# BioSpecimen Exchange for Neurological Disorders (BioSEND)

SBPD 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

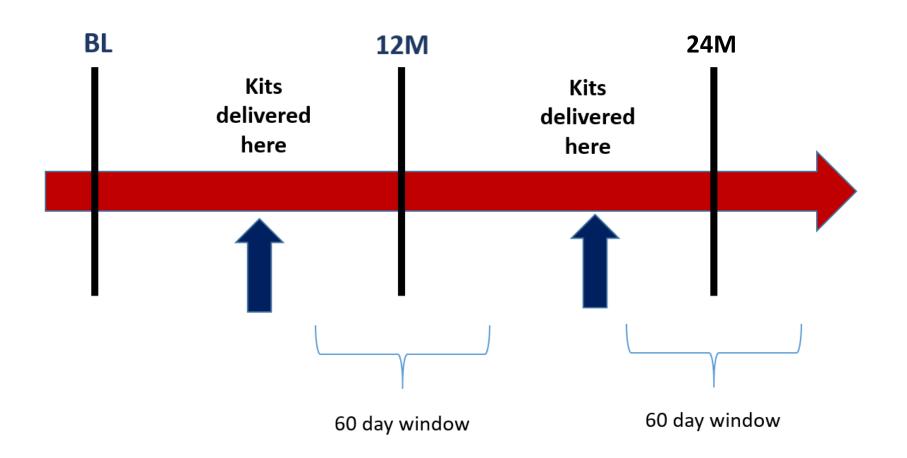


#### SBPD Biospecimen Collection Protocol

	BL	12M	24M
Whole blood (6ml)	X	X	X
Buffy Coat (2 aliquots)	X	X	X
Plasma (6 x 1ml)	X	X	X
RNA (2 x 2.5ml)	X	X	Χ



## **Study Visit Protocol**





### Study Visit Protocol

- After subject completes baseline visit, BioSEND sets up automated kit sending schedule for subject's subsequent visits
- Schedule gives 2 month window around the longitudinal study visit target (1 month on either side)
- BioSEND will send kits prior to start of study window
  - Reduces effort for study coordinators
  - Sites only need to order kits if visit will occur AHEAD of the study visit window
- All study visit target dates are determined from Baseline Visit (not from last study visit date)



#### Study Visit Protocol

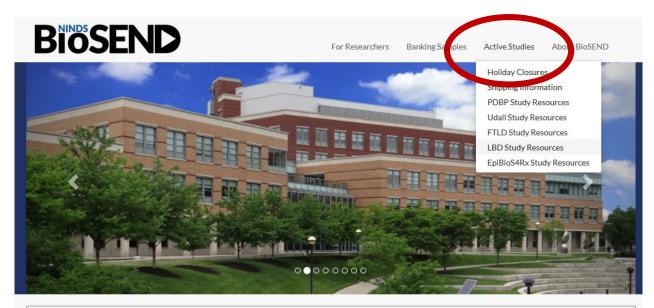
 Automated kits will be shipped to you on a monthly basis. For example, if a subject's visit window opens in October, you will receive the kit for that subject at the end of September.



## Requesting Kits



#### NINDS BioSEND Website







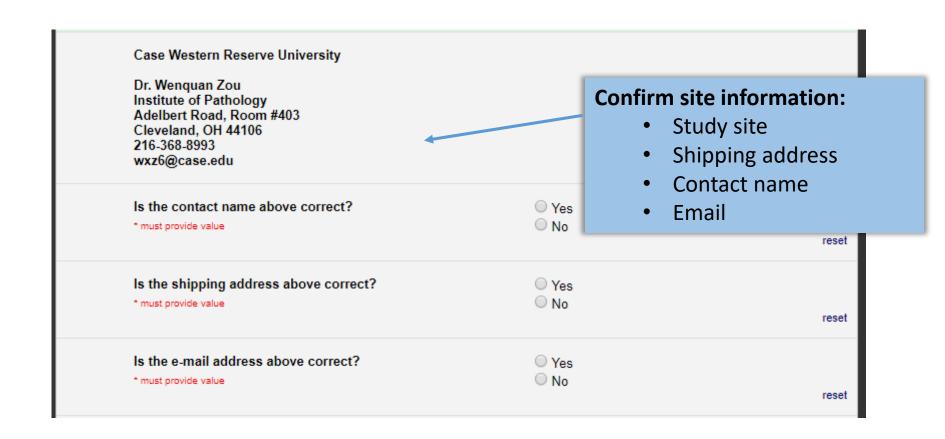
#### BioSEND Kit Request Module



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

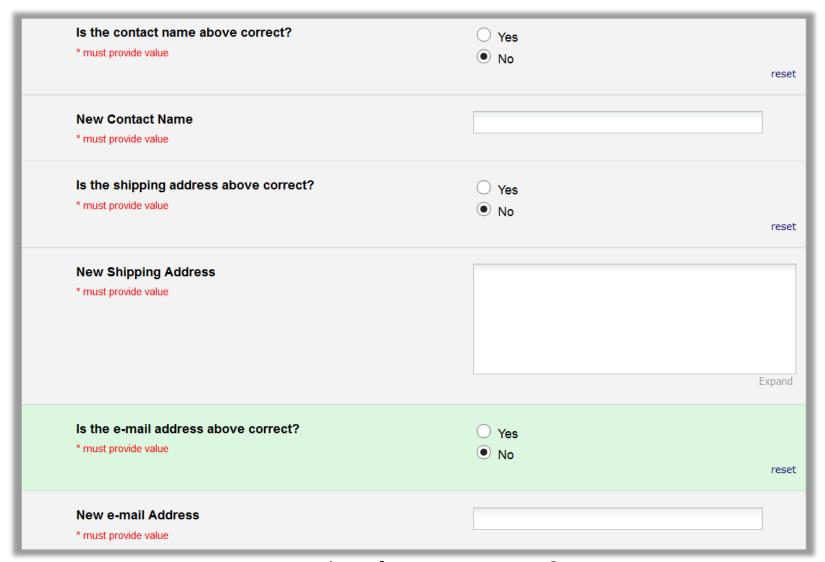


### **BioSEND Kit Request Module**





### 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

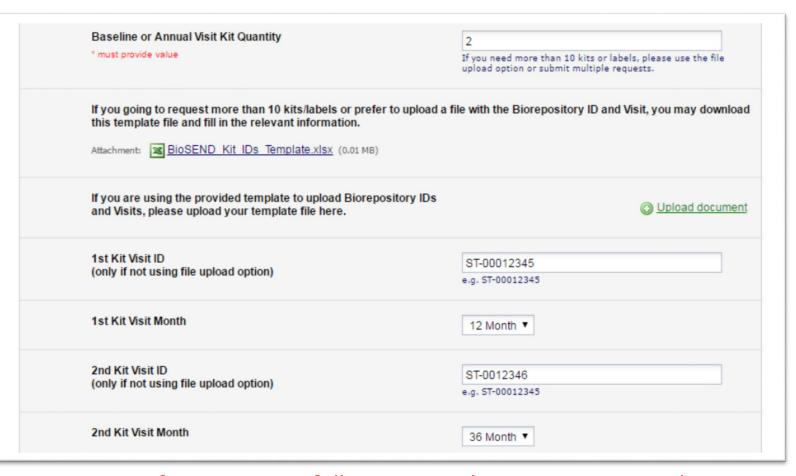
Kit Type  **Please allow two weeks for shipment**  * must provide value	■ Baseline Visit Kit
Baseline Visit Kit Quantity  * must provide value	

- BioSEND creates ST numbers for baseline kits
- Enter kit quantity



#### BioSEND Kit Request Module: Annual Visits

Only use this if the subject will be seen ahead of a study visit window





•If requesting a follow-up visit kit, you must provide us with time point and ST number of the kit you are requesting. Not doing so will delay your shipment, as we cannot complete your request without this information.

#### BioSEND Kit Request Module: Supplemental 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.
Supplemental Kit Quantity  * must provide value	1
Comments	Expand
Each Supplemental Kit Contains:  EDTA tube, 10ml (glass) - 3 EDTA tube, 6ml (plastic) - 3 PAXgene tube, 2.5ml - 3 Siliconized cryotubes, 2ml - 20 Disposable pipette, 3ml - 5 15ml conical (for mixing plasma) - 3 Resalable tube pouches - 9 Cryobox, 25 slot - 2 Biohazard bag w/ absorbent sheet- 5 UN3373, dry ice, and fragile stickers - 3 each	



Contains a variety of extra kit pieces

#### BioSEND Kit Request Module: Extra Supplies

Kit Type  **Please allow two weeks for shipment**  * must provide value	■ Baseline Visit Kit ■ Supplemental Kit ■ Extra Supplies  Please specify in comments if you need kits before the standard two week shipment time.	
6-Tube Bubble Pouch	© 2 © 4	
Cryobox	© 2 © 4	<ul> <li>Allows you to choose specific supplies and particular quantities</li> </ul>
Siliconized Sterile Cryogenic Vial (2 ml)	○ 10 ○ 20	reset
FedEx return Airbill	© 2 © 4	reset



#### BioSEND Kit Request Module: Multiple Orders

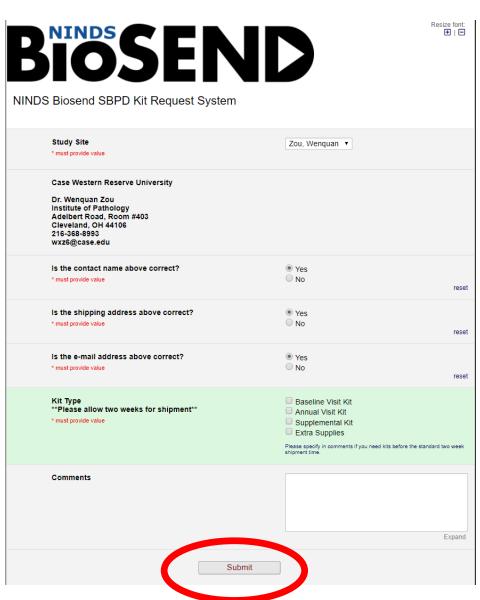
Kit Type  **Please allow two weeks for shipment**  * must provide value	<ul> <li>✓ Baseline Visit Kit</li> <li>✓ Annual Visit Kit</li> <li>✓ Supplemental Kit</li> <li>✓ Extra Supplies</li> <li>Please specify in comments if you need kits before the standard two week shipment time.</li> </ul>
Baseline Visit Kit Quantity  * must provide value	
Annual Visit Kit Quantity  * must provide value	Please provide ST number and visit month.

 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

Specimen Label

ST-10001234: SBPD:BL



**BioSend** 

0001234567



ST-10001234 BL

**WBLD** 

**Identify study** 

**Identify individual biospecimens** 



#### Case Label

ST-10001234: SBPD:BL



**BioSend** 





**Biorepository Name** 



#### Case Labels

#### Case labels are placed:

- On the plastic biohazard bag of the cryovial transport box.
- On the plastic biohazard bag for the PAXgene™ tubes.
- On the lid of frozen shippers











#### Collection and Aliquot Tube Label



### Collection and Aliquot Tube Label

Collection and Aliquot Tube Labels are placed on:

- All collection tubes
- All aliquot tubes (Cryovials)

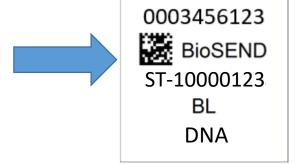
Be sure that the tube has the correct specimen type on the label



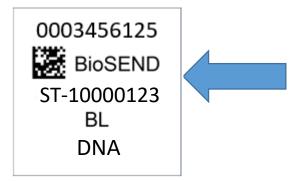


## **Aliquot Labels**

 Keep samples in sequential order when labeling and storing











## Sample Collection & Processing

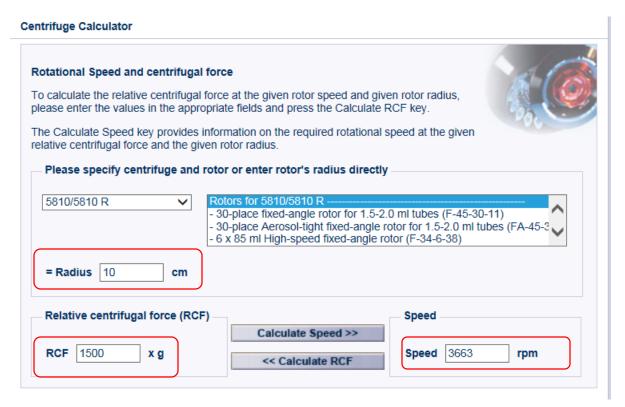
#### **Reminders:**

- 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 plasma and CSF aliquots, please freeze samples upright in the cryobox provided



#### **Calculating Centrifugation Speed**

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



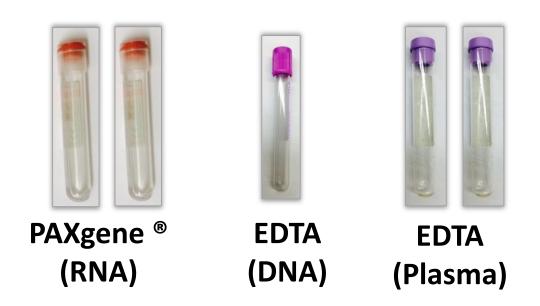
\*The 3663 rpm speed was calculated using a hypothetical radius of 10 cm and a RCF of 1500 x g.



Refer to Appendix F in the BioSEND Biologics Manual for further information regarding the centrifugation of samples

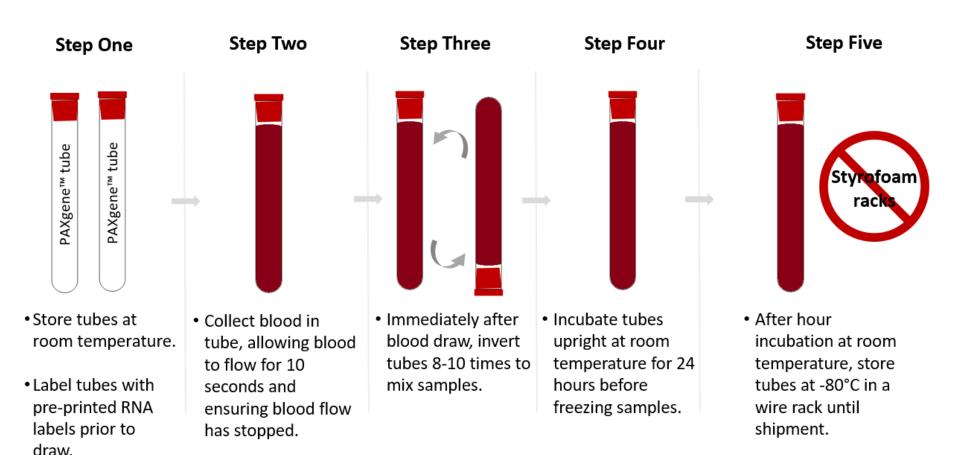
## Order of Specimen Collection

- 1. PAXgene™ tube for RNA
- 2. EDTA 6 ml (purple top) blood collection for whole blood (banking)
- 3. EDTA **10 ml (lavender top)** blood collection for plasma and buffy coat





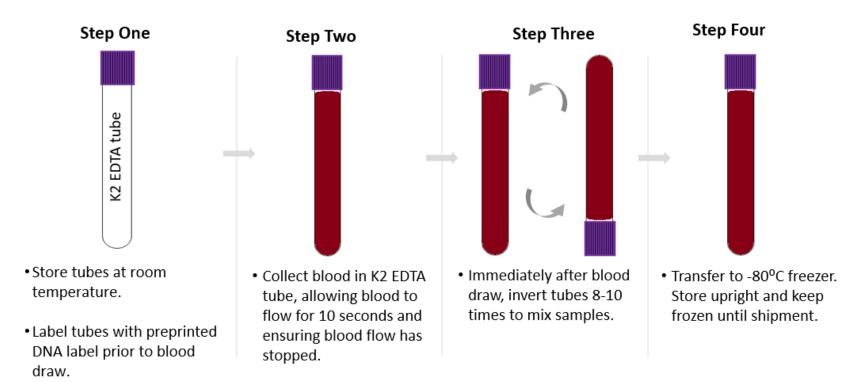
#### PAXgene™ Preparation (2.5ml Tube)





#### Whole Blood Preparation – 6 ml K2 EDTA (Purple Top) Tube

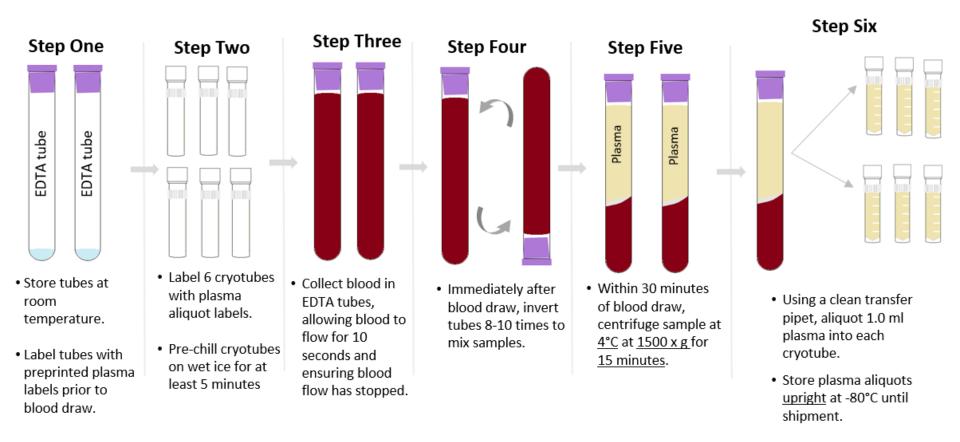






#### Plasma Preparation –10 ml EDTA (Purple Top) Tube

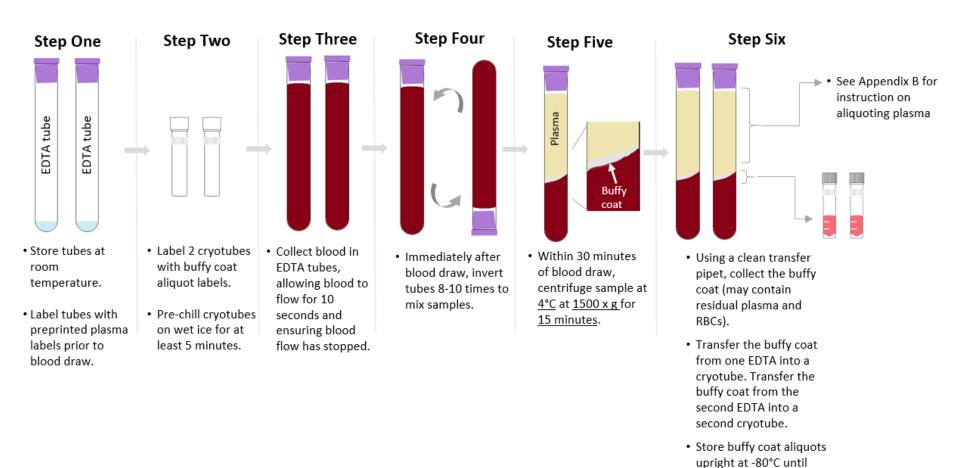






#### Buffy Coat Preparation –10 ml EDTA (Purple Top) Tube



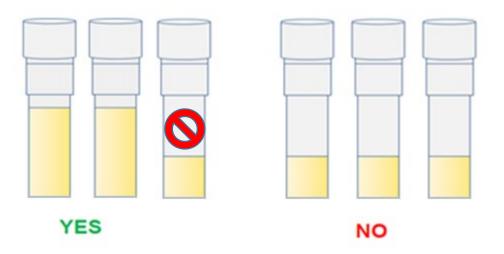


shipment.



#### **Plasma Aliquots**

- Fill cryovials to 1ml
- Over-filled vials may burst in freezer
- Ship material to BioSEND
  - 6 Plasma aliquots
  - 2 Buffy Coats
  - 2 RNA Tubes
  - 1 Whole Blood
- Do NOT send residual volumes to BioSEND





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

#### Issue #1: Blood draw 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 blood 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



### Frozen Samples

- All samples are shipped frozen
  - Plasma, Buffy Coats, Whole Blood for DNA extraction, 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.



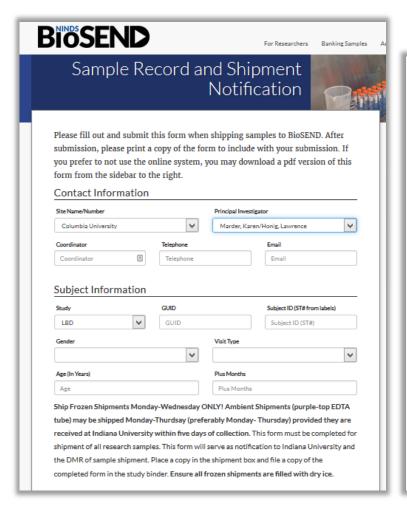


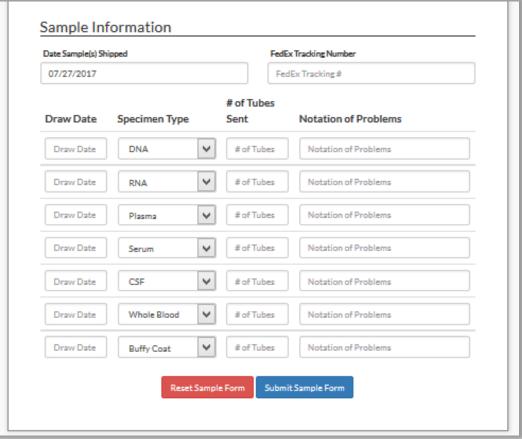
## Sample Shipment Notification Form

				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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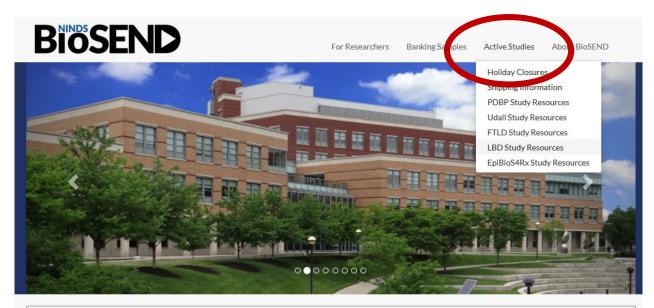
### Sample Shipment Notification Form, Online







### 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?**

