

## **The Late Effects of TBI (LETBI) Study Manual of Procedures Manual of Procedures - IU Site**

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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.



Biospecimen Exchange for Neurological Disorders

National Institute of Neurological Disorders and Stroke  
Biorepository:

**BioSpecimen Exchange for Neurological Disorders, BioSEND**

**Biospecimen Collection, Processing, and Shipment Manual for**

The **Late Effects of TBI (LETBI)** – Indiana University Site

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## **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.

## **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

## **3.0 BioSEND INFORMATION**

### **3.1 BioSEND Contacts**

**Tatiana Foroud, PhD, Principal Investigator**

**Claire Wegel, Project Manager**

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

#### **General BioSEND Contact Information**

317-278-6158

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

Website: [www.BioSEND.org](http://www.BioSEND.org)

#### **BioSEND Address**

BioSEND

Indiana University School of Medicine 351

W. 10<sup>th</sup> 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.

### 3.3 Holiday Schedules

- BioSEND will be closed on the following days (ie, unable to accept samples or to provide kits).

### 3.4 Holiday Observations

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
July 19 <sup>th</sup>	Juneteenth
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 Day

Please note that BioSEND is open only to essential operations the last two weeks of the year. BioSEND will send advance notification of this closure to all study staff and will post a notification on biosend.org

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

#### 4.0 Protocol Schedule for Biospecimen Submission to BioSEND- LETBI

Visit	V0	V1	V2
EDTA Tube (10ml, plastic)	2	2	2

## 5.0 SPECIMEN COLLECTION KITS, SHIPPING KITS AND SUPPLIES

Research specimen collection kits will be provided by BioSEND. BioSEND will provide supplies only for specimens that are to be sent back to the BioSEND repository.

### 5.1 Kit Supply to Study Sites

Each individual site will be responsible for ordering kits from BioSEND. We advise sites to proactively confirm kits are on hand ahead of study visits.

Within the kit request module, there is a drop down menu to request kits based on site institution. Kits and individual items can be ordered as required through the kit request module.

The link to the kit request module is shown below:

- LETBI: <http://kits.iu.edu/biosend/letbi>

Please allow **TWO weeks** for kit orders to be processed and ready for pick-up.

Kits may be picked up from BioSEND at the following address:

IU Innovation Center (TK)  
351 W. 10<sup>th</sup> Street.  
Indianapolis, IN 46202-5188



## 5.2 Specimen Collection Kit Contents

Kits provide the necessary supplies to collect samples from a given subject. 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.

### **Baseline/Longitudinal Collection Kit – IU Site**

2 – 10ml EDTA tubes, plastic
1 – Biohazard bag with absorbent sheet
1 – Specimen/Case label set

### 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
- Test tube rack
- Sharps bin and lid

## 6.0 SPECIMEN LABELS

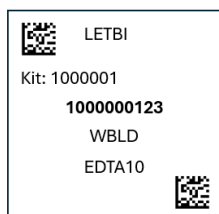
Labels must be affixed on all collection and aliquot tubes to prevent sample mix-ups and ensure chain-of-custody tracking. BioSEND provides labels for all samples being collected and returned to BioSEND. The site is responsible for providing labels for any specimens that will be retained at the site.

### 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.



The **Specimen Labels** are placed on all blood collection tubes.

## 6.2 Affixing Labels

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

- Place blood collection labels on **ALL** collection 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.
- Place label **horizontally** on the tube (wrapped around sideways if the tube is upright); see below.



**Incorrect**



**Correct**

## **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 Collection Tubes for BioSEND**

1. EDTA (purple top, 10ml) x 2 for plasma and buffy coat

### **7.2 Blood Collection Protocols**

1. EDTA (purple top) blood collection for plasma and buffy Coat **(Appendix B)**

## 8.0 Packaging and Tubing Instructions

After collection, tubes should be packaged in the provided biohazard bag an absorbent sheet. Do not include samples from more than one subject or visit in a single biohazard bag. **Tubes should be sent to the processing lab within two hours of collection.**

### 8.1 BioSEND Sample Form

All samples sent to BioSEND must include the BioSEND Sample Form. Please include a hard copy with the samples and email a notification to [BioSEND@iu.edu](mailto:BioSEND@iu.edu) and [jugbstat@iu.edu](mailto:jugbstat@iu.edu). The sample form should be emailed prior to tubing the samples. **Please include "Noyes" in the subject line.**

### 8.2 Tube Station

All samples should be sent to Tube Station 260 (Noyes Pavilion). Sample may be tubed Monday-Friday from 8:30AM-4PM only. Samples cannot be hand delivered to this location; samples must go through the tube station. Utilization of a courier service is also acceptable.

## **9.0 Data Queries and Reconciliation**

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.

The LETBI Study team will be collaborating with BioSEND to reconcile information captured in the database compared to samples received and logged at BioSEND. Information that appears incorrect in the Clinical database will be queried through the standard system. Additional discrepancies that may be unrelated to data entry will be resolved with the Principal Investigator in a separate follow up communication. If applicable, a non-conformance report will be provided to sites.

Data discrepancies with samples shipped and received at BioSEND may result from:

- Missing samples
- Incorrect samples collected and shipped
- Damaged or incorrectly prepared samples
- Unlabeled or mislabeled samples

## **10.0 APPENDICES**

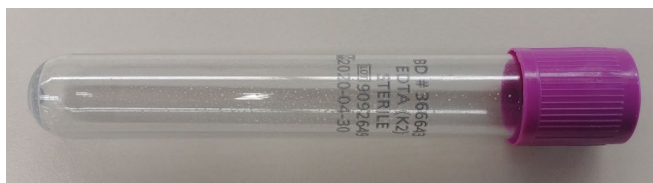
Appendix B: Whole Blood Collection for Plasma and Buffy Coat

Appendix I: BioSEND Sample Form



## Appendix B – Whole Blood Collection for Isolation of Plasma

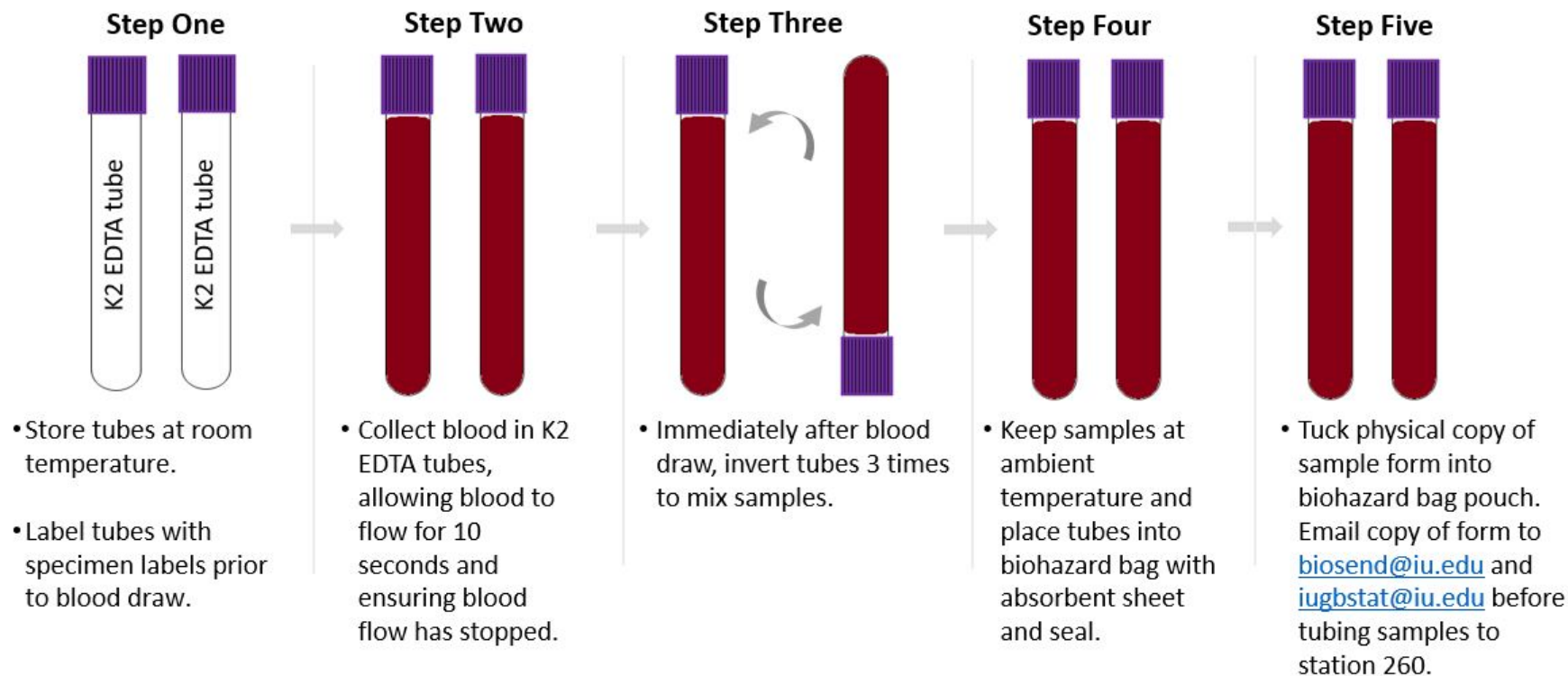
10 ml Purple-Top EDTA tubes (plastic) are provided by BioSEND for the collection of plasma and buffy coat.



1. Store empty purple-top EDTA tubes at room temperature 64°F – 77°F (18°C to 25°C) prior to use.
2. Place provided specimen labels on 10 ml purple-top EDTA tubes. Please note that BioSEND only provides labels and supplies for samples that are to be returned to BioSEND.
3. Using a blood collection set and a holder, collect blood into the purple top 10 ml EDTA 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.
4. 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.
  5. Immediately after blood collection, gently invert/mix (180 degree turns) the purple-top EDTA tubes 3 times. **Do not shake the tubes!**
  6. Place tubes into provided biohazard bag with absorbent sheet and seal. Please a physical copy of the BioSEND Sample Form (Appendix I) in the biohazard bag pouch.
  7. Notify BioSEND and the IUGB lab of incoming samples **prior to tubing**. Notification should be in the form of the completed BioSEND Sample Form emailed to [biosend@iu.edu](mailto:biosend@iu.edu) and [iugbstat@iu.edu](mailto:iugbstat@iu.edu). **Please include "Noyes" in the subject line.**
  8. Tube samples to station #260 (Noyes Pavilion). Samples may be tubed Monday-Friday from 8:30AM-4PM only. Samples must be delivered via the tube station; hand deliveries to the Noyes Pavilion lab are not possible. **Samples should be delivered to the lab within 2 hours of collection.**



## **BioSEND Sample Form**

Study:

Site Name:

Principal Investigator:

Coordinator:

Telephone:

Email:

**Please list only ONE subject per Sample Record Summary and Shipment Notification Form**

GUID:

Kit Number

Sex:

Visit Type:

**Instructions: Samples should be tubed to station #260 (Noyes Pavilion). Samples should be sent Monday-Friday only, between 8:30 AM - 4:00 PM.** This form must be completed for shipment of all research samples. Please email a copy to at biosend@iu.edu and iugbstat@iu.edu prior to tubing samples. A physical copy should also be included with the samples.

Date of Collection	Time of Collection	Sample Type	Number of Tubes Sent
		Whole Blood for Plasma and Buffy Coat	

**Comments:**