# BioSpecimen Exchange for Neurological Disorders (BioSEND)

MBPS Training Webinar



## **BioSEND Training Webinar Overview**

- 1. Study Reminders
- 2. Site Equipment
- 3. Biospecimen Collection Protocol
- 4. Study Visit Protocol
- 5. Kits & Samples
  - Requesting Kits
  - Labels
  - Sample Collection & Processing
  - Sample Shipment
- BioSEND Website
- 6. Contact Information



## **Study Reminders**

#### Please remember...

- Biospecimens are limited, valuable resources.
- Standardization and quality are key!
- Reference the BioSEND Manual of Procedures as needed.
- Do not replace or supplement any kit components without first receiving approval from BioSEND.



# Site Equipment

#### The following items are to be supplied by the site:

- Personal protective equipment
- Alcohol prep pads
- Butterfly needles and hubs
- Tourniquet
- Gauze pads
- Bandages
- Sharps bin and lid

- Microcentrifuge tube rack
- Test tube rack
- Crushed ice
- 4°C Centrifuge
- -80°C Freezer
- Dry ice



# MBPS Biospecimen Collection Protocol

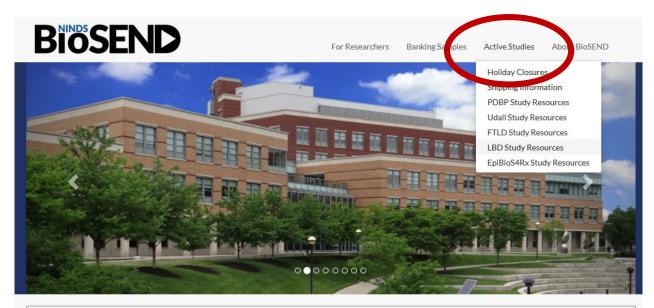
	BL	12M
DNA (6ml)	X	
Whole Blood (6ml)	X	X
Plasma (6 x 1ml)	X	X
Buffy Coat (2 x 1ml)	X	X
Serum (6 x 1ml)	X	X
RNA (2 x 2.5ml)	X	X
CSF (10 x 1ml)	X	X



# Requesting Kits



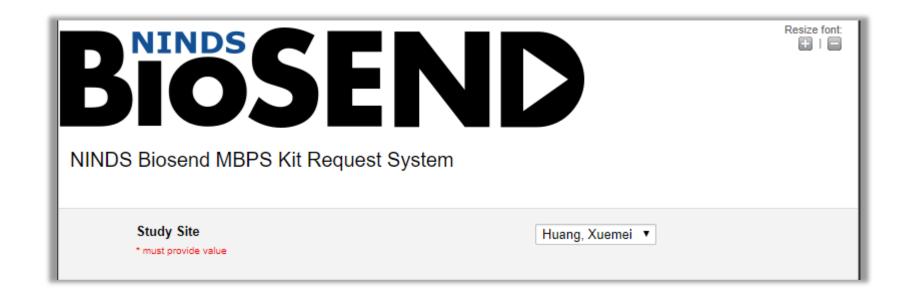
#### NINDS BioSEND Website







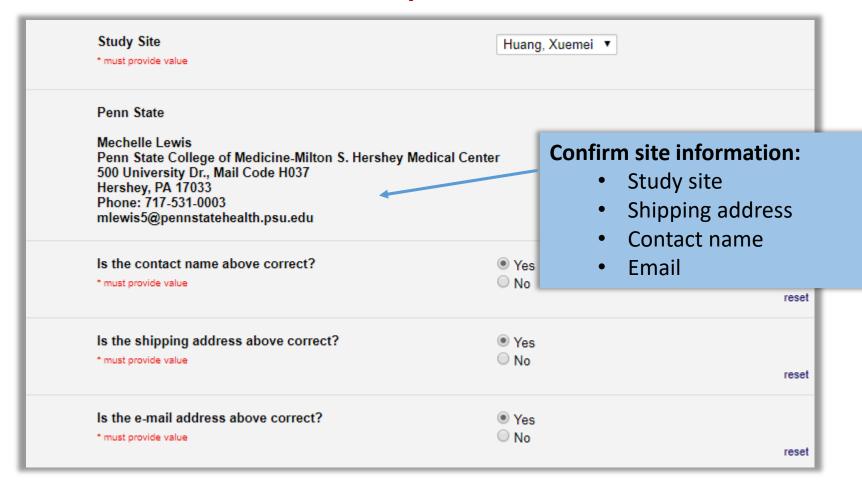
## BioSEND Kit Request Module



- http://kits.iu.edu/biosend/mbps
- Choose your site PI from the drop-down list.

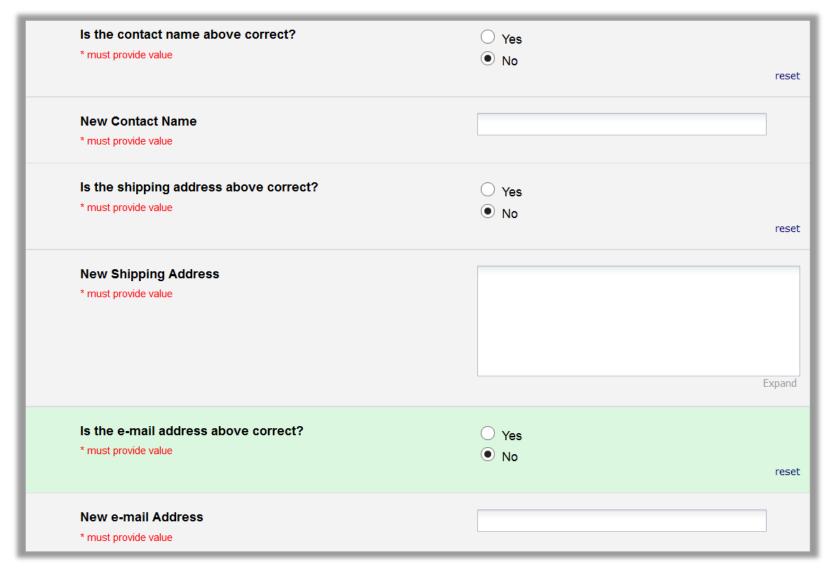


# **BioSEND Kit Request Module**





# BioSEND Kit Request Module





- Is the information correct?
- Provide the correct information if needed

## BioSEND Kit Request Module: Kit Type

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

Baseline Visit Kit

Annual Visit Kit

Supplemental Kit

Extra Supplies

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



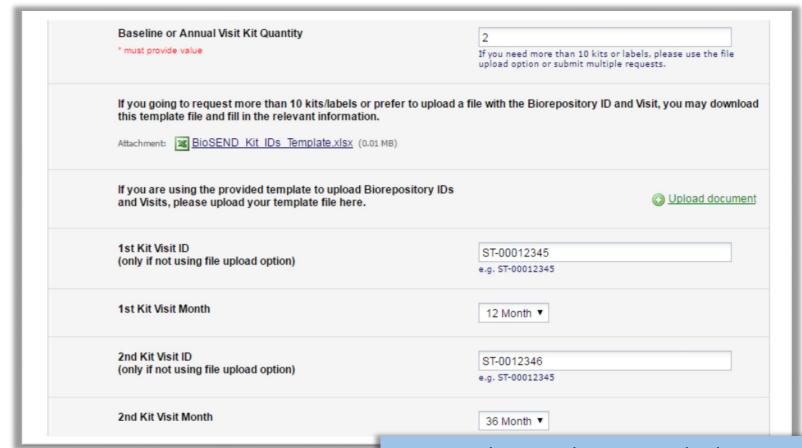
## BioSEND Kit Request Module: Baseline Kit

Kit Type  **Please allow two weeks for shipment**  * must provide value	■ Baseline Visit Kit ■ Annual Visit Kit ■ Supplemental Kit ■ Extra Supplies  Please specify in comments if you need kits before the standard two week shipment time.	
CSF Sprotte Needle Gauge * must provide value	○22 ○24 reset	
Baseline Visit Kit Quantity  * must provide value	If you need more than 10 kits or labels, please use the file upload option or submit multiple requests.	

- BioSEND creates ST numbers for baseline kits. The ST# is the biorepository subject ID and will stay with the subject throughout the study.
- Enter preferred CSF gauge and quantity needed



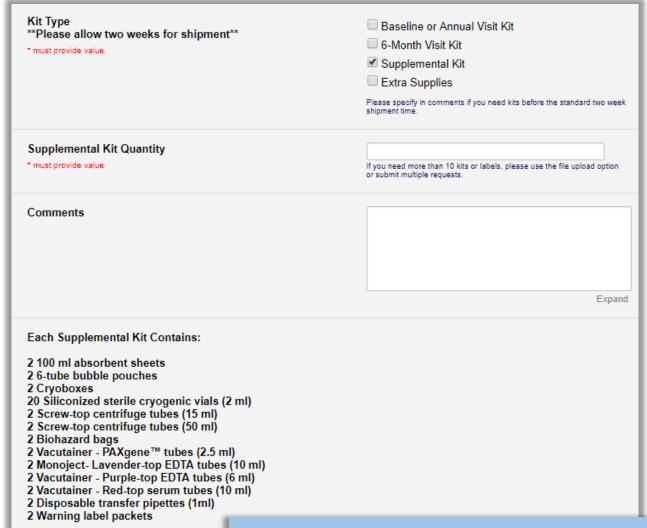
# BioSEND Kit Request Module: Annual Visits



For annual visits, please provide the ST# and visit of the follow-up kit needed. We cannot complete your request without this information.



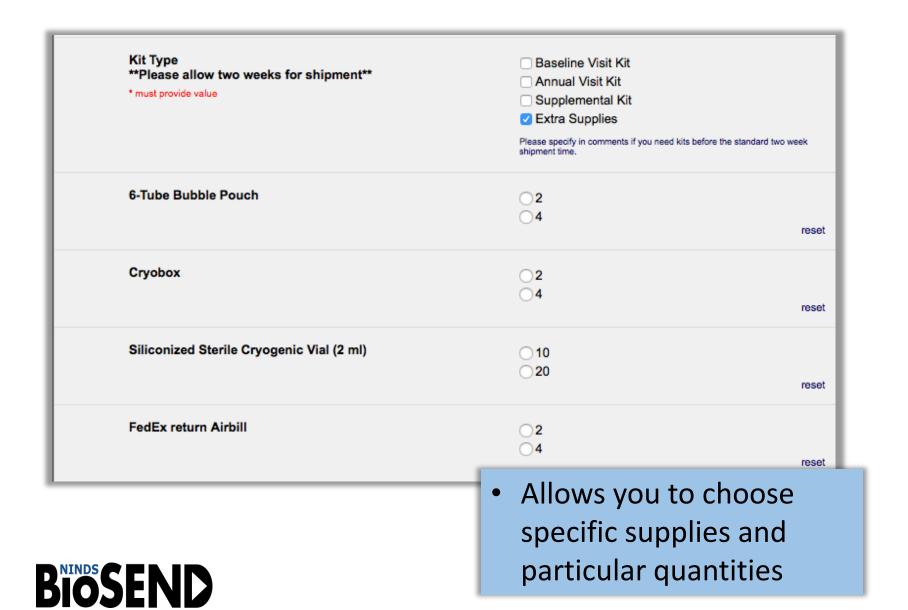
#### BioSEND Kit Request Module: Supplemental Kit





Contains a variety of extra kit pieces

#### BioSEND Kit Request Module: Extra Supplies



#### BioSEND Kit Request Module: Multiple Orders

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

\* must provide value

- Baseline Visit Kit
- Annual Visit Kit
- Supplemental Kit
- Extra Supplies

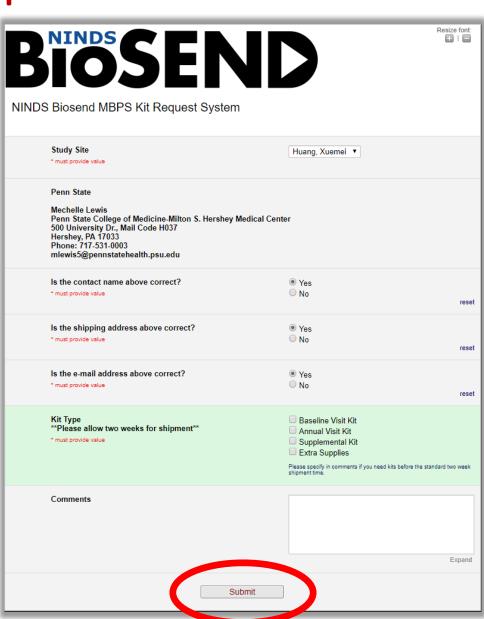
Please specify in comments if you need kits before the standard two week shipment time.

 You can order more than one type of kit in a single kit request



# BioSEND Kit Request Module: Submit

- Click "Submit" to turn in your request.
- The BioSEND staff will notify you that your request has been received and address any issues.





# Labels



# Types of Labels

Case Label

ST-10001234: MBPS:BL



**BioSend** 

Specimen Label

0004618561



BioSEND

ST-10001234

BL

DNA

**Identify study and PI** 

**Identify individual biospecimens** 



## Case Label

ST-10001234: MBPS:BL





**BioSend** 



**Biorepository Name** 



#### Case Labels

#### Case labels are placed:

- On the biohazard bag of the cryovial transport box.
- On the biohazard bag for the whole blood (EDTA) and PAXgene™ tubes.
- On the lid of frozen shippers











## Collection and Aliquot Tube Label

0004618561



**BioSEND** 

ST-10001234 BL

DNA













# Collection and Aliquot Tube Label

Collection and Aliquot Tube Labels are placed on:

- All collection tubes
- All aliquot tubes (Cryovials)

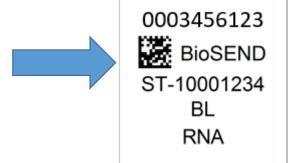
Be sure that the tube has the correct specimen type on the label



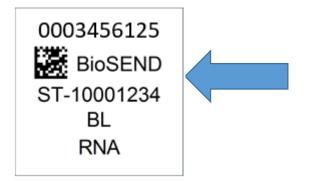


# **Aliquot Labels**

 Keep samples in sequential order when labeling and storing











# Sample Collection & Processing

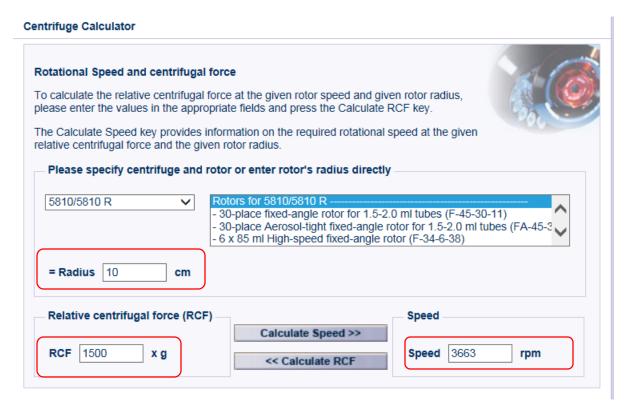
#### **Reminders:**

- Collection of biospecimen blood samples should be from subjects who have been <u>fasting for 8 hours</u> or more. If fasting is not feasible, follow suggested low-fat diet.
- G force ≠ RPM
- All specimens should be frozen and stored <u>UPRIGHT</u>
  - For RNA and whole blood specimens, please freeze samples upright in a non-styrofoam rack
  - For plasma, buffy coat, serum, and CSF aliquots, please freeze samples upright in the cryobox provided



## **Calculating Centrifugation Speed**

https://www.eppendorf.com/CA-en/centrifuge-speed-calculator/



\*The 3663 rpm speed was calculated using a hypothetical radius of 10 cm and a RCF of 1500 x g.



# Order of Specimen Collection

- 1. Serum **10 ml (red top)** blood collection for serum
- 2. PAXgene™ tube for RNA
- 3. EDTA 6 ml (purple top) blood collection for DNA (only at BL visit)
- 4. EDTA **10 ml (lavender top)** blood collection for plasma and buffy coat
- 5. EDTA 6 ml (purple top) blood collection for frozen Whole Blood



Serum



PAXgene (RNA)



EDTA (DNA)



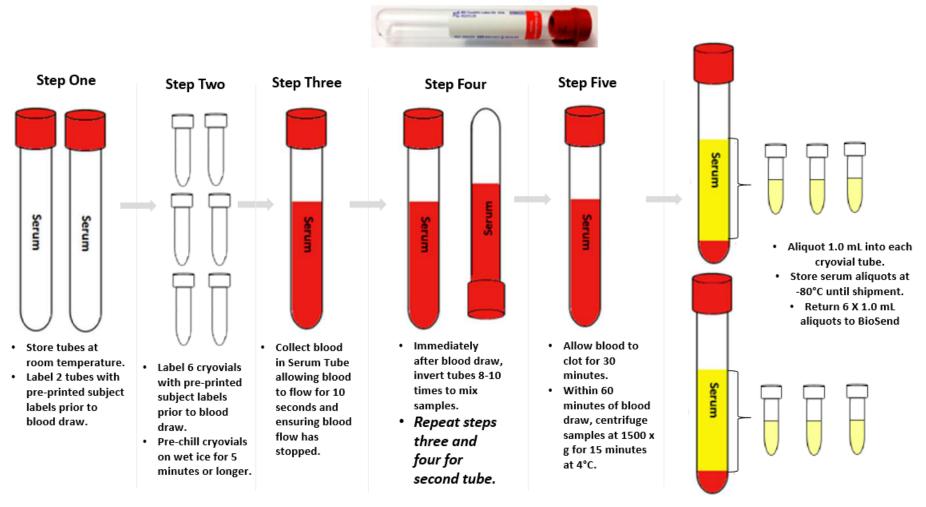
EDTA (Plasma)



EDTA (WB)



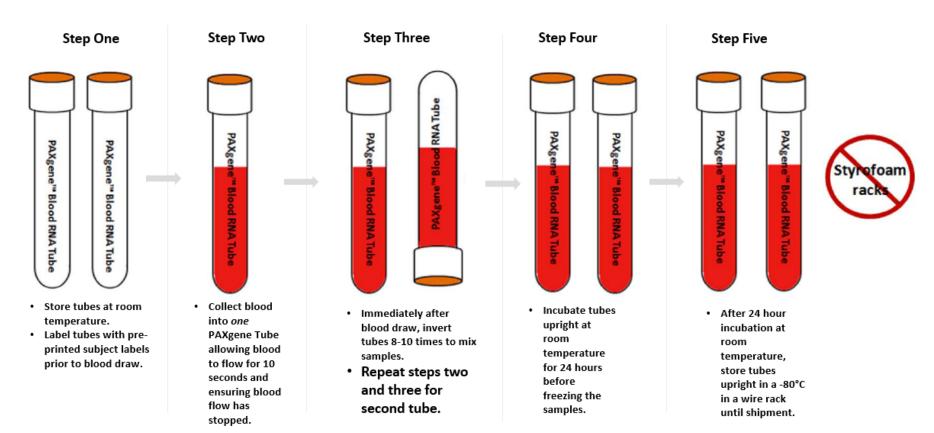
#### Serum Preparation (10ml Red Top Tube)





#### PAXgene<sup>™</sup> Preparation (2.5ml Tube)

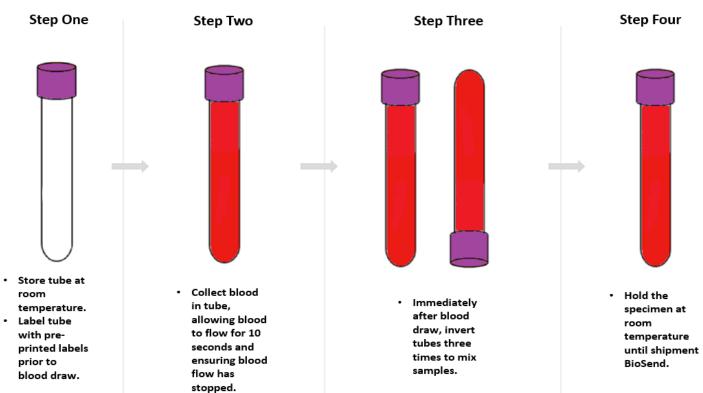






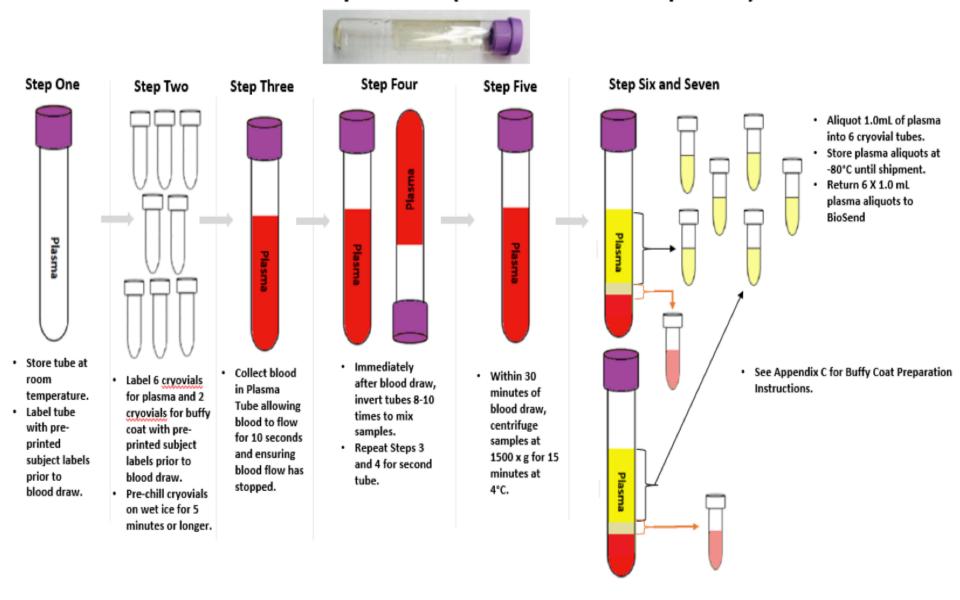
#### **DNA Preparation (6 ml Lavender Top Tube)**





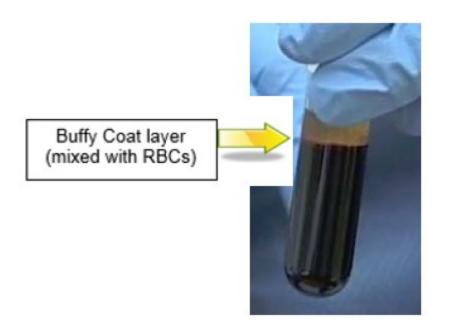


#### Plasma Preparation (10ml Lavender Top Tube)



### BIOSEND

## **Buffy Coat Collection**



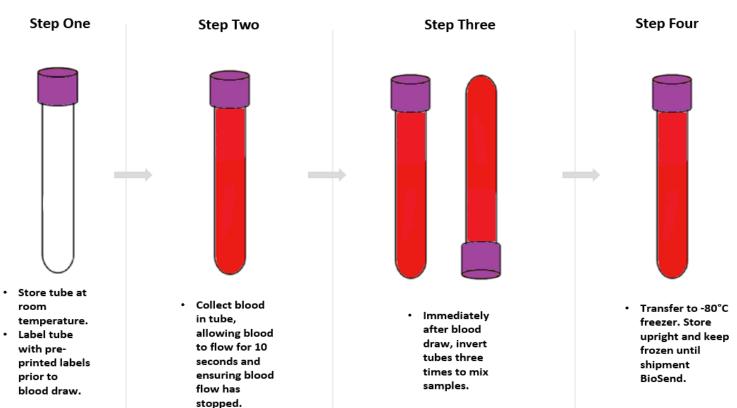


Collect the buffy coat layer using the transfer pipet provided. Residual plasma as well as some RBCs will be included in this collection. A buffy coat will be reddish in color due to RBCs.



#### Whole Blood (6 ml Lavender Top Tube)





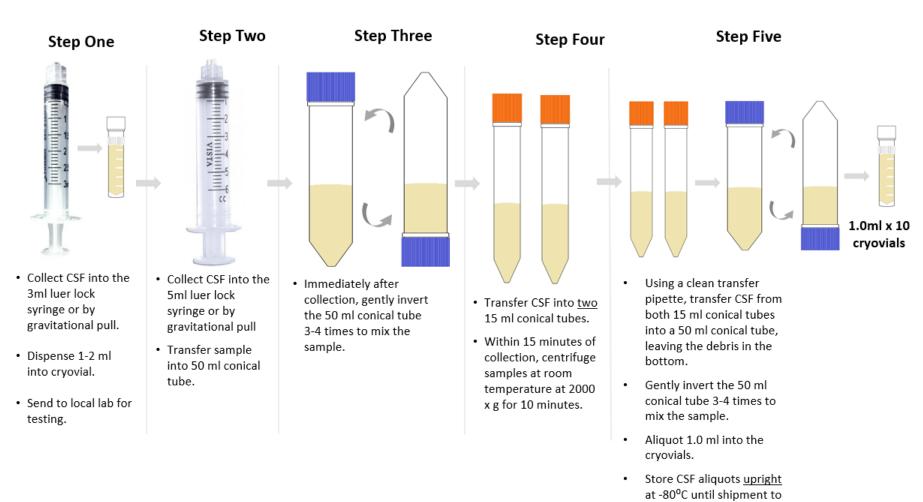


#### **Lumbar Puncture Procedure**

- 24g or 22g spinal needle provided in custom LP tray
- Prepare transfer and aliquot tubes (NOT in LP tray but in kit)
  - Label first!
  - Do NOT pre-chill aliquot tubes



#### CSF Collection and Preparation (15-20 ml total)

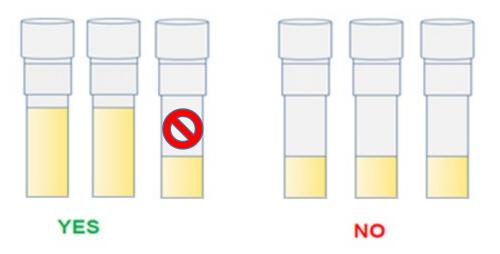


BioSEND.



#### Serum, Plasma, Buffy Coat and CSF Aliquots

- Fill cryovials to 1ml
- Over-filled vials may burst in freezer
- Ship material to BioSEND
  - 6 Serum aliquots
  - 6 Plasma aliquots
  - 2 Buffy Coat
  - 10 CSF aliquots
  - 2 Paxgene
  - 1 frozen EDTA for whole blood
  - 1 ambient EDTA for DNA (at BL only)
- Do NOT send residual volumes to BioSEND





#### **Blood Collection: Troubleshooting**

#### Issue #1: Collection tube with little/no vacuum

- Always check expiration dates before beginning blood draw and discard expired tubes
  - Tubes expire on last day of month printed on tube
- Store tubes at ambient temperature
  - Extreme temperatures can affect vacuum
- Keep extra collection tubes from supplemental kit nearby during blood draw to replace "bad" tubes
- If frequent occurrence, report tube type and lot numbers to Indiana University



#### **Blood Collection: Troubleshooting**

#### Issue #2: Hemolyzed (pink/red) serum and plasma

Cause: Blood Collection Methods	Corrective Action
Improper venipuncture site	Draw from median cubital, basalic, and cephalic veins from antecubital region of arm
Prolonged tourniquet use	Tourniquet should be released after no more than 1 min, excessive fist clenching should be avoided
Not allowing alcohol to dry on skin before venipuncture	Without touching, allow the venipuncture site to air dry
Lumen of needle too close to inner wall of vein (indicated by slow blood flow)	
Use of too large/small bore needle resulting in excess force applied to blood	Avoid using too small/large needle. Needle size dependent on the subject's physical characteristics & amount of blood to be drawn. Most commonly used sizes are 19 – 23.
Pulling/pushing plunger too fast while drawing/transferring blood	Avoid drawing the syringe plunger too forcefully when collecting blood
	Ensure all blood collection assemblies are fitted securely, to avoid frothing



Reference: BD's "Tech Talk" newsletter, Vol. 2, No. 2, October 2003 (http://www.bd.com/vacutainer/pdfs/techtalk/TechTalk Jan2004 VS7167.pdf)

#### **Blood Collection: Troubleshooting**

#### Issue #2: Hemolyzed (pink/red) serum and plasma

Cause: Sample Processing Methods	Corrective Actions
Vigorous mixing/shaking	Gently invert blood collection tube when mixing additive with specimen, follow guidelines in Biologics Manual regarding number of times to invert each type of tube
Not allowing serum to clot for recommended time	Serum tubes without clot activator should be allowed to clot for 60 min in a vertical position
Exposure to excessive heat or cold	Keep samples at ambient temp
Prolonged contact of serum/plasma with cells	Do not store uncentrifuged samples beyond recommended time



Reference: BD's "Tech Talk" newsletter, Vol. 2, No. 2, October 2003 (http://www.bd.com/vacutainer/pdfs/techtalk/TechTalk Jan2004 VS7167.pdf)

# Sample Shipment



# **Ambient Sample Shipment**

- 6 ml purple (EDTA) whole blood for DNA collection tube
  - Collected at BL visit
- Monday Thursday only via FedEx Priority Overnight
- Schedule FedEx pickup
- Email Sample Record and Shipment Notification Form including the FedEx tracking number AHEAD OF SHIPMENT to BioSEND



## **Ambient Shipper Components**

Styrofoam shipper with outer cardboard box

IATA 'Contents' Sheet



Biohazard bag with absorbent material

Cool pack (place in fridge prior to collection/shipment)

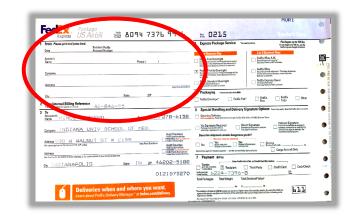
Collection tube will be in blood kit



### Labeling Ambient Sample Shipments

- Apply the UN3373 label to the outside of the cardboard box.
- Place the box and a copy of the Sample Record and Shipment Notification Form in the Clinical Pak and seal the Pak.
- Complete the "From" portion of the air waybill with your name, address, and phone number.
- Apply the air waybill to the outside of the package.







#### **Shipping Ambient Samples**

- Ship the sample(s) to BioSEND on the day of collection.
- If this is not possible, hold at room temperature until shipping can be arranged.
- Sample(s) must be received at BioSEND within 5 days of collection. Please do not ship these samples on Fridays.



#### Frozen Samples

- All other samples are shipped frozen
  - Plasma, buffy coat, serum, CSF, whole blood and PAXgene™
- Ship Monday-Wednesday Only via FedEx Priority Overnight
- Schedule FedEx pickup
- Email Sample Record and Shipment Notification Form including FedEx tracking number AHEAD OF SHIPMENT





### **Packaging and Shipping Frozen Samples**









Pack bags, place upright & side-by-side

**FILL** dry ice to top of box



## **Packaging & Shipping Troubleshooting**

#### **Issue: Broken/Damaged Tubes**

Cause	Preventative Action
Over filling tubes	Fill tubes to suggested volume. If any sample still remains, place in an additional tube
Improper packaging	Ensure the tubes are securely placed into the bubble wrap pouch and are placed in a separate bag from the boxed plasma, serum, and CSF.
Rough shipping conditions	Extra bubble wrap may be needed to pad blood tubes
Extreme changes in temperature (ambient→freezer; freezer→dry ice)	Wrapping the tubes in bubble wrap before freezing may help slow the cooling process



# Shipping Frozen Samples

- Hold packaged samples in a -80°C freezer until pickup.
- Samples should be received at BioSEND within 2 weeks of collection.



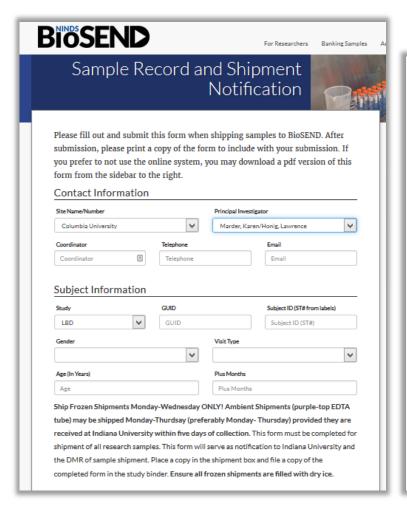


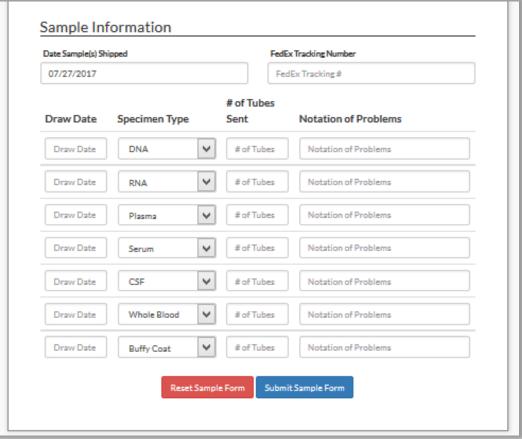
### Sample Shipment Notification Form

				1						
Study:										
Site Name:				Pr	rincipal Inve	estigator:				
Coordinator:			Te	elephone:			Email:			
	Please list only O	NE subject per	r Sample	Record Su	ummary an	d Shipmer	nt Notifica	tion Form		
GUID:				Subject ID	(ST# from	pre-printed	l labels):			
Gender:						Vi	sit Type:			
Age in Years:						Plus	Months:			
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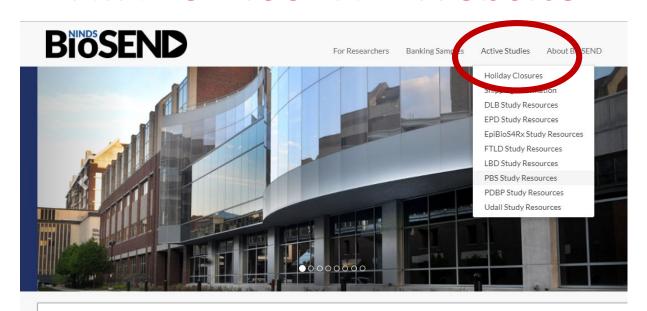
### Sample Shipment Notification Form, Online







#### NINDS BioSEND Website







# **Holiday 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
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



#### **BioSEND Contact Information**

• Questions?

Please contact: Claire Wegel (cwegel@iu.edu)

Email: biosend@iu.edu



## **Questions?**

