An intermediate-Size Expanded Access Protocol for Amyotrophic Lateral Sclerosis with Pridopidine (Pridopidine EAP2) Study Manual of Procedures

Update: Version 09.2025

September 2025

Section	Change
Document Footer	Updated to “Version (September 2025)”
Appendix I	Updated specimen processing form link

BioSEND

Biospecimen Exchange for Neurological Disorders

National Institute of Neurological Disorders and Stroke Biorepository:

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

Biospecimen Collection, Processing, and Shipment Manual for

An Intermediate-Size Expanded Access Protocol for Amyotrophic Lateral Sclerosis with Pridopidine (Pridopidine EAP2) Study

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:

- Plasma
- Buffy Coat

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
RBC	Red Blood Cells
RCF	Relative Centrifugal Force
RPM	Revolutions Per Minute
EAP	Expanded Access Program

3.0 BioSEND Information

3.1 BioSEND Contacts

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General BioSEND Contact Information
Phone: 317-278-6158
Email: biosend@iu.edu
Website: www.BioSEND.org

Sample Shipment Mailing Address
BioSEND
Indiana University School of Medicine
351 W. 10th Street, TK-217
Indianapolis, IN 46202-4118

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.

For packaging and shipment details, please refer to Appendix K (Frozen Shipping Instructions)

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 reports 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.
- **Weekend/holiday deliveries will not be accepted.**

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 19th	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 surrounding the week of Thanksgiving and the last two weeks of the year. BioSEND will post notice of these closures on biosend.org and send email reminders in advance. Please contact biosend@iu.edu if you are unsure whether the day you plan to ship is permissible.

Please see https://biosend.org/holiday-closures for additional information.

4.0 Protocol Schedule for Biospecimen Submission to BioSEND – PRIDO

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.

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

Collection Tube	Drawn At	Specimen Type	Aliquot Volume	Total Number of Aliquots/Tubes to be sent to BioSEND
2 EDTA (plastic) Blood Collection Tube, 10ml	BL, Week 12, Week 52 and Week 104/ ET	Plasma	1.5ml	6
	BL, Week 12, Week 52 and Week 104/ ET	Buffy Coat*	~500-750ul	2

Note: All samples in this protocol will ship frozen to BioSEND

*If participant does not consent to DNA collection and banking, the buffy coat specimens should not be collected from the EDTA tubes; only plasma will be collected for these participants. This will not impact the blood volume to draw (20mls total) and the number of EDTA tubes to collect (2 tubes), as this quantity of blood is required to produce sufficient plasma. Please see Appendix B for details.

5.0 Specimen Collection Kits and Supplies

BioSEND will provide a sufficient number of labels and supplies only for those specimens that are to be shipped back to the BioSEND repository. Any tubes that will remain at the collection site or shipped to other repositories should be labeled accordingly.

5.1 Ordering Kits and Supplies

Study sites are responsible for ordering study kits. We advise sites to proactively confirm kits are on hand ahead of study visits.

Kits and individual items can be ordered as required through the BioSEND kit request module:

- **PRIDO**: http://kits.iu.edu/biosend/prido

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

5.2 Kit Contents

Collection kits contain the following (for each subject) and provide the necessary supplies to collect samples from a given subject visit. 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.*

Shipping kits contain the supplies to ship up to two subject visits' worth of samples (that is, two cryoboxes may be shipped in a single shipper).

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

Frozen Shipping Kit	
Supply	**Amount**
Plastic Biohazard bag with absorbent sheet	2
UPS Airbill Sleeve	1
Shipping box/Styrofoam container	1
UN3373 Category B Label	1
Fragile label	1
Dry ice label	1

5.3 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, 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)

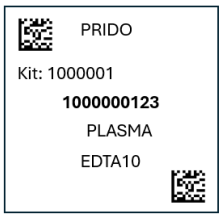
6.0 Specimen Labels

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 specific packing materials. See Appendix K for further instructions.

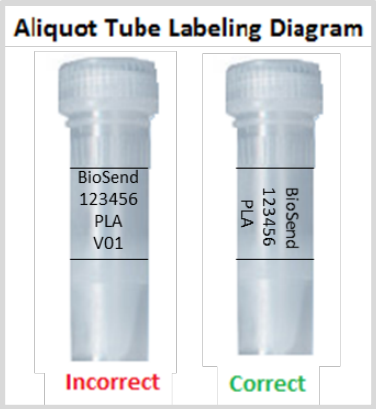


The **Specimen Labels** are placed on all blood collection and aliquot tubes. Each Specimen Label has a unique barcode that is tied to the Kit. The labels indicate the specimen type, as well as the collection tube for that specimen. For example, the label to the right would be placed on a plasma aliquot 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 blood specimen labels on **ALL** collection and aliquot tubes **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 specimen 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) and **just below the ridges** of the aliquot tubes (see attached labeling diagram).



- 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.**

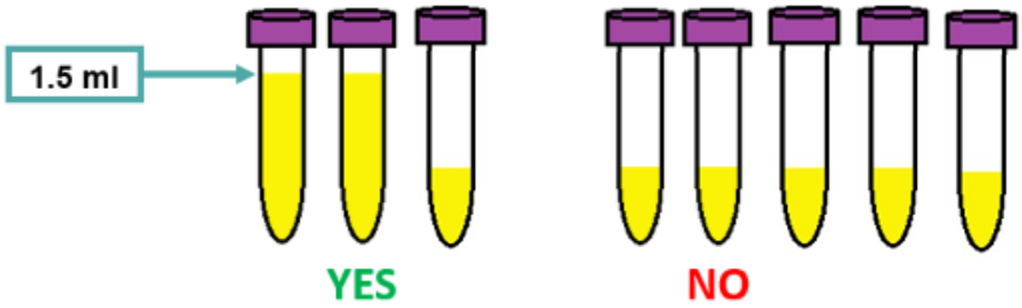
7.1 Blood Collection Protocols

1. Whole Blood Collection for Plasma and Buffy Coat **(Appendix B)**

7.2 Filling Aliquot Tubes

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.

Please generate as many standard-sized (1.5ml) plasma aliquots as possible. Less standard sized aliquots (with potentially one residual aliquot) is preferable to more aliquots with non-standard volume. Buffy Coats will generally be between 0.5ml-1ml in volume.



To assist in the preparation and aliquoting of samples, colored caps are used for the aliquot tubes. The chart below summarizes the association between cap color and type of aliquot.

Cap Color	Specimen Type
Purple	Plasma
Clear	Buffy Coat

8.0 Packaging and Shipping Instructions

ALL study personnel responsible for shipping should be certified in biospecimen shipping. If not available at your University, 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 Sample 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

All samples are shipped frozen. 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 46202-4118

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 Plasma and Buffy Coat

Appendix I: Sample 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.

    a. Note: If participant does not consent to collection and storage of DNA, do not collect the buffy coat specimens. Plasma samples should still be collected for these participants. The quantity of blood drawn and the collection tubes used will not change, as this quantity of blood is still required to produce sufficient plasma.

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. he 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!**

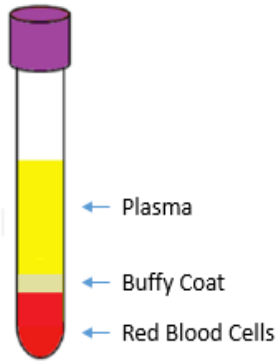
8. Within 30 minutes of blood collection, centrifuge balanced tubes for 15 minutes at 1500 RCF (x g) at 4°C. It is critical that the tubes be centrifuged at the appropriate speed and temperature to ensure proper plasma separation.

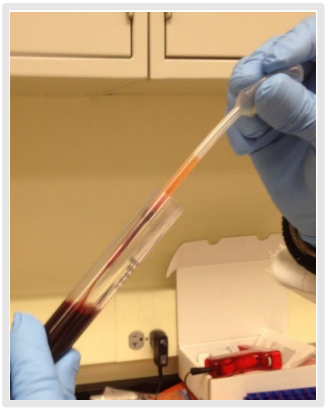
9. Remove the plasma by tilting the tube and placing the pipette tip along the lower side of the wall. **Use caution not to touch the buffy coat or packed red blood cells at the bottom of the tube so that the plasma is not contaminated** (see below). Using a disposable tipped micropipette, transfer plasma 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 specimens. The buffy coat aliquot is expected to have a reddish color from the red blood cells.

    Note: If participant does not consent to collection and storage of DNA, this step should be skipped.



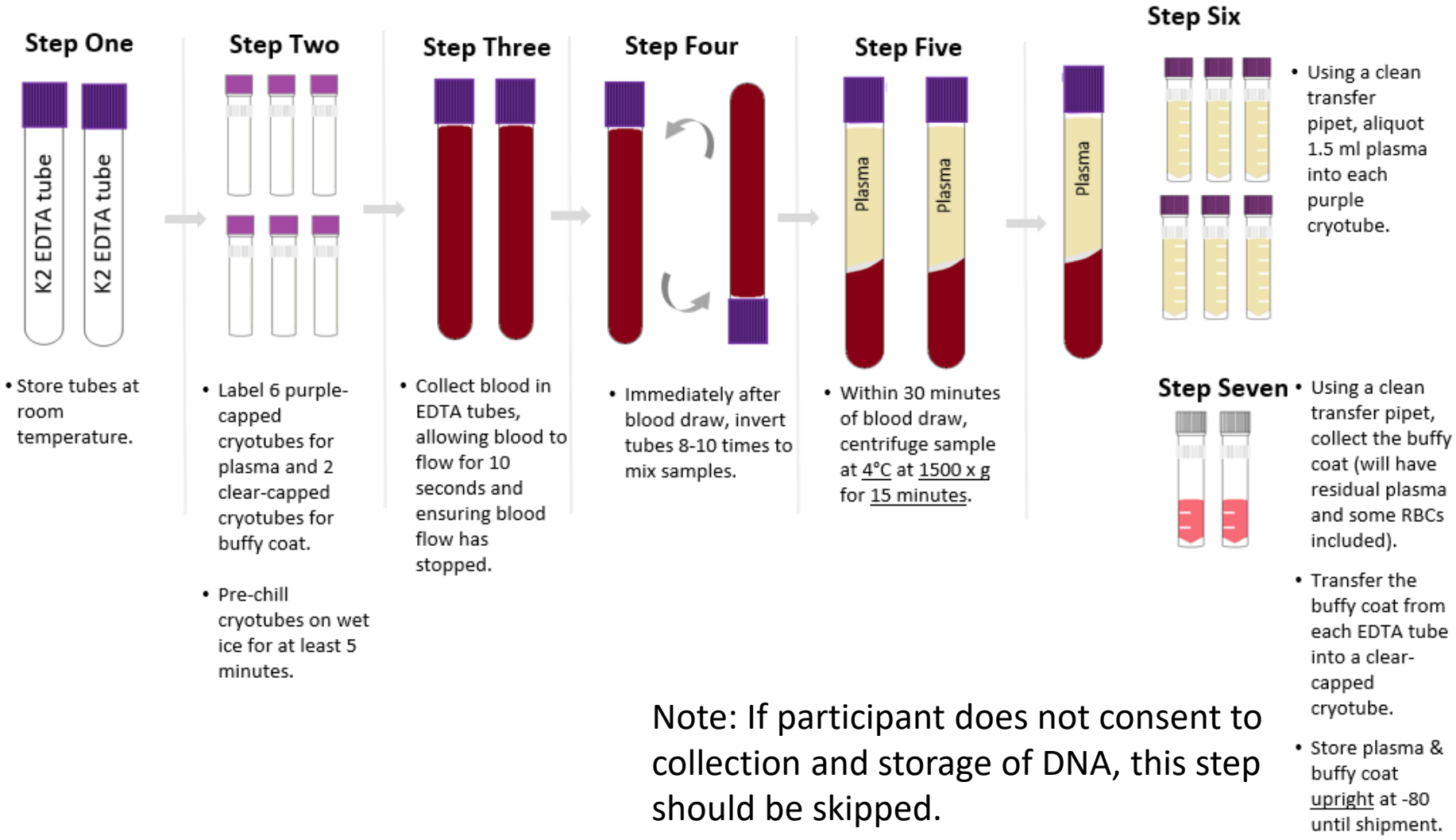


11. After plasma and buffy coat has been aliquoted into cryovials, **discard** the 10ml EDTA collection tubes. Do not send these tubes to BioSEND.

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.



Note: If participant does not consent to collection and storage of DNA, this step should be skipped.

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. A copy of this form should also be included in the shipper. A copy of the form will be emailed to you upon completion. BioSEND will receive an automated notification of your shipment went you click the "Submit" button on the Frozen Shipping Manifest; no additional notification is required. If you are unable to submit the Frozen Shipping Manifest via REDCap, please notify BioSEND at biosend@iu.edu instead.

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

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.

Clicking "Submit" at the end of the Frozen Shipping Manifest portion of the form will send an automatic notification to BioSEND of your shipment.

If unable to access REDCap during collection and processing, the form on the following may be printed and completed by hand. If your site has a separate processing lab from your coordinating team, you can share this form with them so that they may capture and return this data to you. This form is provided to aid with processing data collection. Data should still be entered into the REDCap (http://kits.iu.edu/biosend/PRIDOSampleForm) when site staff is able to do so.

PRIDO Specimen Collection And Processing Form

Protocol: An Intermediate-Size Expanded Access Protocol for Amyotrophic Lateral Sclerosis with Pridopidine (Pridopidine EAP2)

Please complete the Specimen Collection and Processing Form, below.

Study Site

- ◯ 701 - Massachusetts General Hospital, Sean M. Healey & AMG Center for ALS Research
- ◯ 704 - California Pacific Medical Center - Forbes Norris MDA/ALS Research Center
- ◯ 708 - Columbia University Irving Medical Center
- ◯ 710 - Duke University
- ◯ 713 - Johns Hopkins University
- ◯ 714 - Lahey Hospital and Medical Center
- ◯ 716 - Medical College of Wisconsin
- ◯ 718 - Mayo Clinic Jacksonville
- ◯ 721 - SUNY Upstate Medical University
- ◯ 724 - The University of Chicago
- ◯ 726 - University of Kansas Medical Center
- ◯ 731 - University of Wisconsin School of Medicine and Public Health
- ◯ 741 - Washington University School of Medicine in St. Louis
- ◯ 747 - Stony Brook University
- ◯ 753 - Georgetown University Medical Center
- ◯ 754 - University of California San Diego (UCSD)
- ◯ 763 - Providence ALS Center
- ◯ 769 - Texas Neurology
- ◯ 777 - University of California, Irvine
- ◯ 779 - University of Colorado Anschutz Medical Campus
- ◯ 781 - University of Iowa Hospitals and Clinics
- ◯ 783 - University of Massachusetts Chan Medical School
- ◯ 790 - University of Pennsylvania
- ◯ 792 - University of Southern California
- ◯ 789 - University of North Carolina
- ◯ 810 - Mayo Clinic Rochester
- ◯ 812 - Northwestern University Feinberg School of Medicine
- ◯ 816 - University of Puerto Rico Medical Sciences Campus, CHALS-CCT
- ◯ 818 - Cedars-Sinai Medical Center
- ◯ 833 - Hospital for Special Care
- ◯ 842 - University of South Florida
- ◯ 844 - Barrow Neurological Institute
- ◯ 859 - Ohio Health
- ◯ 892 - Virginia Commonwealth University
- ◯ 901 - Nerve and Muscle Center of Texas
- ◯ 903 - Las Vegas Clinic
- ◯ 907 - Temple University Lewis Katz School of Medicine
- ◯ 916 - Thomas Jefferson University
- ◯ 918 - Austin Neuromuscular Center
- ◯ 929 - Saint Alphonsus Regional Medical Center
- ◯ 946 - University of Minnesota
- ◯ 949 - Hackensack University Medical Center
- ◯ 951 - Essentia Health
- ◯ 952 - Nova Southeastern University
- ◯ 953 - Rush University
- ◯ 959 - The University of Alabama at Birmingham (UAB Department of Neurology)
- ◯ 970 - UT Southwestern Medical Center
- ◯ 973 - Charleston Area Medical Center

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.	_____
Clinical ID:	_____
Sex (used for DNA quality control)	◯ Male ◯ Female ◯ Other
Did participant consent to the collection and storage of DNA?	◯ Yes ◯ No
Visit	◯ Baseline ◯ 12 Week ◯ 52 Week ◯ 104 Week/ET
Kit Number	_____

Blood Collection and Processing

Name of Sample Processor

_____
(First and last name of site staff who processed the samples)

Date of venipuncture blood collection

_____

Time of venipuncture blood collection

_____
(Use 24 Hour clock)

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

Was blood collected and processed for PLASMA EDTA?

◯ Yes
◯ No

Blood volume collected for PLASMA EDTA

_____
(mL)

Reason volume was less than standard

◯ Difficult stick/poor veins
◯ Patient dehydrated
◯ Bad tube vacuum
◯ Other

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)

Other reason:

_____

Number of PLASMA EDTA aliquots created

_____
(Each aliquot should be 1.5 mL)

Number of BUFFY COAT aliquots created

_____

Date PLASMA EDTA and BUFFY COAT were placed in freezer

_____

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

_____

PRIDO 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

_____

Study Site:

_____

Clinical ID:

_____

Visit:

_____

IU Kit Number:

_____

Date of blood collection:

_____

PLASMA EDTA

Number of PLASMA EDTA aliquots shipped:

_____

Number of BUFFY COAT 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.

Name of Shipper

_____

(First and last name of site staff preparing this shipment)

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.

   - 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 Sample Collection and Processing form (Appendix I).

3. Print a copy of the Shipping Manifest portion of the Appendix I.

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

5. Place the cryobox in a clear 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 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).

8. Fully cover the cryobox with approximately 2 inches of dry ice.

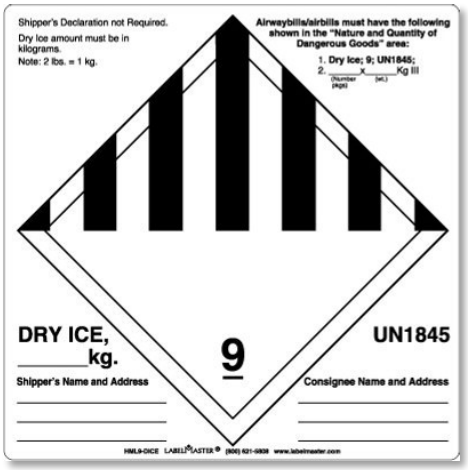
9. If including additional biohazard bags in package, include a layer of dry ice (approximately 2 inches) between each biohazard bag. Do not include more than two cryoboxes in a single shipper.

10. The inner Styrofoam® shipping container must contain approximately 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.

11. Replace the lid on the Styrofoam® container. Place the completed Shipping Manigest 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.

12. 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.

13. 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

- Do not cover any part of this label with other stickers, including pre-printed address labels.

IMPORTANT!
Complete the required fields on your airway bill and Class 9 Dry Ice labels, or courier may reject or return your package.

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. **Complete the Shipping Manifest portion of Sample Collection and Processing Form. Submitting this form via REDCap will automatically notify BioSEND of shipment. If unable to use the REDCap version of the form, complete the PDF version in the MOP and notify BioSEND by email (biosend@iu.edu), with an attachment of the form Do not ship until you've contacted and notified BioSEND staff about the shipment in advance.**

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.