

STUDY SITE ID (RECORDED ON LABEL): ________________________________

DATE BLOOD WAS DRAWN:__________________________________________

DONOR YEAR OF BIRTH: __________  DONOR SEX: ________________
NCRAD Website
PSDC Study Specific Webpage
https://ncrad.org/resource_psdc.html
NCRAD Website

Helpful Pages

• https://ncrad.org/holiday_closures.html
• https://ncrad.org/friday_blood_draws.html

What to do for Friday Blood Draws

NCRAD is not open for business on Saturday or Sunday; therefore, we ask that no samples be shipped on a Friday. We cannot guarantee the conditions in which the samples will be held by the shipping courier over the weekend. It is important to have plans in place for each type of sample to be held over the weekend prior to shipping. Please refer to the table below for how to handle samples drawn on a Friday.

When possible, please only ship frozen samples on Monday-Wednesday. There is always the potential for an unexpected shipping courier delay and by shipping Monday through Wednesday there should be enough time to receive the samples before the weekend.

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Tube Type</th>
<th>Product</th>
<th>Shipment Method</th>
<th>Friday Draw Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Blood</td>
<td>Sodium Heparin</td>
<td>PBMC</td>
<td>Ambient</td>
<td>DO NOT DRAW ON FRIDAY. Must be drawn on Monday – Thursday.</td>
</tr>
<tr>
<td>Whole Blood</td>
<td>EDTA Tube</td>
<td>DNA Only</td>
<td>Ambient</td>
<td>Do NOT refrigerate. Please keep sample at room temperature until the specimen can be shipped via next day delivery methods the following Monday.</td>
</tr>
</tbody>
</table>

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>
Nonconformance Issues

- Sample aliquots and collection tubes frozen at an angle/inverted

- Fields left blank on Sample and Shipment Notification Forms
  - Last time subject ate often left blank/unknown
  - Incorrect data reported on Sample and Shipment Notification Forms

- Multiple low volume plasma/CSF aliquots

Recommendation:
Place aliquots in Argos boxes/tube rack in freezer *upright* until shipment. Store samples for at least 8 hours in freezer.

Recommendation:
Complete Sample Notification forms during the participant study visit as samples are processed.

Recommendation:
Lay out cryovials in a row and aliquot in order until plasma/CSF is depleted.
Nonconformance Cont.

• All frozen samples for a participant not sent within one shipment box (Paxgene tube, plasma, buffy coat, and serum aliquots should be kept together)
• Aliquots arriving to NCRAD without labels
• Sample forms not faxed or scanned to NCRAD the day before shipment

**Recommendation:**
Ship Samples to NCRAD utilizing the Notification Form, by RAVE ID. Do not throw away labels until samples are packed and shipped.

**Recommendation:** No samples should be held ambient for any period of time at the site. Ensure all samples are frozen or shipped by end of the day.

• PBMC sample not shipped the day of blood draw
Contact Information

• Questions?

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