



**Cerebral Autoregulation, Brain Perfusion, and Neurocognitive  
Outcomes After Traumatic Brain Injury (CAPCOG-TBI)**

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BIOSPECIMEN COLLECTION & PROCESSING

# Specimen Uniformity and Quality

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GENERAL REMINDERS

# Specimen Uniformity and Quality

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Most biomarkers are sensitive to *time* and *temperature*

- Standardization of processing across sites is key
- Reference the *BioSEND Specimen Collection, Processing, and Shipment Manual* as needed
- Do not replace or supplement any kit components without first receiving approval from BioSEND/NINDS

Questions? Email [biosend@iu.edu](mailto:biosend@iu.edu)

# Site Equipment

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Sites will need to supply the following items:

## Phlebotomy

- Gloves
- Alcohol wipes
- Butterfly needles
- Tourniquet
- Gauze pads
- Bandages
- Sharps bin and lid



# Site Equipment

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Sites will need to supply the following items:

## Processing

- Crushed ice
- Microcentrifuge tube rack
- Calibrated pipettes and pipette tips
- Centrifuge capable of maintaining 4°C
- -80°C Freezer
- Dry ice



# Collection Protocol

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Sample Type & Volume	BL	3M	6M	12M
Plasma aliquots, 1.5ml	6	6	6	6
Serum aliquots, 1.5ml	6	6	6	6
Buffy Coat	2	2	2	2
Whole Blood, 3ml	1	1	1	1
CSF aliquots*, 1.5ml	5	5	5	5

*\*CSF will only be collected on a subset of participants. Up to 5 aliquots may be generated for a single participant-visit*

# Kit Ordering – Biosend.org

The screenshot shows the Biosend.org website navigation menu. The 'Active Studies' link is circled in red. Below the navigation menu is a grid of three images with captions: 'About BioSEND' (a building with trees), 'Banking Samples' (a metal container), and 'Biospecimens' (a dark container with a label). The 'Biospecimens' image has a white box overlaid with the text 'and other neuropsychiatric to researchers'.

**NINDS BioSEND**    Accessing Biospecimens    Banking Samples    **Active Studies**    About BioSEND

AJPD Study Resources	MBPS Study Resources	SPARX3 Study Resources
CHANGE-HD Study Resources	PBS Study Resources	Udall Study Resources
DLB Study Resources	PHD3 Study Resources	Holiday Closures
DVRP Study Resources	PSP Study Resources	Shipping Information
EpiBioS4Rx Study Resources	SBPD Study Resources	Sample Shipment Form
LBD Study Resources	CRC-SCA Study Resources	
LETBI Study Resources	READISCA Study Resources	

**About BioSEND**    **Banking Samples**    **Biospecimens**

and other neuropsychiatric to researchers


# Kit Ordering – Study Resource Page

Study-specific resource page available. Will include:

- Link to Kit Request Module
- Link to Sample Collection & Processing Form
- Manual of Procedures
- Training Slides

**BIOSEND** NINDS    Accessing Biospecimens    Banking Samples    Active Studies    About BioSEND

## Clinical Research Consortium for SCA (CRC-SCA) Study Page



Welcome CRC-SCA Study staff, coordinators, and PIs. This section encompasses study specific tools and resources for your reference. If you have any questions, comments, or new ideas please contact biosend@iu.edu or by phone directly at (317)278-0594.

### Specimen Table

Cohort	Population	Plasma	Genomic DNA	Serum	CSF
MBPS	Participants with a diagnosis of SCA 1, 2, 3, 6, or 7	✓	✓	✓	✓

### Study Resources

**Kit Request Module**

Please follow the below link to access the CRC-SCA Kit Request Module. This link will direct you to a REDCap database where study coordinators and staff may request kits, individual supplies, and/or labels. Please allow a total of two weeks for kit requests to be compiled and delivered to your site.

[Kit Request System](#)

### Downloads

- Sample Shipment Form (pdf)
- Manual of Procedures
- New Coordinator Training Slides

### Additional Resources

- Online Sample Form
- Kit Request System

### Contact Us

biosend@iu.edu  
317-278-0594



# Confirm/Update Shipping Information

Select your Study Site from the drop down box to populate the most current information we have for your site. Please confirm or update your site's information as needed.

<b>Study Site</b> <small>* must provide value</small>	Indiana University
Indiana University School of Medicine Carolyn Dunifon Dept. of Medical & Molecular Genetics 351 West 10th Street, TK-318 Indianapolis, IN 46202-3002 (317) 274-5751 cdunifon@iu.edu	
<b>Is the contact name above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No <a href="#">reset</a>
<b>New Contact Name</b> <small>* must provide value</small>	Claire Wegel
<b>Is the shipping address above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <a href="#">reset</a>
<b>Is the e-mail address above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <a href="#">reset</a>
<b>Is the phone number above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <a href="#">reset</a>

*Note: The form includes blue arrows pointing to the 'Study Site' dropdown, the contact information text, and the 'New Contact Name' input field. Dashed boxes highlight the 'Study Site' dropdown and the 'Verify contact information and update if needed' text.*

# Kit Ordering – Kit Options

Selecting a kit option will populate contents for that kit

## Kit Type

**\*\*Please allow two weeks for shipment\*\***

\* must provide value

- Blood Collection Kit
- CSF Processing Kit
- Frozen Shipping Kit
- Supplemental Kit
- Extra Supplies

Please specify in comments if you need kits before the standard two week shipment time.

## Blood Collection Kit contains:

- 6 - Cryovial (Sarstedt®) with purple cap, 2ml
- 2 - Cryovial (Sarstedt®) with clear cap, 2ml
- 6 - Cryovial (Sarstedt®) with red cap, 2ml
- 2 - EDTA (plastic) tube, 10ml
- 2 - Serum (plastic) tube, 10ml
- 1 - EDTA (plastic) tube, 3ml
- 1 - Bubble-tube sleeve
- 3 - Disposable pipet, 3ml
- 1 - Cryobox, 25 cell
- 1 - Label set (kit & specimen labels)

# Kit Ordering – Blood Kits

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## Kit Type

**\*\*Please allow two weeks for shipment\*\***

\* must provide value

- Blood Collection Kit
- CSF Processing Kit
- Frozen Shipping Kit
- Supplemental Kit
- Extra Supplies

Please specify in comments if you need kits before the standard two week shipment time.

Kits are not specific to a subject or time point. After collection, sites will indicate the subject and time point to which BioSEND should link the samples.

# CSF Kits

<b>Kit Type</b> <b>**Please allow two weeks for shipment**</b> <small>* must provide value</small>	<input checked="" type="checkbox"/> Blood Collection Kit <input checked="" type="checkbox"/> CSF Processing Kit <input type="checkbox"/> Frozen Shipping Kit <input type="checkbox"/> Supplemental Kit <input type="checkbox"/> Extra Supplies  <small>Please specify in comments if you need kits before the standard two week shipment time.</small>
<b>Blood Collection Kit Quantity</b> <small>* must provide value</small>	<input type="text" value="5"/>
<b>CSF Processing Kit Quantity</b> <small>* must provide value</small>	<input type="text" value="2"/>

- CSF processing kits are ordered independently of blood kits, as CSF will not be collected at every visit
- All specimen labels (including CSF) will be included in the Blood Collection Kit. If CSF is not collected at a visit, you may discard these extra labels

# Extra Supplies

This option allows you to order individual kit components. For ex, if you have a kit with blood tubes that have expired, you may order new collection tubes to replace them.

<b>Kit Type</b> <b>**Please allow two weeks for shipment**</b> <small>* must provide value</small>	<input type="checkbox"/> V01 Visit Kit <input type="checkbox"/> Follow-Up Visit Kit (select Visit Type below) <input type="checkbox"/> CSF Kit <input type="checkbox"/> Supplemental Kit <input checked="" type="checkbox"/> Extra Supplies
<small>Please specify in comments if you need kits before the standard two week shipment time.</small>	
<b>Individual Tube Bubble Pouch</b>	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
<b>25-Slot Cryobox</b>	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
<b>Siliconized Cryovial (2 ml)</b>	<input type="radio"/> 10 <input type="radio"/> 20 <a href="#">reset</a>
<b>Air waybill envelope</b>	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a> <small>Plastic envelope to affix air waybill to package</small>
<b>Lumbar Puncture Trays with Lidocaine, 24g</b>	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
<b>Lumbar Puncture Trays with Lidocaine, 22g</b>	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
<b>Medication Transfer Filter Straws (for LP)</b>	<input type="radio"/> 2 <input type="radio"/> 4 <a href="#">reset</a>
<b>15ml conical tube, individually wrapped</b>	<input type="radio"/> 2 <input type="radio"/> 4

# Submit Request

- Click “Submit” to send order to BioSEND; staff will confirm receipt of your order
- Please allow two week turn-around time for kit shipments
- If urgent request needed, please note date needed by in comments and email BioSEND. We cannot guarantee urgent requests, but will do our best to accommodate.

**NINDS BioSEND** AAA

NINDS Biosend CRC-SCA Kit Request System

Study Site  \* must provide value

Columbia University

Contact Name  
Shipment Address  
Email  
Phone

Is the contact name above correct?  Yes  No \* must provide value [reset](#)

Is the shipping address above correct?  Yes  No \* must provide value [reset](#)

Is the e-mail address above correct?  Yes  No \* must provide value [reset](#)

Is the phone number above correct?  Yes  No \* must provide value [reset](#)

Kit Type \*\*Please allow two weeks for shipment\*\* \* must provide value

V01 Visit Kit  
 Follow-Up Visit Kit (select Visit Type below)  
 CSF Kit  
 Supplemental Kit  
 Extra Supplies

Please specify in comments if you need kits before the standard two week shipment time.

Comments

[Expand](#)

**Submit**

# Sample Labelling

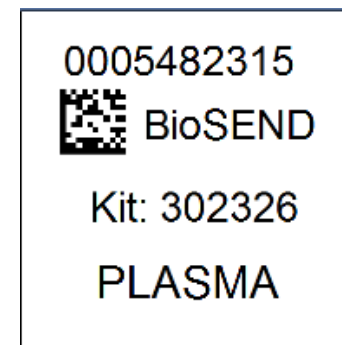
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**Labels are provided by Indiana University for BioSEND samples only**

- Please check that all samples are properly labelled with correct specimen type



Kit Labels



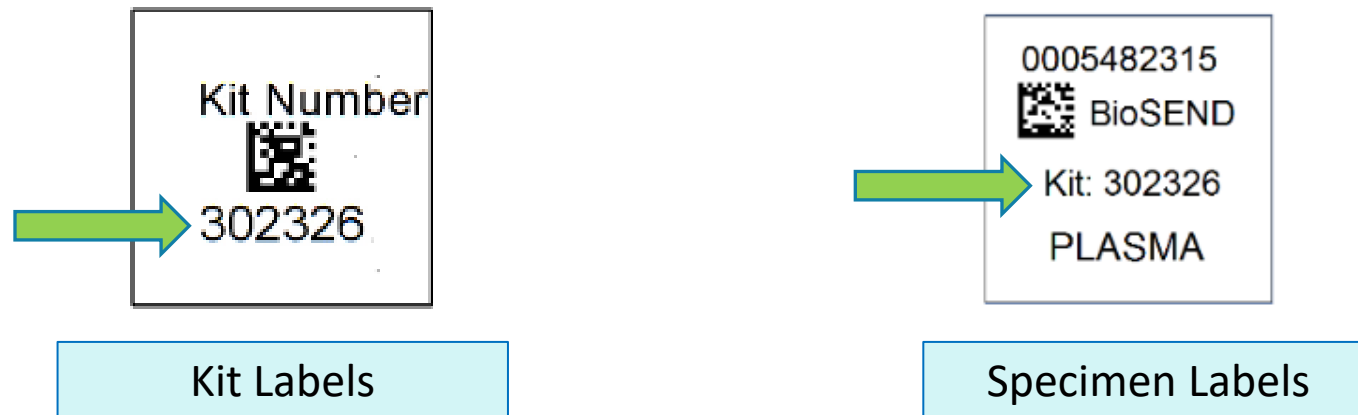
Specimen Labels

# Sample Labelling – Kit Number

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## Kit Number

- Each Blood Collection Kit will have a unique “Kit Number” used to track participant samples and provide quality assurance
- Any kit number can be used for any subject or visit—which is why it is very important to document which kit number was used for which subject and visit





# Sample Labelling – Kit Labels

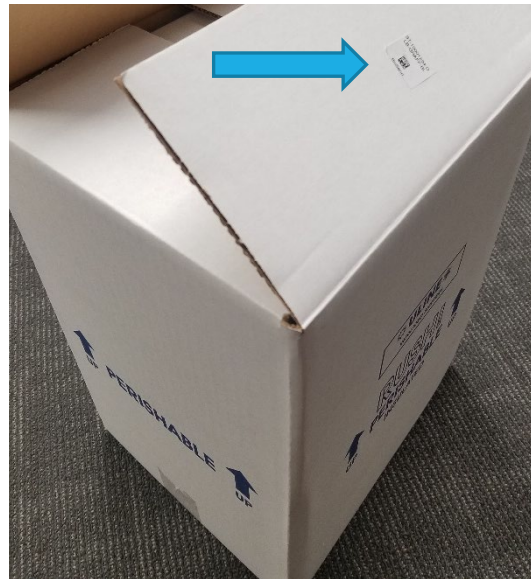
Kit Number



302326

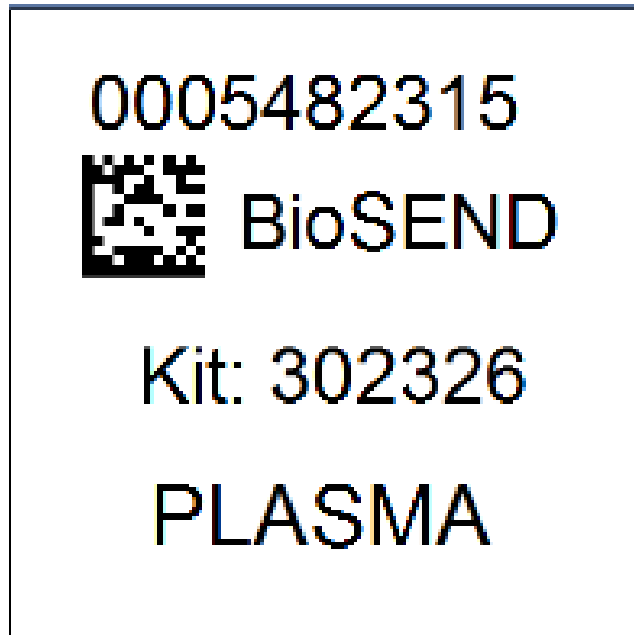
Kit labels are placed:

- On the biohazard bags
- On the lid of frozen shippers



# Sample Labelling – Specimen Labels

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**Unique Barcode**



**Biorepository Name**



**Kit Number**

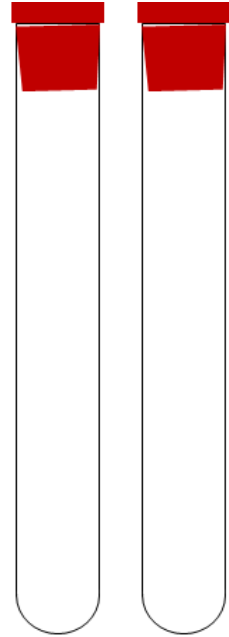


**Sample Type**

# Sample Collection and Processing

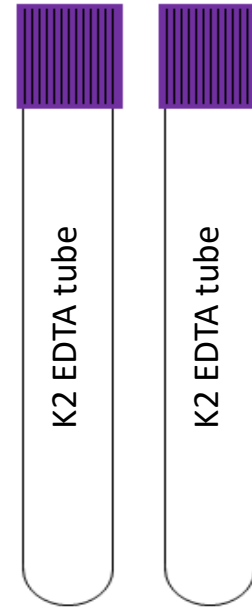
Blood Tube Draw Order

2 x 10ml Serum tubes



**1**

2 x 10ml EDTA tubes



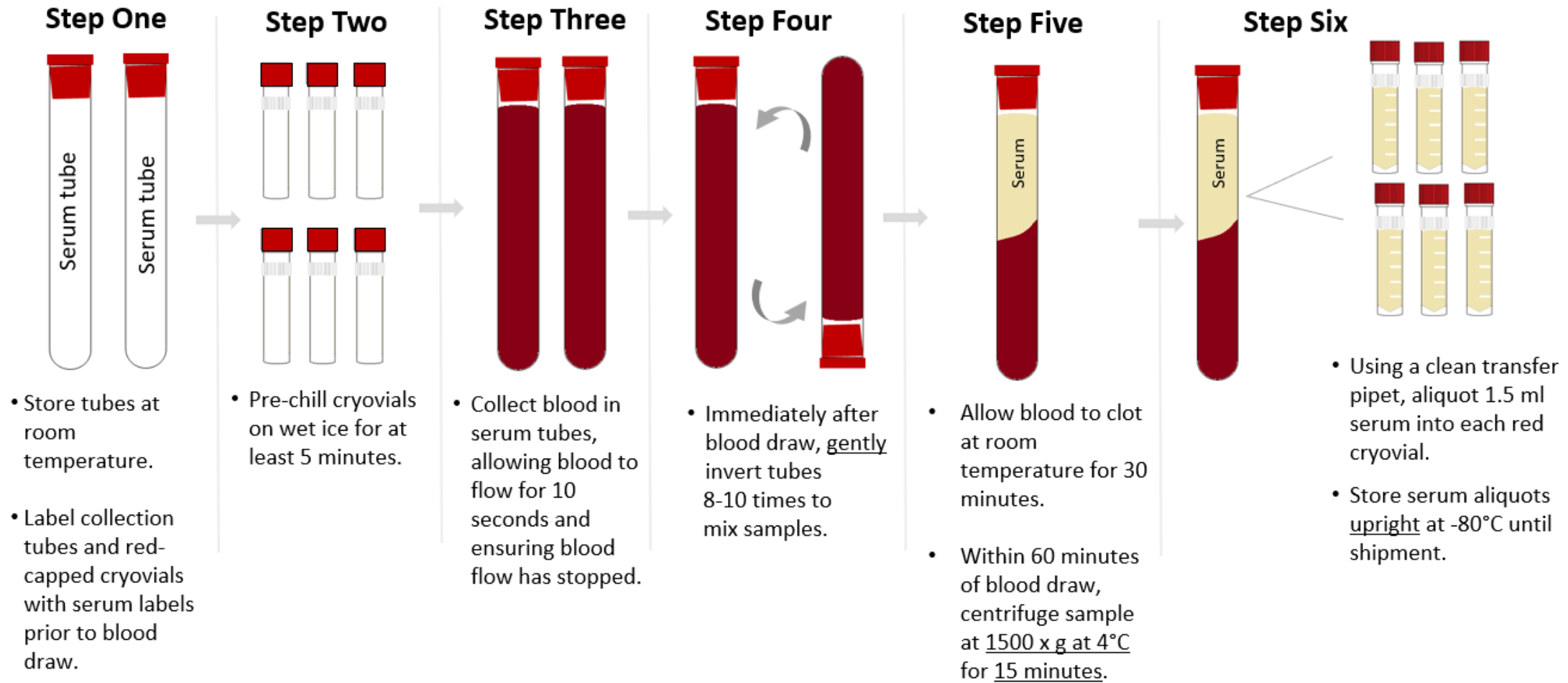
**2**

1 x 3ml EDTA tube

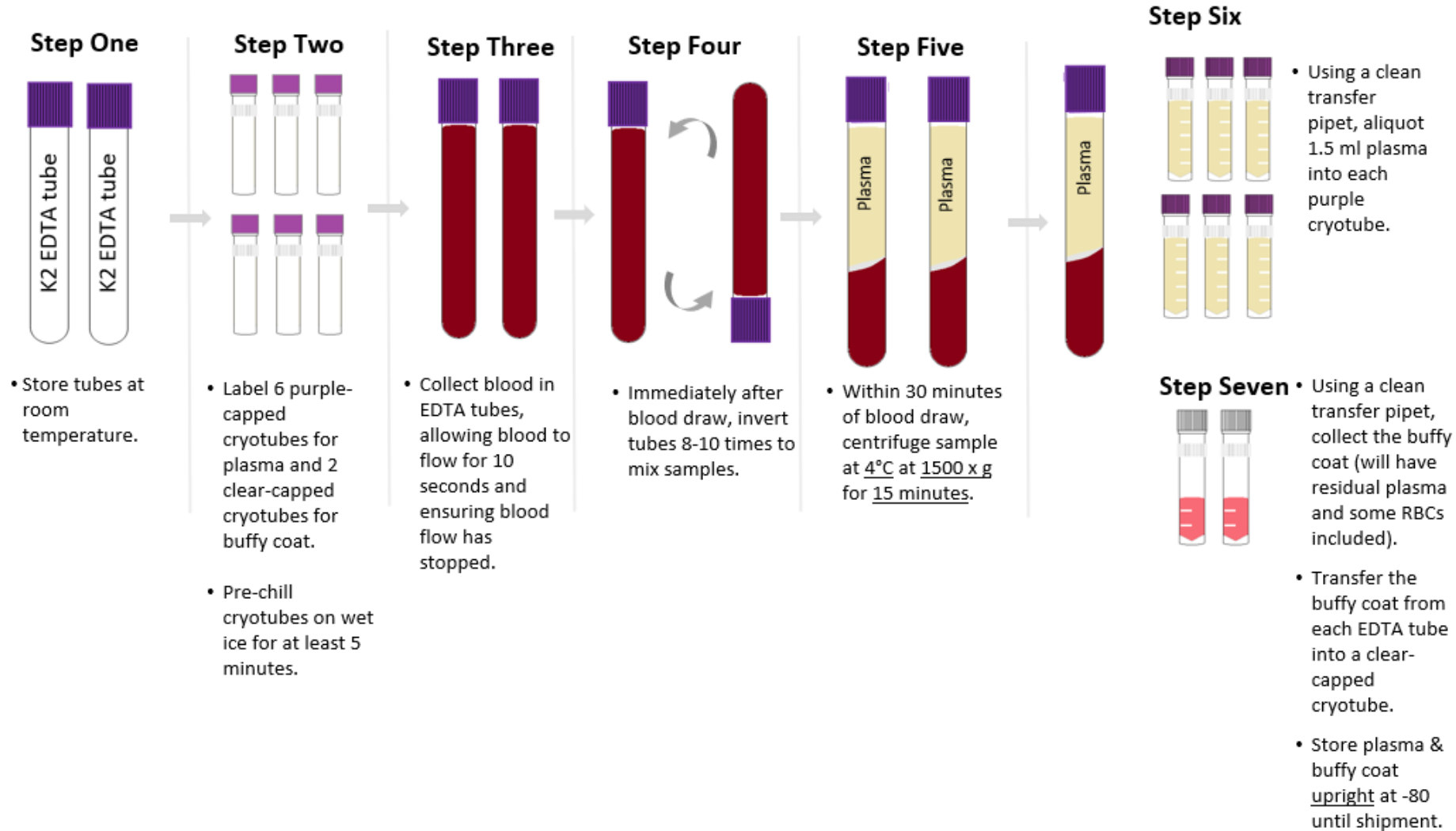


**3**

# Sample Collection and Processing: Serum



# Sample Collection and Processing: Plasma & Buffy Coat



# Sample Collection and Processing: Whole Blood

## Step One



- Store tube at room temperature.
- Label tube with preprinted WBLD label prior to blood draw.

## Step Two



- Collect blood into 3ml EDTA tube, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

## Step Three



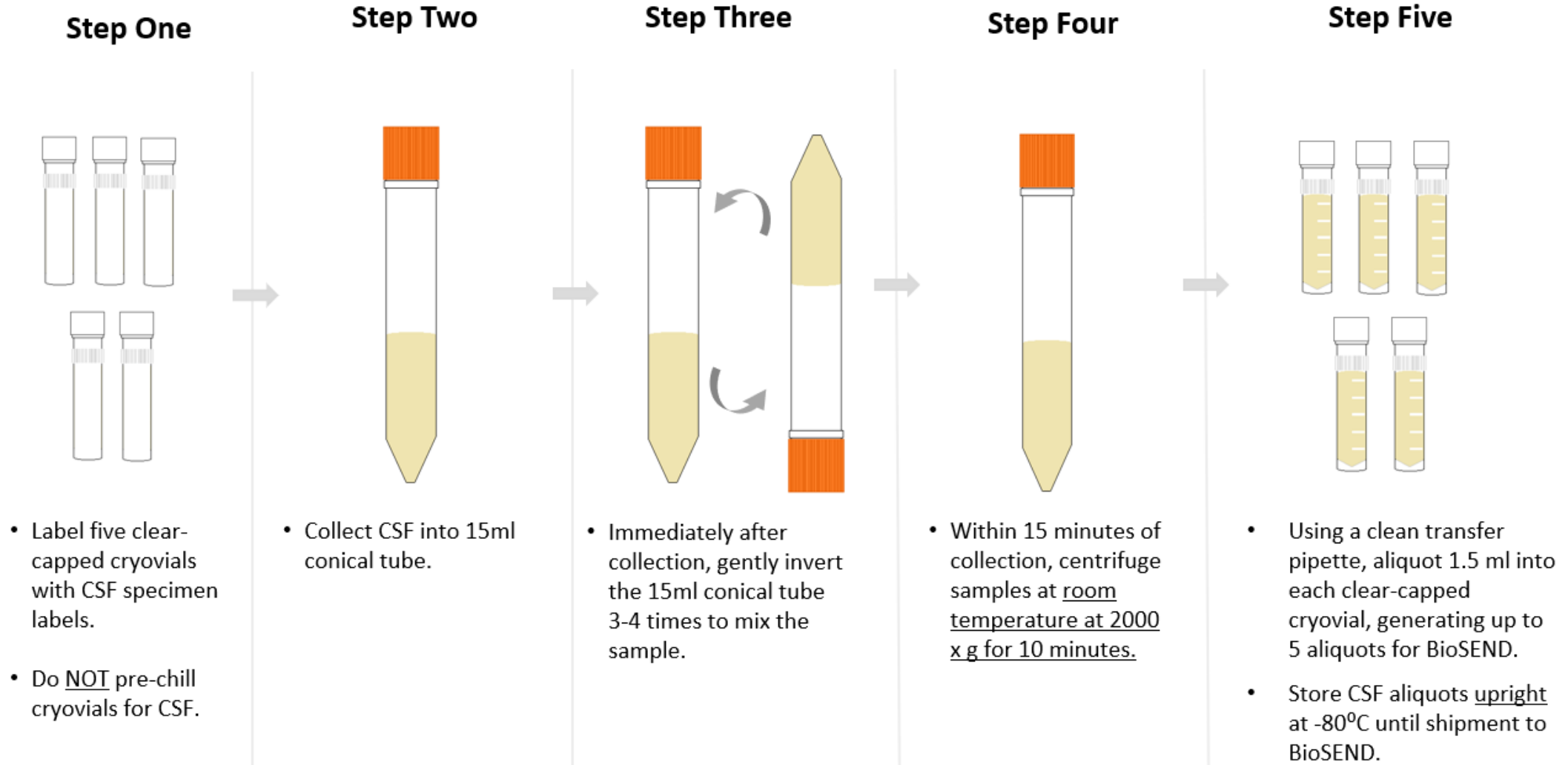
- Immediately after blood draw, invert tube 8-10 times to mix sample.

## Step Four



- Transfer to  $-80^{\circ}\text{C}$ . Store upright and keep frozen until shipment to BioSEND.

# Sample Collection and Processing: CSF



# Shipping Samples: Frozen

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## Packing and Shipping Frozen Samples

- Please ship samples as they are collected (within two weeks of collection)
- All samples ship frozen on dry ice
- Frozen samples should be shipped **Monday through Wednesday only**





# Shipping Samples: Frozen

## Packing and Shipping Frozen Samples

- Fill shippers with a minimum of 10lbs of dry ice
- Place cryobox and whole blood in separate biohazard bags
- Place layer of dry ice in between biohazard bags
- Do not pack shipment until the day of pickup



Class 9 Dry Ice Label should not be covered with other stickers and must be completed correctly, or courier will reject/return your package!

# Shipping Samples

Labeling frozen shippers

Shipper's Declaration not Required.

Dry Ice amount must be in kilograms.

Note: 2 lbs. = 1 kg.

Airwaybills / airmails must have the following:  
1. Dry Ice; 9; UN 1845  
2.  $\frac{\text{Number}}{\text{(Number pkgs)}} \times \frac{\text{wt}}{\text{(wt)}} \text{ Kg}$

Net weight of dry ice in kg

Dry Ice      kg.

Your name & address

Shipper's Name and Address

UN 1845

Consignee Name and Address

IU information and address

06426 1/01 RRD

# Shipping Samples

UPS resources available on BioSEND website on the “Shipping Information” page

The screenshot shows the BioSEND website navigation menu. The logo is 'NINDS BioSEND'. The main navigation items are 'Accessing Biospecimens', 'Banking Samples', 'Active Studies', and 'About BioSEND'. A blue arrow points from 'Banking Samples' to 'Active Studies'. Below 'Active Studies' is a dropdown menu with the following items: 'SPARX3 Study Resources', 'Udall Study Resources', 'Holiday Closures', 'Shipping Information' (highlighted with a blue arrow), 'Sample Shipment Form', and 'Withdrawn Subject Notification'. Below the menu are three small images: a building with green trees, a close-up of a metal container, and a dark interior space.

**NINDS BioSEND**

Accessing Biospecimens      Banking Samples → Active Studies      About BioSEND

- AJPD Study Resources
- CHANGE-HD Study Resources
- DLB Study Resources
- DVRP Study Resources
- EpiBioS4Rx Study Resources
- LBD Study Resources
- LETBI Study Resources
- MBPS Study Resources
- PBS Study Resources
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- PSP Study Resources
- SBPD Study Resources
- CRC-SCA Study Resources
- READISCA Study Resources
- SPARX3 Study Resources
- Udall Study Resources
- Holiday Closures
- Shipping Information**
- Sample Shipment Form
- Withdrawn Subject Notification

# Shipping Information Page

Links on this page to:

1. Generate airwaybills & schedule pickups
2. View printed guide on how to use ShipExec™
3. Request user account and update site address in system
4. View video tutorial for using UPS ShipExec™

## UPS Shipping Resources

1 →

To generate air waybills and schedule UPS pickups for shipments to BioSEND, please visit the UPS ShipExec™ Thin Client [website](#).

2 →

For instructions on how to use the UPS ShipExec™ Thin Client website, please refer to the [BioSEND UPS ShipExec™ Thin Client Guide](#)

3 →

To request a new user account for UPS ShipExec™ Thin Client or to request an update to your site's address in the system, please [use this form](#) to submit your request.

## Navigating UPS ShipExec™

4 →

The screenshot shows the UPS ShipExec™ Thin Client Home Page. At the top, there is a navigation bar with the ShipExec logo and links for Home, My Account, and My Site. Below the navigation bar, the page is titled "Welcome to the ShipExec™ Thin Client Home Page". There are two notification sections: "System Notifications" and "Company Notifications". The "System Notifications" section contains two items: "ShipExec Documentation" and "Importing Your Personal Address Book". The "Company Notifications" section is currently empty. A large video player overlay is centered on the page, showing a play button and a progress bar at the bottom. The video player controls include a play/pause button, a volume icon, a progress bar showing 0:58 / 9:18, a CC icon, a 1x zoom icon, a settings gear icon, and a close button.

# Shipping Samples – UPS ShipExec™

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**If you will be assisting in shipping samples, please request a user account and familiarize yourself with the system well in advance of your first sample shipment**

# Shipping Samples: Frozen

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Please notify BioSEND ahead of shipment

- Please complete the Sample Collection and Processing Form in REDCap ahead of shipment (can be completed day of shipment).
  - A completed copy of this form should be included in the sample shipper
- If you are having trouble with REDCap, please notify BioSEND directly of shipment at [biosend@iu.edu](mailto:biosend@iu.edu)

# Sample Collection and Processing Form

Hyperlinked above

First page captures basic subject and visit information

Please complete the Specimen Collection and Processing Form, below.

Study

CAPCOG-TBI ▾

Study Site

University of Texas Southwestern ▾

Email address of staff member completing this form

*Note: A copy of the completed sample form and the shipping manifest will be sent to this address.*

GUID:

Subject's biological sex (used for DNA quality control)

Visit

IU Kit Number

6 characters remaining





Next Page >>

Save & Return Later

# Sample Collection and Processing Form

Hyperlinked above

Second page captures processing information

Blood Collection and Processing	
Date of venipuncture blood collection	<input type="text"/>  Today M-D-Y
Time of venipuncture blood collection	<input type="text"/>  Now H:M Use 24 Hour clock
1. SERUM (red-top tubes, 10 mL)	
Was blood collected and processed for SERUM?	<input checked="" type="radio"/> Yes <input type="radio"/> No <a href="#">reset</a>
Time of SERUM tube centrifugation	<input type="text"/>  Now H:M Use 24 Hour clock
Duration of SERUM tube centrifugation	<input type="text" value="15"/> minutes
Rate of SERUM tube centrifugation	<input type="text" value="1500"/> x g
Temperature of SERUM tube centrifugation	<input type="text" value="4"/> degrees Celsius
Total volume of SERUM collected	<input type="text"/> mL
Number of SERUM aliquots created for BioSEND	<input type="text"/> Each aliquot should be 1.5 mL
Time SERUM aliquots were placed in freezer	<input type="text"/>  Now H:M Use 24 Hour clock



# Sample Collection and Processing Form

Hyperlinked above

PDF form of responses will be emailed to you. Print a copy and include with shipment.

## CAPCOG-TBI Frozen Shipping Manifest

Please verify/update the information below. When you click the "Submit" button below, a PDF copy of the Frozen Shipping Manifest will be emailed to you for Subject [subj\_id].

Please print a copy of that document and include it in the Kit #[kit\_num] shipping container.

Study	<input type="radio"/> CAPCOG-TBI
Study Site:	<input type="radio"/> Mind Research Network
GUID:	_____
Visit:	<input type="radio"/> BL <input type="radio"/> 3M <input type="radio"/> 6M <input type="radio"/> 12M
IU Kit Number:	_____
Date of blood collection:	_____
Date of CSF collection:	_____
<b>SERUM</b>	
Number of SERUM aliquots shipped:	_____
<b>PLASMA EDTA</b>	
Number of PLASMA EDTA aliquots shipped:	_____
Number of BUFFY COAT aliquots shipped:	_____
<b>WHOLE BLOOD EDTA</b>	
Number of WHOLE BLOOD tubes shipped:	_____

# Shipping Samples: Closures

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

\*Please also consider weather when shipping. UPS will post service updates on their webpage. Please reach out to BioSEND if you are unsure if it is safe to ship.

# Non-Conformance

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Most common non-conformance issues:

- Samples shipped for weekend/holiday delivery
- Sample form incomplete/inaccurate
- Unlabeled or mislabeled tube(s)
- Sample hemolysis



# Non-Conformance

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- BioSEND will notify sites directly of any issues upon receipt
- Non-conformance is reported on a weekly basis to NINDS Continued non-conformance may result in required re-training and notification to site PI
- ***If you are experiencing issues, please reach out to us for help! It is much easier to prevent an issue before sample collection & shipment than trying to fix it after the fact***

# Contacts

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## Indiana University

General Questions/Shipment Notifications:

[biosend@iu.edu](mailto:biosend@iu.edu)

Biorepository Project Manager:

Claire Wegel

[cwegel@iu.edu](mailto:cwegel@iu.edu)

Tel: 317.278.6158

Biorepository Clinical Research Coordinator:

Carolyn Dunifon

[cdunifon@iu.edu](mailto:cdunifon@iu.edu)

Tel: 317.274.5751