Cerebral Autoregulation, Brain Perfusion, and Neurocognitive Outcomes After Traumatic Brain Injury (CAPCOG-TBI) Study Manual of Procedures

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April 2025

Section	Change
Document Footer	Updated to "Version (April 2025)"
Throughout Document	Minor changes made to phrasing and wording. No alterations to procedures were made.

National Institute of Neurological Disorders and Stroke Biorepository:

BioSpecimen **E**xchange for **N**eurological **D**isorders, **BioSEND**

Biospecimen Collection, Processing, and Shipment Manual for **C**erebral **A**utoregulation, Brain **P**erfusion, and Neuro**cog**nitive Outcomes After **T**raumatic **B**rain **I**njury (CAPCOG-TBI)

Table of Contents

1.0 PURPOSE

The purpose of this manual is to provide collection site staff (PIs, study coordinators, and the sample collection and processing teams) at various study sites with instructions for collection and submission of biological samples. It includes instructions for biospecimen submission to the BioSpecimen Exchange for Neurological Disorders (BioSEND) located at Indiana University.

This manual includes instructions for the collection, processing, aliquoting and shipping of the following samples:

- Serum
- Plasma
- Buffy Coat (for DNA extraction)
- Whole Blood
- CSF

These procedures are relevant to all study personnel responsible for processing blood specimens to be submitted to BioSEND.

2.0 ABBREVIATIONS

BioSEND	BioSpecimen Exchange for Neurological Disorders
EDTA	Ethylene Diamine Tetra-acetic Acid
IATA	International Air Transport Association
PDBP	Parkinson's Disease Biomarkers Program
RBC	Red Blood Cells
RCF	Relative Centrifugal Force
RPM	Revolutions Per Minute
LBD	Lewy Body Dementia

3.0 BioSEND Information

3.1 BioSEND Contacts

Tatiana Foroud, PhD, Principal Investigator

Claire Wegel, Project Manager

Email: cwegel@iu.edu

General BioSEND Contact Information
Email: biosend@iu.edu
Website: www.BioSEND.org

Phone: 317-278-6158

Sample Shipment Mailing Address
BioSEND
Indiana University School of Medicine
351 W. 10th Street. TK-217
Indianapolis, IN 46202-5188

3.2 Hours of Operation

Indiana University business hours are from 8 AM to 5 PM Eastern Time, Monday through Friday.

Frozen samples must be shipped Monday- Wednesday only.

Check the weather reports and the shipping courier website to make sure impending weather events (blizzards, hurricanes, etc.) will not impact the shipping or delivery of the samples. Couriers often report anticipated weather delays on their website.

3.3 Holiday Schedules

- Please note that courier services may observe a different set of holidays. Please be sure to verify shipping dates with your courier prior to any holiday.

3.4 Holiday Observations

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

Please note that BioSEND has extended closures to inbound shipments around the Thanksgiving and Christmas holidays. In addition to sending advance notification of these closures to sites, dates will be posted on the BioSEND website. Frozen specimens collected during this period should be held at your site to ship after the first business day in January. If you are ever unsure if it is safe to ship samples, please email biosend@iu.edu to confirm.

4.0 BioSEND Sample Requirements

NINDS approves each study for a specific biospecimen collection protocol. Studies and study sites should make every effort to meet their approved biospecimen collection requirements. The expected number of samples from each site that should be returned to BioSEND are listed in sections 4.1-4.2.

If a sample is not obtained at a particular visit, this should be recorded in the notes section of the Specimen Collection and Processing Form **(see Appendix I).** This form is submitted with your frozen sample shipment to BioSEND.

4.1 Protocol Schedule for Biospecimen Submission to BioSEND – CAPCOG-TBI

Visit (month)	BL	3M	6M	12M
Serum aliquots, 1.5ml	6	6	6	6
Plasma aliquots, 1.5ml	6	6	6	6
Buffy Coat	2	2	2	2
Whole Blood, 3ml	1	1	1	1
CSF, 1.5ml*	5	5	5	5

*Note: CSF will only be collected on a subset of subjects. Due to the nature of CSF collection for this protocol, it is understood that less than 5 aliquots may be collected.

5.0 SPECIMEN COLLECTION KITS, SHIPPING KITS AND SUPPLIES

Research specimen collection kits (except dry ice and equipment listed in Section 5.7) will be provided by BioSEND. BioSEND will provide a sufficient number of labels only for those specimens that are to be shipped back to the BioSEND repository. Any specimens that will remain at the collection site should be labeled accordingly. Ensure that all tubes are properly labeled during processing and at the time of shipment according to Section 6.2.

5.1 Kit Supply to Study Sites

Kits and individual kit components (ie, "Extra Supplies") can be ordered as required through the kit request module. Sites are advised to proactively confirm kits are on hand ahead of study visits.

The link to the kit request module is shown below:

- CAPCOG-TBI: https://redcap.link/capcogtbi

Please allow **TWO weeks** for kit orders to be processed and delivered.

5.2 Specimen Collection Kit Contents

Collection kits contain the following (for each subject) as designated per your protocol and/or NINDS resource development agreement. Do not replace or supplement any of the tubes or kit components provided with your own supplies unless you have received approval from the NINDS/BioSEND Study team to do so. *Please store all kits at room temperature until use*

CAPCOG-TBI Blood Collection Kit	
Supply	**Amount**
Cryovial (Sarstedt®) with purple cap, 2ml	6
Cryovial (Sarstedt®) with clear cap, 2ml	2
Cryovial (Sarstedt®) with red cap, 2ml	5
EDTA (plastic) tube, 10ml	2
Serum (plastic) tube, 10ml	2
EDTA (plastic) tube, 3ml	1
Bubble-tube sleeve	1
Disposable pipet, 3ml	3
Cryobox, 25 cell	1
Label set (kit & specimen labels)	1

CAPCOG-TBI CSF Processing Kit	
Supply	**Amount**
Conical tube (individually wrapped), 15ml	1
Disposable pipet, 3ml	1
Cryovial (Sarstedt®) with clear cap, 2ml	5

Frozen Shipping Kit*	
Supply	**Amount**
Plastic Biohazard bag with absorbent sheet	4
UPS Airbill Sleeve	1
Shipping box/Styrofoam container	1
UN3373 Category B Label	1
Fragile label	1
Dry ice label	1

*Note: one kit contains the supplies to ship samples for up to two subject-visits (ie, 4 total biohazard bags of samples)

CAPCOG-TBI Supplemental Kit	
Supply	**Amount**
Cryovial (Sarstedt®) with purple cap, 2ml	10
Cryovial (Sarstedt®) with clear cap, 2ml	10
Cryovial (Sarstedt®) with red cap, 2ml	10
EDTA (plastic) tube, 10ml	5
EDTA (plastic) tube, 3ml	5
Serum (plastic) tube, 10ml	5
Bubble-tube sleeve	5
Conical tube (individually wrapped), 15ml	3
Disposable pipet, 3ml	10
Cryobox, 25 cell	3
Plastic Biohazard bag with absorbent sheet	5
UPS Airbill Sleeve	3
UN3373 Category B Label	3
Fragile label	3
Dry ice label	3

5.4 Site Required Equipment

The following materials and equipment are necessary for the processing of specimens at the collection site and are to be **supplied by the local site**:

- Personal Protective Equipment: lab coat, nitrile/latex gloves, safety glasses
- Tourniquets
- Alcohol Prep Pads
- Gauze Pads
- Bandages
- Butterfly needles and hubs
- Microcentrifuge tube rack
- Test tube rack
- Sharps bin and lid

In order to process samples consistently across all projects and ensure the highest quality samples possible, project sites must have access to the following equipment:

- Centrifuge capable of ≥ 1500 rcf (1500 x g) with refrigeration to 4°C
- -80°C Freezer

In order to ship specimens, you must provide:

- Dry ice (minimum 10 pounds per shipment)

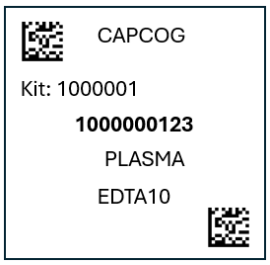
6.0 SPECIMEN LABELS

Labels must be affixed on all collection and aliquot tubes to prevent sample mix-ups and ensure chain-of-custody tracking. BioSEND provides labels for all samples being collected and returned to BioSEND. The site is responsible for providing labels for biospecimens that will be retained at the site. If labels are provided but the sample is not collected, please discard the unused labels.

6.1 Types of Labels

Each kit contains all labels required for the return of biospecimens to BioSEND.

The **Kit Labels** do not indicate a specimen type, but are affixed on BioSEND forms and on packaging materials. See shipping appendices for further instructions.

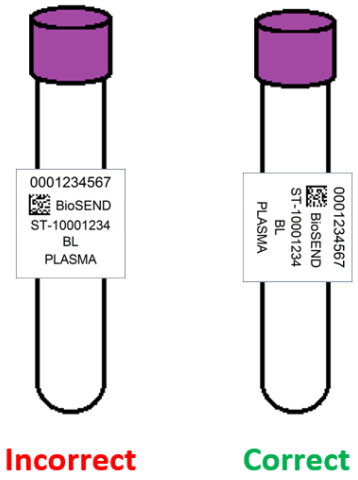


The **Specimen Labels** are placed on all sample collection and aliquot tubes. Each Specimen Label has a unique barcode that is tied to the Kit. The labels indicate the specimen type, as well as the collection tube for that specimen. For example, the label to the right would be placed on a plasma aliquot generated from a 10ml EDTA tube.

6.2 Affixing Labels

In order to ensure the label adheres properly and remains on the tube, follow these instructions:

- Place specimen labels on **ALL** collection tubes and cryovials **BEFORE** sample collection, sample processing, or freezing. This will help to ensure the label properly adheres to the tube before exposure to moisture or different temperatures.
- The blood collection tube labels contain a 2D barcode on the left hand side of the label. When turned horizontally, the barcode should be closer to the top (cap end) of the tube.
- Place label **horizontally** on the tube (wrapped around sideways if the tube is upright); see below.



- Take a moment to ensure the label is **completely affixed** to each tube. It may be helpful to roll the tube between your fingers after applying the label.

7.0 SPECIMEN COLLECTION AND PROCESSING PROCEDURES

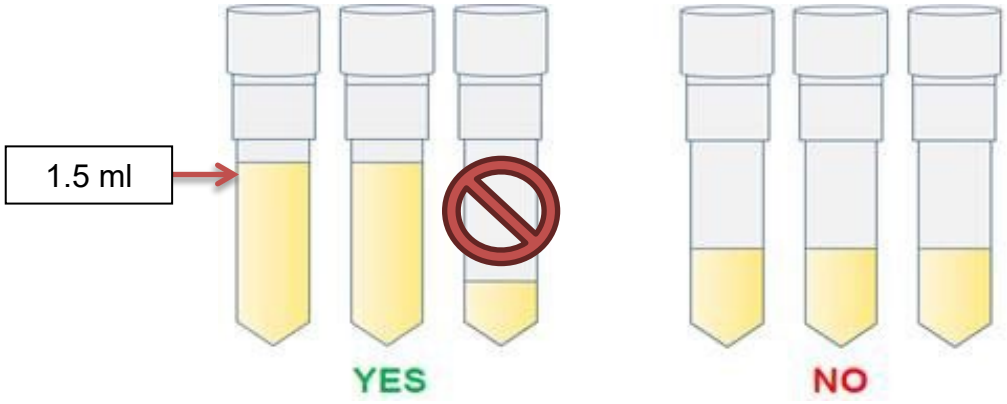
Consistency in sample collection and processing is essential for biomarker studies. All samples are drawn in the same order and then processed in a uniform fashion. **Please read the instructions before collecting any specimens. Have all your supplies and equipment out and prepared prior to drawing blood.**

7.1 Blood Collection Protocols

- Appendix B: Whole Blood Collection for Isolation of Plasma and Buffy Coat
- Appendix D: Whole Blood Collection (No Processing)
- Appendix F: Whole Blood Collection for the Isolation of Serum

7.4 Filling Aliquot Tubes (Plasma)

In order to ensure that BioSEND receives a sufficient amount of sample for processing and storage, and to avoid cracking of the tubes prior to shipment, each aliquot tube should be filled to the assigned volume (refer to detailed processing instructions for average yield per sample). Over-filled tubes may burst once placed in the freezer, resulting in a loss of that sample. Each site is supplied with sufficient collection tubes to provide the specimen volume described in the Protocol Schedules for Biospecimen Submission (see Section 4). Specimens collected in addition to those described in Section 4 are collected at the site's discretion and are not returned to BioSEND.



8.0 Packaging and Shipping Instructions

ALL study personnel responsible for shipping should be certified in biospecimen shipping. If not available at your institution, training and certification is available through the CITI training site (Course titled "Shipping and Transport of Regulated Biological Materials" at https://www.citiprogram.org/).

8.1 Specimen Collection and Processing Form

The Specimen Collection and Processing Form should be completed for all samples submitted to BioSEND. Please see Appendix I for further instructions.

8.2 Shipping Instructions

Please reference Appendix K for frozen shipping instructions and Appendix Q for generating airway bills and scheduling pick-ups.

8.3 Shipping Address

All samples are shipped to the BioSEND laboratory:

BioSEND
Indiana University School of Medicine
351 W. 10th Street. TK-217
Indianapolis, IN 46202-5188

9.0 Reconciliation and Non-Conformance

Appendix I must be completed the day that samples are collected to capture information related to sample collection and processing. This form includes information that will be used to reconcile sample collection and receipt, as well as information essential to future analyses.

BioSEND will contact the site as soon as possible when a discrepancy or issue is found with either the samples or paperwork.

Common non-conformance issues that will result in BioSEND staff contacting your site include:

- Missing samples (samples documented on the sample form that are not physically present in the shipment)
- Incorrect samples collected and shipped
- Damaged or incorrectly prepared samples
- Unlabeled or mislabeled samples
- Samples frozen and stored longer than three months at the site

10.0 APPENDICES

Appendix B: Whole Blood Collection for Isolation of Plasma and Buffy Coat

Appendix D: Whole Blood Collection (No Processing)

Appendix F: Whole Blood Collection for the Isolation of Serum

Appendix G: Cerebrospinal Fluid Processing

Appendix I: Specimen Collection and Processing Form

Appendix K: Frozen Shipping Instructions

Appendix Q: UPS ShipExec™ Thin Client Instructions

Appendix B – Whole Blood Collection for Plasma and Buffy Coat

Whole Blood Collection for Plasma and Buffy Coat using 10 ml EDTA (plastic) tubes

1. Store empty EDTA (plastic) tubes at room temperature 64°F – 77°F (18°C to 25°C) prior to use.

2. Place "PLASMA" specimen labels on 10 ml EDTA tubes and on the six purple-capped 2 ml cryovial tubes. Place "BUFFY COAT" specimen labels on the two clear-capped 2ml cryovial tubes.

3. Pre-chill the labeled cryovials on wet ice for at least 5 minutes.

4. Set centrifuge to 4°C to pre-chill before use. Time needed to pre-chill the centrifuge to 4°C will depend on your centrifuge model.

5. Using a blood collection set and a holder, collect blood into the purple top 10 ml EDTA (plastic) tubes using your institution's recommended procedure for standard venipuncture technique.

   The following techniques shall be used to prevent possible backflow:
   a. Place donor's arm in a downward position.
   b. Hold tube in a vertical position, below the donor's arm during blood collection.
   c. Release tourniquet as soon as blood starts to flow into the tube.
   d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

6. Allow at least 10 seconds for a complete blood draw to take place in each tube. Ensure that the blood has stopped flowing into the tube before removing the tube from the holder. The tube vacuum is designed to draw 10 ml of blood into the tube.

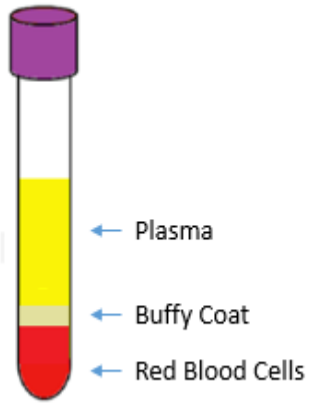
7. Immediately after blood collection, gently invert/mix (180 degree turns) the EDTA tubes 8 – 10 times. **Do not shake the tubes!**

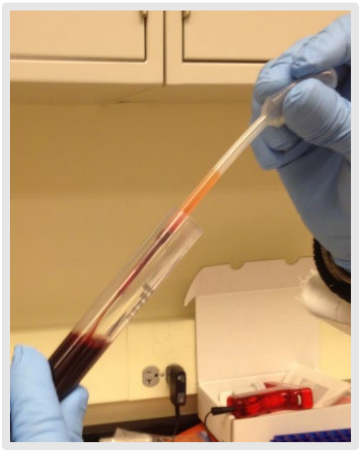
8. Within 30 minutes of blood collection, centrifuge balanced tubes for 15 minutes at 1500 RCF (x g) at 4°C. It is critical that the tubes be centrifuged at the appropriate speed and temperature to ensure proper plasma separation.

9. Remove the plasma by tilting the tube and placing the pipette tip along the lower side of the wall. **Use caution not to touch the buffy coat or packed red blood cells at the bottom of the tube so that the plasma is not contaminated** (see below). Using a disposable tipped micropipette, transfer plasma into the purple-capped cryovials. Aliquot 1.5 ml per cryovial. If you cannot obtain 6 plasma aliquots, please note "low volume draw" on the Sample Record

and Shipment Notification form (Appendix I) under “Notification of Problems”. Each 10 ml EDTA tube should yield approximately 4-5 ml of plasma.

10. After plasma has been removed from the EDTA tubes, aliquot buffy coat layer (see figure below) into clear-capped cryovial using a disposable graduated micropipette. All of the buffy coat from a single 10 ml EDTA tube will be placed into one cryovial, resulting in two buffy coat spceimens. The buffy coat aliquot is expected to have a reddish color from the red blood cells.





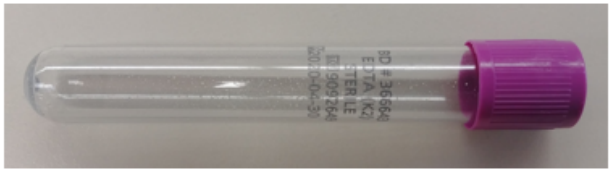
11. After plasma and buffy coat has been aliquoted into cryovials, **discard** the 10ml EDTA collection tubes. Do not send these tubes to BioSEND.

12. Complete the Sample Collection and Processing Form (Appendix I).

13. Place the labeled cryovials in the 25 slot cryobox. Place the cryobox UPRIGHT on dry ice. Transfer to **-80°C freezer as soon as possible, within 2 hours of blood draw**. Store all samples at -80°C until shipped to BioSEND on dry ice.

14. Ship the frozen plasma aliquots to BioSEND according to Appendix K – Frozen Shipping Instructions.

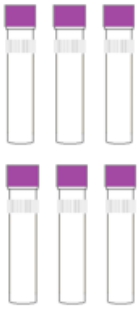
Plasma Preparation –10 ml EDTA (Purple Top) Tube



Step One

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

Step Two

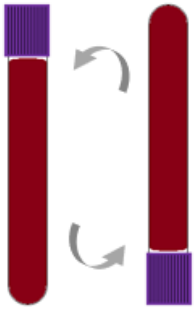


- Label 6 purple-capped cryotubes for plasma and 2 clear-capped cryotubes for buffy coat.
- Pre-chill cryotubes on wet ice for at least 5 minutes.

Step Three

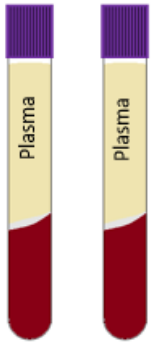
- Collect blood in EDTA tubes, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Four



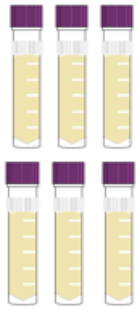
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

Step Five



- Within 30 minutes of blood draw, centrifuge sample at 4°C at 1500 x g for 15 minutes.

Step Six



- Using a clean transfer pipet, aliquot 1.5 ml plasma into each purple cryotube.

Step Seven

- Using a clean transfer pipet, collect the buffy coat (will have residual plasma and some RBCs included).
- Transfer the buffy coat from each EDTA tube into a clear-capped cryotube.
- Store plasma & buffy coat upright at -80 until shipment.

Appendix D – Whole Blood Collection (No Processing)

One 3ml Purple-Top EDTA Tube is provided by BioSEND for Whole Blood collection (to be shipped to BioSEND FROZEN; no processing required).

1. Store empty tubes and collection supplies at room temperature, 64°F - 77°F (18°C to 25°C) before use.

2. Place pre-printed specimen label (WBLD) on the **one 3ml purple top EDTA tube** prior to blood draw.

3. Using a blood collection set and a holder, collect whole blood into the tubes using your institution's recommended procedure for standard venipuncture technique.

   The following techniques shall be used to prevent possible backflow:

   a. Place donor's arm in a downward position.
   b. Hold tube in a vertical position, below the donor's arm during blood collection.
   c. Release tourniquet as soon as blood starts to flow into tube.
   d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

4. **Immediately after blood collection, gently invert/mix (180 degree turns) the EDTA tube 8-10 times. Do not shake the tube!**

5. Complete the Sample Collection and Processing Form (Appendix I).

6. Place the Purple-Top EDTA in a **WIRE** or **PLASTIC** rack. Do **NOT** use a Styrofoam rack. This will cause the Purple-Top EDTA tube to crack when frozen. Place the Purple-Top EDTA tube immediately to a **-80°C Freezer.**

7. Ship the whole blood tube to BioSEND according to **Appendix K - Frozen Shipping Instructions.**

WBLD Preparation – 1 x 3 ml K2 EDTA (Purple Top) Tube

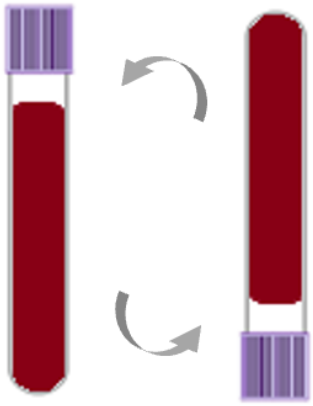
Step One

- 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◦C. Store upright and keep frozen until shipment to BioSEND.

Appendix F – Whole Blood Collection for Isolation of Serum

Whole Blood Collection for Isolation of Serum: 10 ml red-top serum (plastic) tubes and cryovials are provided by BioSEND for the collection of serum.

1. Store empty serum determination (red-top) tubes at room temperature 64°F – 77°F (18°C to 25°C) prior to use.

2. Place pre-printed specimen labels noted as "SERUM" on the serum determination red-top tubes and on six of the red-capped 2 ml cryovials prior to blood draw. Six cryovials will be shipped to BioSEND.

3. Pre-chill labeled cryovials on wet ice for at least 5 minutes or longer.

4. Set centrifuge to 4°C to pre-chill before use. Time needed to pre-chill the centrifuge to 4°C will depend on your centrifuge model.

5. Using a blood collection set and a holder, collect blood into the 10 ml red-top serum (plastic) tubes using your institution's recommended procedure for standard venipuncture technique.

   The following techniques shall be used to prevent possible backflow:
   a. Place donor's arm in a downward position
   b. Hold tube in a vertical position, below the donor's arm during blood collection
   c. Release tourniquet as soon as blood starts to flow into tube.
   d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

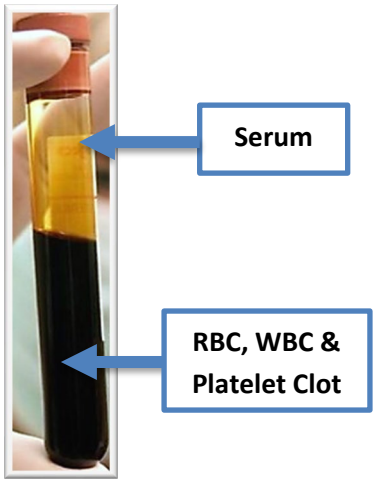
6. Allow at least 10 seconds for a complete blood draw to take place in each tube. Ensure that the blood has stopped flowing into the tube before removing the tube from the holder. The tube with its vacuum is designed to draw 10 ml of blood into the tube.

7. Immediately after blood collection, **gently** invert/mix (180 degree turns) the serum determination tube 8-10 times. **Do not shake the tubes!**

8. Allow blood to clot at room temperature for **at least 30 minutes.**

   - Within 30 to 60 minutes from blood collection, centrifuge balanced tubes for 15 minutes at 1500 RCF (x g) at 4°C. It is critical that the tubes be centrifuged at the appropriate speed and temperature to ensure proper serum separation.

9. Remove the serum by tilting the tube and placing the pipette tip along the lower side of the tube wall. Use caution to pipet only the serum layer and not the red blood cell layer. Using a disposable tipped micropipette, transfer serum into the pre-labeled cryovials. Aliquot 1.5 ml per cryovial. Send 6 x 1.5 ml aliquots to BioSEND.



10. Complete the Sample Collection and Processing Form (Appendix I). Please note any issues that may have occurred during collection and processing.

11. Place the labeled cryovials in the 25 slot cryovial box. Transfer to -80°C Freezer as soon as possible, **ensuring cryovials are frozen upright**. Store all samples upright at -80°C until shipped to BioSEND on dry ice.

12. Ship the frozen serum aliquots to BioSEND according to Appendix K – Frozen Shipping Instructions.

Serum Preparation –10 ml Serum (Red Top) Tube

Step One

- Store tubes at room temperature.
- Label collection tubes and red-capped cryovials with serum labels prior to blood draw.

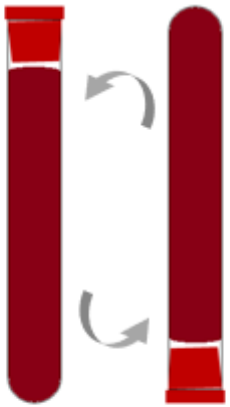
Step Two

- Pre-chill cryovials on wet ice for at least 5 minutes.

Step Three

- Collect blood in serum tubes, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Four

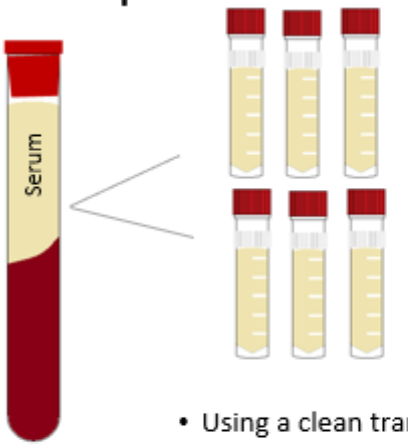


- Immediately after blood draw, gently invert tubes 8-10 times to mix samples.

Step Five

- Allow blood to clot at room temperature for 30 minutes.
- Within 60 minutes of blood draw, centrifuge sample at 1500 x g at 4°C for 15 minutes.

Step Six



- Using a clean transfer pipet, aliquot 1.5 ml serum into each red cryovial.
- Store serum aliquots upright at -80°C until shipment.

Appendix G — Cerebrospinal Fluid Collection

1. CSF may be collected on a subject via an External Ventricular Drainage (EVD). Procedures for inserting the EVD and collecting fluid from the system are governed by local Neuro ICU protocols.

2. BioSEND will provide the supplies to generate up to five 1.5ml aliquots of CSF. It understood that CSF is collected on a case-by-case basis and this is the maximum number of expected aliquots, not the minimum.

CSF Processing Guidelines:

a. Label cryovials with CSF specimen labels prior to collection and processing. **CSF cryovials should remain at room temperature; do not pre-chill these tubes.**

b. Collect CSF into 15ml conical tube.

c. Immediately after collection, gently invert the 15ml conical 3-4 times to mix the sample.

d. Within 15 minutes of collection, centrifuge the CSF samples at 2000 x g for 10 minutes at **room temperature**, 64°F – 77°F (18°C to 25°C).

e. After centrifugation, pipette (micropipette preferred) 1.5 ml of CSF directly into each of the pre-labeled cryovials to be sent to BioSEND.

f. Place the labeled cryovials in the 25-slot cryobox and place **upright** on dry ice. Transfer to **-80°C Freezer.** Store all samples at -80°C until shipped to BioSEND on dry ice.

g. Complete the Specimen Collection and Processing Form (Appendix I). Ship the CSF aliquots to BioSEND according to Appendix K – Frozen Shipping Instructions.

CSF Collection and Preparation

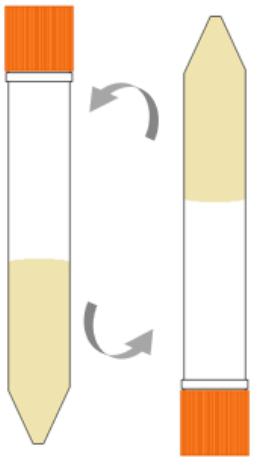
Step One

- Label five clear-capped cryovials with CSF specimen labels.
- Do NOT pre-chill cryovials for CSF.

Step Two

- Collect CSF into 15ml conical tube.

Step Three



- Immediately after collection, gently invert the 15ml conical tube 3-4 times to mix the sample.

Step Four

- Within 15 minutes of collection, centrifuge samples at room temperature at 2000 x g for 10 minutes.

Step Five

- Using a clean transfer pipette, aliquot 1.5 ml into each clear-capped cryovial, generating up to 5 aliquots for BioSEND.
- Store CSF aliquots upright at -80^{o}C until shipment to BioSEND.

Appendix I – Sample Collection and Processing Form

A Sample Collection and Processing Form must be completed for each subject-visit submitted to BioSEND. This form includes a Frozen Shipping Manifest that should be completed in advance of shipping to BioSEND also be physically included in the shipper. The form can be completed via REDCap by following the bellow link:

- **Link to Sample Collection and Processing Form:** https://redcap.link/CAPCOGTBISampleForm

Please note that there is a Save & Return option at the bottom of the survey. This may be used if, for example, you are ready to complete the Collection and Processing portion of the form, but not yet ready to complete the Frozen Shipping Manifest.

It is preferred that you complete the form online via the REDCap link above. However, a copy of the printed form is available on the following pages, should you need a back-up option. Please note that if you do not complete the form online, you will need to email a copy of the form directly to biosend@iu.edu prior to shipment.

CAPCOG-TBI Specimen Collection And Processing Form

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)	◯ Male ◯ Female ◯ Other
Visit	◯ BL ◯ 3M ◯ 6M ◯ 12M
IU Kit Number	_____

Blood Collection and Processing

Date of venipuncture blood collection

_____

Time of venipuncture blood collection

_____
(Use 24 Hour clock)

1. SERUM (red-top tubes, 10 mL)

Was blood collected and processed for SERUM?

◯ Yes
◯ No

Time of SERUM tube centrifugation

_____
(Use 24 Hour clock)

Duration of SERUM tube centrifugation

_____
(minutes)

Rate of SERUM tube centrifugation

_____
(x g)

Temperature of SERUM tube centrifugation

_____
(degrees Celsius)

Total volume of SERUM collected

_____
(mL)

Number of SERUM aliquots created for BioSEND

_____
(Each aliquot should be 1.5 mL)

Time SERUM aliquots were placed in freezer

_____
(Use 24 Hour clock.)

SERUM storage temperature

_____
(degrees Celsius)

SERUM notes

_____

2. PLASMA and BUFFY COAT (Purple-top EDTA tubes, 10 mL)

Was blood collected and processed for PLASMA EDTA?

◯ Yes
◯ No

Time of PLASMA EDTA tube centrifugation

_____
(Use 24 Hour clock)

Duration of PLASMA EDTA tube centrifugation

_____
(minutes)

Rate of PLASMA EDTA tube centrifugation

_____
(x g)

Temperature of PLASMA EDTA tube centrifugation

_____
(degrees Celsius)

Total volume of PLASMA EDTA collected

_____
(mL)

Number of PLASMA EDTA aliquots created for BioSEND

_____
(Each aliquot should be 1.5 mL)

Number of BUFFY COAT aliquots created for BioSEND

_____

Time PLASMA EDTA and BUFFY COAT were placed in freezer

_____
(Use 24 Hour clock.)

PLASMA EDTA and BUFFY COAT storage temperature

_____
(degrees Celsius)

PLASMA EDTA notes

_____

3. WHOLE BLOOD (EDTA tube, 3 mL)

Was blood collected for WBLD?

◯ Yes
◯ No

Time WBLD was placed in freezer

_____
(Use 24 Hour clock)

WBLD storage temperature

_____
(degrees Celsius)

WHOLE BLOOD notes

_____

CSF Processing

Was CSF collected?
◯ Yes
◯ No

Date of CSF collection
_____

Time of CSF collection
_____
(Use 24 Hour clock)

Time of CSF centrifugation
_____
(Use 24 Hour clock)

Duration of CSF centrifugation
_____
(minutes)

Rate of CSF centrifugation
_____
(x g)

Was CSF centrifuged at room temperature?
◯ Yes
◯ No
(degrees Celsius)

Temperature of CSF centrifugation
_____
(degrees Celsius)

Total volume of CSF collected
_____
(mL)

Number of CSF aliquots created
_____

Time CSF aliquots were placed in freezer
_____
(Use 24 Hour clock)

CSF storage temperature
_____
(degrees Celsius)

CSF notes
_____

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	◯ CAPCOG-TBI
Study Site:	◯ Mind Research Network
GUID:	_____
Visit:	◯ BL ◯ 3M ◯ 6M ◯ 12M
IU Kit Number:	_____
Date of blood collection:	_____
Date of CSF collection:	_____

SERUM

Number of SERUM aliquots shipped:	_____

PLASMA EDTA

Number of PLASMA EDTA aliquots shipped:	_____
Number of BUFFY COAT aliquots shipped:	_____

WHOLE BLOOD EDTA

Number of WHOLE BLOOD tubes shipped:	_____

CSF

Number of CSF aliquots shipped: _____

Shipping Information - Please complete.

Frozen shipments should be sent Monday-Wednesday only. Please check for holiday closures prior to shipping. Contact us at biosend@iu.edu if you are unsure whether or not it is safe to ship.

Date of shipment: _____

Did/will you use the IU UPS interface to generate the shipping label?
- ◯ Yes
- ◯ No

Which shipping service did you use?
- ◯ UPS
- ◯ FedEx
- ◯ World Courier
- ◯ Other

What is the shipment tracking number? _____

Appendix K – Frozen Shipping Instructions

IMPORTANT!

Frozen samples must be shipped Monday – Wednesday only, using Next Day Air delivery

Please be aware of holidays and inclement weather and plan your shipments accordingly. Reach out to biosend@iu.edu if you have any questions

Specimens being shipped to BioSEND are Category B UN3373 specimens and as such must be triple packaged and compliant with IATA Packing Instructions. *See the latest eEdition of the IATA regulations for complete documentation.*

Triple packaging consists of a primary receptacle(s), a secondary packaging, and a rigid outer packaging. The primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging. Secondary packaging must be secured in outer packaging with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

IATA Packing and Labeling Guidelines

- The primary receptacle (cryovials or blood collection tubes) must be leak proof and must not contain more than 1 L total.
- The secondary packaging (plastic canister or biohazard bag) must be leak proof and if multiple blood tubes are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent direct contact with adjacent blood tubes.
- Absorbent material must be placed between the primary receptacle (cryovials or blood collection tubes) and the secondary packaging. The absorbent material must be of sufficient quantity to absorb the entire contents of the specimens being shipped. Examples of absorbent material are paper towels, absorbent pads, cotton balls, or cellulose wadding.
- A shipping manifest listing the specimens being shipped must be included between the secondary and outer packaging.
- The outer shipping container must display the following labels:
  - ✓ Sender's name and address
  - ✓ Recipient's name and address
  - ✓ Responsible persons (shipper and recipient)
  - ✓ The words "Biological Substance, Category B"
  - ✓ UN3373
  - ✓ Class 9 label including UN 1845, and net weight of dry ice contained

BioSEND Packaging and Shipment Instructions – Frozen Shipments

1. Generate airway bill and schedule courier pick-up, as needed. Airway bills should be generated day of shipment to avoid errors in billing.

    - For instructions on generating airway bills and scheduling using the UPS ShipExec™ Thin Client system, see Appendix Q.

2. Record the tracking number onto the Shipping Manifest portion of the Sample Collection and Processing Form (see Appendix I for details).

3. Print a copy of the Sample Collection and Processing form.

4. Place all frozen labeled cryovials in the cryobox. Only include specimens from one subject in each cryobox.

5. Place the cryobox in a plastic biohazard bag (do NOT remove the absorbent material found in the bag), and seal the biohazard bag according to the instructions on the bag. Affix a Kit Label to the outside of the biohazard bag.

6. Place approximately 2-3 inches of dry ice in the bottom of the Styrofoam® shipping container.

7. Place labeled whole blood tube in provided bubble sleeve and seal.

8. Place the whole blood tube in a plastic biohazard bag (do NOT remove the absorbent material found in the bag), and seal the biohazard bag according to the instructions on the bag. Affix a Kit Label to the outside of the biohazard bag.

9. Place the biohazard bag containing the cryobox into the provided Styrofoam® shipping container on top of the dry ice. Please ensure that the cryobox is placed so that the cryovials are upright in the shipping container (as pictured).

10. Fully cover the cryobox with approximately 2 inches of dry ice. Do not include more than 2 subjects' worth of samples in a single shipper (ie, do not include more than four total biohazard bags).

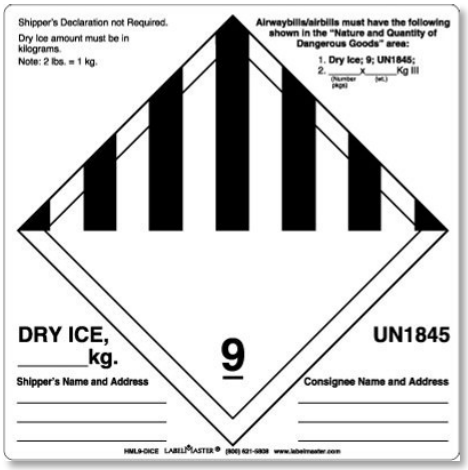
11. If including additional biohazard bags in package, include a layer of dry ice (approximately 2 inches) between each biohazard bag.

12. The inner Styrofoam® shipping container must contain at least 10 lbs (or 4.5 kg) of dry ice. The dry ice should entirely fill the inner box to ensure the frozen state of the specimens.

13. Replace the lid on the Styrofoam® container. Place the completed Sample Collection and Processing form in the package on top of the Styrofoam® lid for each patient specimen, and close and seal the outer cardboard shipping carton with packing tape.

14. Print a copy of your UPS® airway bill generated through the UPS ShipExec™ Thin Client system (see Appendix Q). Place airway bill into the provided airway bill envelope and affix envelope to package.

15. Complete the Class 9 UN 1845 Dry Ice Label with the following information:
    - Your name and return address
    - Net weight of dry ice in kg (this amount must match the amount recorded on the airway bill)
    - Consignee name and address:



BioSEND
IU School of Medicine
351 W. 10th Street
TK-217
Indianapolis, IN 46202

16. Apply all provided warning labels (UN3373, Dry Ice Label and Fragile Label), taking care not to overlap labels with each other or with airway bill.

17. Hold packaged samples in -80°C freezer until time of courier pick-up/drop-off.

18. Specimens should be sent to the address below. Frozen shipments should be sent Monday through Wednesday only to avoid shipping delays on Thursday or Friday.

BioSEND
IU School of Medicine
351 W. 10th Street
TK-217
Indianapolis, IN 46202

19. Notify BioSEND of shipment by completing and submitting the Sample Collection and Processing Form with Shipping Manifest in REDCap in advance of shipment. "Submitting" the form will automatically notify BioSEND. If you are having difficulties submitting via REDCap, please notify BioSEND of shipment directly at biosend@iu.edu

20. Use courier tracking system to ensure the delivery occurs as scheduled and is received by BioSEND.

In addition to tracking and reconciliation of samples, the condition and amount of samples received are tracked by BioSEND for each sample type. Investigators and clinical coordinators for each project are responsible for ensuring that the requested amounts of each fluid are collected to the best of their ability and that samples are packed with sufficient amounts of dry ice to avoid thawing in the shipment process.

Appendix Q - UPS ShipExec™ Thin Client Instructions

***** The shipment label in ShipExec should not be created until the day of shipment *****

1) Log in to the UPS ShipExec™ Thin Client website: https://kits.iu.edu/UPS or https://kits.iu.edu/ups.
    a. To request an account, complete the following survey: https://redcap.uits.iu.edu/surveys/?s=88TTWY3KAF
2) Find the "Shipping" dropdown menu in the top left corner of the screen and click on "Shipping and Rating".
3) Once the Indiana University page loads, look for the "Study Group" dropdown menu under "Shipment Information" on the right side of the screen. Choose your study from the dropdown menu.
4) After selecting your study, click on the magnifying glass icon on the left side of the screen under "Ship From".
5) An address book and filters will populate the screen. On the right side of the screen, a list of all the site addresses within the study you selected should populate.
    a. Filter the list down more by looking to the left side of the screen and searching for their address by filling in the "Company", "Contact", or "Address 1" fields. Click on the Search button when ready.
    b. Once you have found your site address, click on the "Select" button to the left of the address.
6) Make sure your address populated in the fields under "Ship From" on the main page.
    a. If you accidentally selected the wrong address, click on the "Reset" button on the bottom right of the screen. After the page reloads and clears the information, select your study again from the "Study Group" menu and click on the magnifying glass icon again to search for your correct address.
    b. To change the address for your site and study group, please complete the following survey: https://redcap.uits.iu.edu/surveys/?s=88TTWY3KAF
7) Enter the total weight of your package in the "Weight" field on the right side of screen under the name of your study.
    a. Leave the "Dry Ice Weight" field empty or enter "0" if shipping an ambient sample.
8) Enter the weight of the dry ice for frozen shipments in the "Dry Ice Weight" field.
    a. The "Dry Ice Weight" field can *never* be higher than the "Weight" field.
    b. **(Steps 9-10 can be skipped if you do not need to schedule a pickup)**
9) After entering the weights, click on the blue "Pickup Request" button.
10) When the Create Pickup Request box pops up, enter information into all the fields provided.
    a. Enter the "Earliest Time Ready" and "Latest Time Ready" in 24-hour format.
        i. Scheulde pickup at a minimum 1 hour *before* the "Earliest Time Ready"
    b. Choose a name and phone number that is the best contact if the UPS driver has question related to picking up your package
    c. Entering the "Room Number" and "Floor" will help the UPS driver locate your package
        i. The "Floor" field only allows numerical characters while the "Room Number" field is free text.
    d. Click "Save" when done.
11) Once you are certain that all the correct information has been entered, click the "Ship" button in the bottom right corner of the screen.
12) If no red error messages pop up at the top of your screen after clicking on "Ship", then you should have 2 downloaded PDF files: Shipment Receipt & UPS Package Label

a. Shipment Receipt will list a “Pickup No.” that references your specific package if there is ever an issue with UPS picking up your package

13) Print out the UPS airway bill to any printer at your location.
    a. Fold the UPS airway bill and slide it inside the plastic UPS sleeve.
    b. 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.
14) Place your package in the spot designated in your pickup request, or wherever your daily UPS pickups occur.
15) If you need to reprint your airway bill or void your shipment, click on “History” at the top of the main screen.
    a. If your shipment does not automatically pop up, enter the date of shipment and then click “Search”.
    b. To reprint your airway bill, click on the printer icon to the far left under “Action”
    c. To void your shipment, click on the “X” icon to the far left under “Action”
        i. If you created an airway bill that you no longer need, you must void the shipment to ensure your study will not be charged for the shipment.