

NINDS Biorepository

BioSpecimen Exchange for Neurological Disorders, BioSEND

PDBP Coordinator Training

November 2015

BioSEND Staff

- Casey Bales, Project Manager
- Colleen Mitchell, Laboratory Manager
- Tatiana Foroud, Principal Investigator



BioSEND Contact Information

- Questions?

Please contact Casey Bales:

- Phone: 317-278-0495
- Email: biosend@iu.edu

Timeline for Biorepository Transition

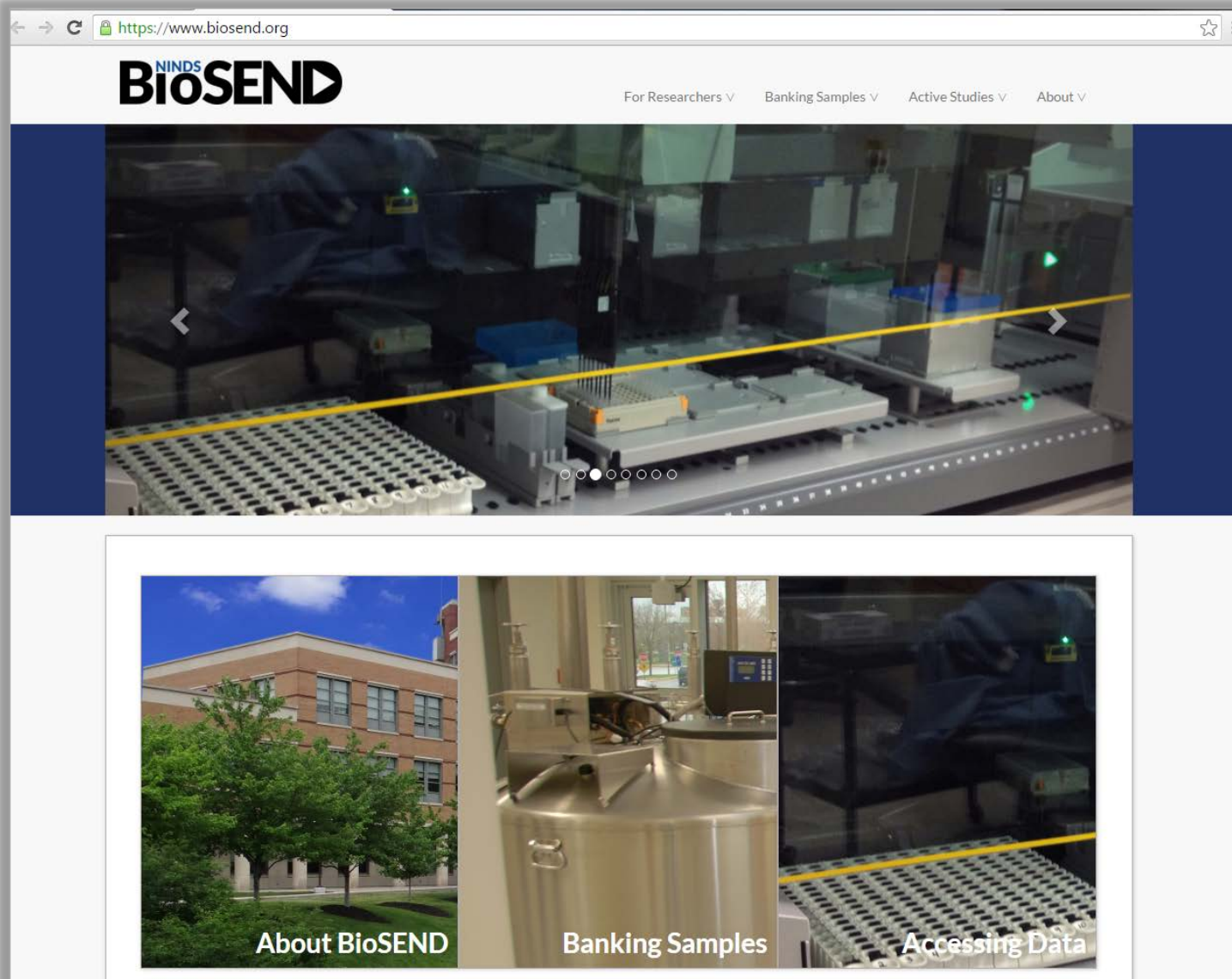
November

- Nov 25 – Last day for sites to use kits provided by Coriell
- Nov 30 – Last day for sites to send study samples back to Coriell

December

- Nov 30 - Sites use kits and labels provided by BioSEND
- Nov 30 – Sites begin to send study samples back to BioSEND

NINDS BioSEND Website



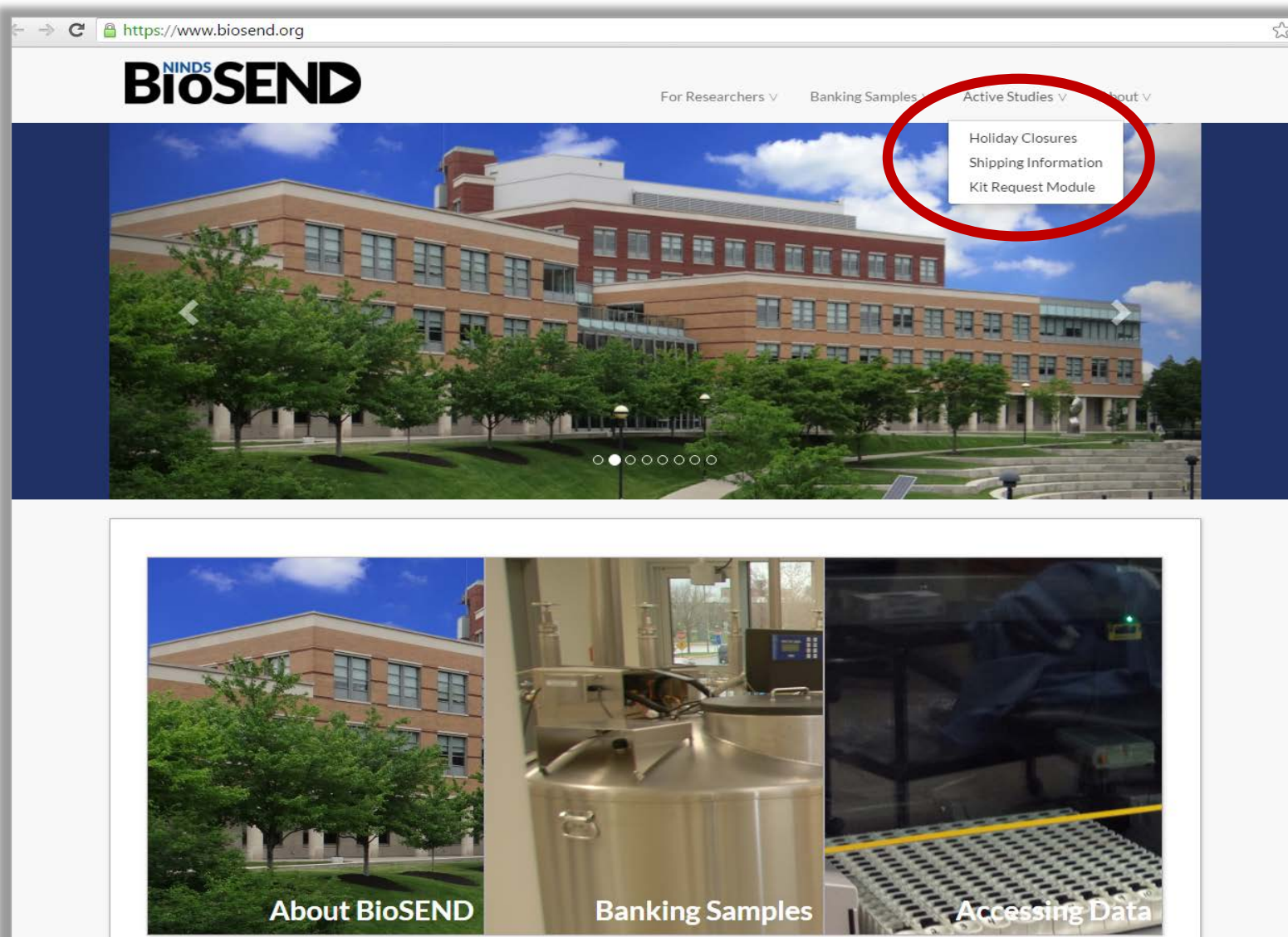
<https://www.biosend.org/>

Scope of Transition Training

- Focus only on elements that are changing with the transition
 - Requesting kits
 - Labels
 - Changes in specimen collection or processing
 - Shipping samples to BioSEND
- For any new coordinators or specimen processing staff
 - BioSEND provides training in all aspects of sample collection, processing and shipping

Requesting Kits



NINDS BioSEND Website



<https://www.biosend.org/>

BioSEND Kit Request Module

NINDS
BioSEND

Resize font:  | 

NINDS BioSEND PDBP and PD Related Studies Kit Request System

Study Site
* must provide value

Submit

REDCap Software - Version 6.5.16 - © 2015

- Albin, Roger (PDBP)
- Dauer, William (PDBP/UDALL)
- Dawson, Ted / Rosenthal, Liana (PDBP)
- Dewey, Rich (PDBP)
- Huang, Xuemei (PDBP)
- Saunders-Pullman, Rachel (PDBP)
- Scherzer, Clemens (PDBP)
- Standaert, David (PDBP/UDALL)
- Vaillancourt, David (PDBP)
- West, Andrew (PDBP)
- Zhang, Jing (PDBP)

- <http://kits.iu.edu/biosend/pd>
- **Choose your site PI from the drop-down list.**

BioSEND Kit Request Module

Study Site
* must provide value

Dawson, Ted / Rosenthal, Liana (PDBP) ▼

Johns Hopkins University - Dawson, Ted/Rosenthal Liana

Nadine Yoritomo, RN
Senior Research Nurse Coordinator
Johns Hopkins University
Green Spring Falls Concourse
10751 Falls Road, Suite 250
Lutherville, MD 21093
(410) 616-2822
nyorito1@jhmi.edu

Is the contact name above correct?
* must provide value

☒ Yes
☐ No

reset

Is the shipping address above correct?
* must provide value

☒ Yes
☐ No

reset

Is the e-mail address above correct?
* must provide value

☒ Yes
☐ No

reset

Confirm site information:

- Study site
- Shipping address
- Contact name
- Email

BioSEND Kit Request Module

Is the contact name above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
New Contact Name <small>* must provide value</small>	<input type="text"/>	
Is the shipping address above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
New Shipping Address <small>* must provide value</small>	<div><input type="text"/></div> <div>Expand</div>	
Is the e-mail address above correct? <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
New e-mail Address <small>* must provide value</small>	<input type="text"/>	

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

BioSEND Kit Request Module: Type by Site

Example A

Kit Type

* must provide value

- ☐ Baseline Visit Kit (w/DNA)
- ☐ Supplemental Kit
- ☐ Extra Supplies

Example B

Kit Type

* must provide value

- ☐ Baseline Visit Kit (w/DNA)
- ☐ Follow-up Visit Kit (wo/DNA)
- ☐ CSF Kit
- ☐ Supplemental Kit
- ☐ Extra Supplies

- Each PDBP site uses slightly different kit components
- Kits differ based on baseline and longitudinal visits
 - Typical difference is the collection of a blood tube for DNA only at the baseline visit

BioSEND Kit Request Module: Kit Type

Kit Type
* must provide value

☐ Baseline Visit Kit (w/DNA)
☐ Follow-up Visit Kit (wo/DNA)
☐ CSF Kit
☐ Supplemental Kit
☐ Extra Supplies

Comments

Expand

Submit

- Choose your kit type
- Only kit types used by your site will show up as a selection

BioSEND Kit Request Module: Baseline Kit

Kit Type
* must provide value

☒ Baseline Visit Kit (w/DNA)
☐ Follow-up Visit Kit (wo/DNA)
☐ CSF Kit
☐ Supplemental Kit
☐ Extra Supplies

Baseline Kit Quantity
* must provide value

Comments


Expand

Each PDBP Baseline Collection Kit Contains:

- 3 - Monoject - Lavender-top EDTA tube (10 ml)
- 3 - Vacutainer - Red-top serum tube (10 ml)
- 2 - Vacutainer - Purple-top EDTA tubes (6 ml)
- 4 - Vacutainer - PAXgene tubes (2.5 ml)
- 36 - Siliconized cryovials, sterile (2ml)
- 1 - Cryobox
- 1 - Warning label packet (incl. dry ice label)
- 2 - Shipping instruction sheets
- 1 - FedEx Overpack
- 2 - FedEx return Airbills
- 1 - Shipping container for dry ice shipments
- 1 - Shipping kit for ambient shipments
- 2 - Biohazard bag
- 2 - 100 ml absorbent sheet
- 2 - 6-tube bubble pouch
- 30 - Cryohold pre-printed labels

- BioSEND creates ST numbers for baseline kits
- Enter quantity
- List of kit contents shown below

BioSEND Kit Request Module: Follow-up Kit

Follow-up Visit Kit Quantity <small>* must provide value</small>	<input type="text" value="2"/> <small>Single requests are limited to 10 Follow-Up kits. If you need more than 10 kits, please use the file upload option or submit multiple requests.</small>
<p>If you going to request more than 10 kits or prefer to upload a file with the Biorepository ID and Visit, you may download this template file and fill in the relevant information.</p> <p>Attachment:  BioSEND_Kit_IDs_Template.xlsx (0.01 MB)</p>	
<p>If you are using the provided template to upload Biorepository IDs and Visits, please upload your template file here.</p>	+ Upload document
1st Follow-up Visit ID (only if not using file upload option)	<input type="text" value="ST-00012345"/> <small>e.g. ST-00012345</small>
1st Follow-up Visit Month	<input type="text" value="6 Month"/>
2nd Follow-up Visit ID (only if not using file upload option)	<input type="text" value="ST-00012346"/> <small>e.g. ST-00012345</small>
2nd Follow-up Visit Month	<input type="text" value="24 Month"/>

- Up to 10 kits:
 - Enter the PDBP Subject ID - ST Number (Example: ST00012345)
 - Enter the follow up visit month

BioSEND Kit Request Module: Follow-up Kit

Follow-up Visit Kit Quantity


* must provide value

Single requests are limited to 10 Follow-Up kits. If you need more than 10 kits, please use the file upload option or submit multiple requests.

If you are going to request more than 10 kits or prefer to upload a file with the Biorepository ID and Visit, you may download this template file and fill in the relevant information.

Attachment:  [BioSEND_Kit_IDs_Template.xlsx](#) (0.01 MB)

If you are using the provided template to upload Biorepository IDs and Visits, please upload your template file here.

 [Upload document](#)

Comments

Expand

- More than 10 kits – download template

BioSEND Kit Request Module: Follow-up Kit

BioSEND_Kit_IDs_Template - Excel

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW ACROBAT

Clipboard: Cut, Copy, Paste, Format Painter

Font: Calibri, 11, Bold, Italic, Underline, Text Color, Background Color

Alignment: Wrap Text, Merge & Center

Number: General, \$, %, .00, .00

	A	B	C	D	E	F	G	H	I	J	K
1	Biorepository ID	Visit Month									
2	(e.g. ST-00012345)	(e.g. 12 month)									
3	ST-00012345	6									
4	ST-00012346	12									
5	ST-00012347	6									
6	ST-00012348	24									
7	ST-00012349	30									
8	ST-00012350	36									
9	ST-00012351	6									
10	ST-00012352	12									
11	ST-00012353	30									

- Complete template with ST numbers & visit types

BioSEND Kit Request Module: Follow-up Kit

Follow-up Visit Kit Quantity

* must provide value

Single requests are limited to 10 Follow-Up kits. If you need more than 10 kits, please use the file upload option or submit multiple requests.

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Attachment:  [BioSEND_Kit_IDs_Template.xlsx](#) (0.01 MB)

If you are using the provided template to upload Biorepository IDs and Visits, please upload your template file here.

 [Upload document](#)

Comments

Expand

BioSEND Kit Request Module: CSF Kit

Kit Type
* must provide value

☐ Baseline Visit Kit (w/DNA)
☐ Follow-up Visit Kit (wo/DNA)
☒ CSF Kit
☐ Supplemental Kit
☐ Extra Supplies

CSF Kit Quantity
* must provide value

Comments

Expand

Each CSF Collection Kit contains:

21 - Siliconized cryovials, sterile (2ml)
2 - Orange screw-top centrifuge tubes (15ml)
1 - Blue screw-top conical tube (50ml)
1 - LP tray with 24 gauge Sprotte needle

Submit

- Enter quantity

BioSEND Kit Request Module: Supplemental Kit

Kit Type
* must provide value

☐ Baseline Visit Kit (w/DNA)
☐ Follow-up Visit Kit (wo/DNA)
☐ CSF Kit
☒ Supplemental Kit
☐ Extra Supplies

Comments

Expand

Each Supplemental Kit Contains:

- 2 100 ml absorbent sheets
- 2 6-tube bubble pouches
- 2 Cryoboxes
- 10 Siliconized sterile cryogenic vials (2 ml)
- 2 Screw-top centrifuge tubes (15 ml)
- 2 Screw-top centrifuge tubes (50 ml)
- 2 Biohazard bags
- 2 Vacutainer - PAXgene™ tubes (2.5 ml)
- 2 Monoject- Lavender-top EDTA tubes (10 ml)
- 2 Vacutainer - Purple-top EDTA tubes (6 ml)
- 2 Vacutainer - Red-top serum tubes (10 ml)
- 2 Warning label packets

Submit

- Contains a variety of extra kit pieces

BioSEND Kit Request Module: Extra Supplies

Kit Type <small>* must provide value</small>	<input type="checkbox"/> Baseline Visit Kit (w/DNA) <input type="checkbox"/> Follow-up Visit Kit (wo/DNA) <input type="checkbox"/> CSF Kit <input type="checkbox"/> Supplemental Kit <input checked="" type="checkbox"/> Extra Supplies
6-Tube Bubble Pouch	<input type="radio"/> 2 <input type="radio"/> 4
Cryobox	<input type="radio"/> 2 <input type="radio"/> 4
Siliconized Sterile Cryogenic Vial (2 ml)	<input type="radio"/> 10 <input type="radio"/> 20
FedEx return Airbill	<input type="radio"/> 2 <input type="radio"/> 4
Lumbar Puncture Trays with Lidocaine	<input type="radio"/> 2 <input type="radio"/> 4
Needles - Introducer	<input type="radio"/> 5

- Allows you to choose specific supplies and particular quantities

BioSEND Kit Request Module: Multiple Orders

Kit Type

* must provide value

- ☒ Baseline Visit Kit (w/DNA)
- ☒ Follow-up Visit Kit (wo/DNA)
- ☒ CSF Kit
- ☒ Supplemental Kit
- ☒ Extra Supplies

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

BioSEND Kit Request Module: Submit

NINDS BioSEND

NINDS BioSEND PDBP and PD Related Studies Kit Request System

Study Site: Dewey, Rich (PDBP) * must provide value

UT Southwestern Medical Center - Dewey, Rich
Ashley Gerald
5323 Harry Hines Blvd.
J 3.134
Dallas, TX 75390
(214) 648-0212
ashley.gerald@utsouthwestern.edu

Is the contact name above correct? * must provide value
☐ Yes ☐ No reset

Is the shipping address above correct? * must provide value
☐ Yes ☐ No reset

Is the e-mail address above correct? * must provide value
☐ Yes ☐ No reset

Kit Type * must provide value
☐ Baseline Visit Kit (w/DNA)
☐ Follow-up Visit Kit (wo/DNA)
☐ CSF Kit
☐ Supplemental Kit
☐ Extra Supplies

Comments Expand

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



- Identifies Study and Study PI

- Collection & Aliquot Tube Label



- Identifies individual biospecimens

Case Label



ST-10000032:

PDBP-WEST:

BL



BioSend

Subject Number

**Study – Principal Investigator
Visit**

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 the shipping canisters.
- *On lid of frozen shippers (pre-labeled)*



Collection and Aliquot Tube Label



0000293080

Biospecimen Number



BioSend

Study = BioSEND

51334

Case Number

ST-123456

Subject Number

DNA

Specimen Type

Collection and Aliquot Tube Label

Collection and Aliquot Tube Labels are placed on:

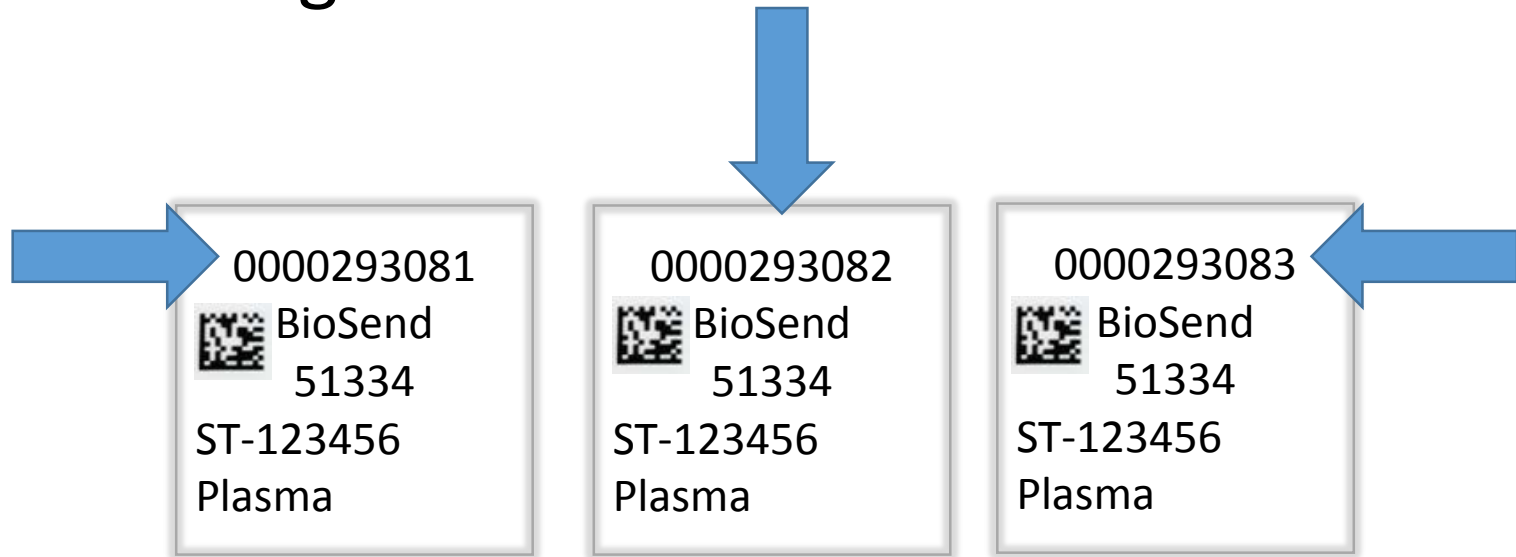
- All collection tubes
- All aliquot tubes (Cryovials)

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



Aliquot labels

- Keep samples in sequential order when labeling and storing



Changes in Specimen Collection/Processing

DNA Collection: Baseline* Visits Only

- Replace yellow top ACD tube (8.5 ml) with a purple top EDTA tube (6.0 ml)
- IU extraction optimized for EDTA tube

Old DNA Tube



New DNA Tube



* One study site collects DNA at the 6 month visit

Purple vs Lavender Tubes

Lavender Tube

- 10 ml
- Whole blood for Plasma



Purple Tube

- 6 ml
- Whole blood
- Whole blood for DNA

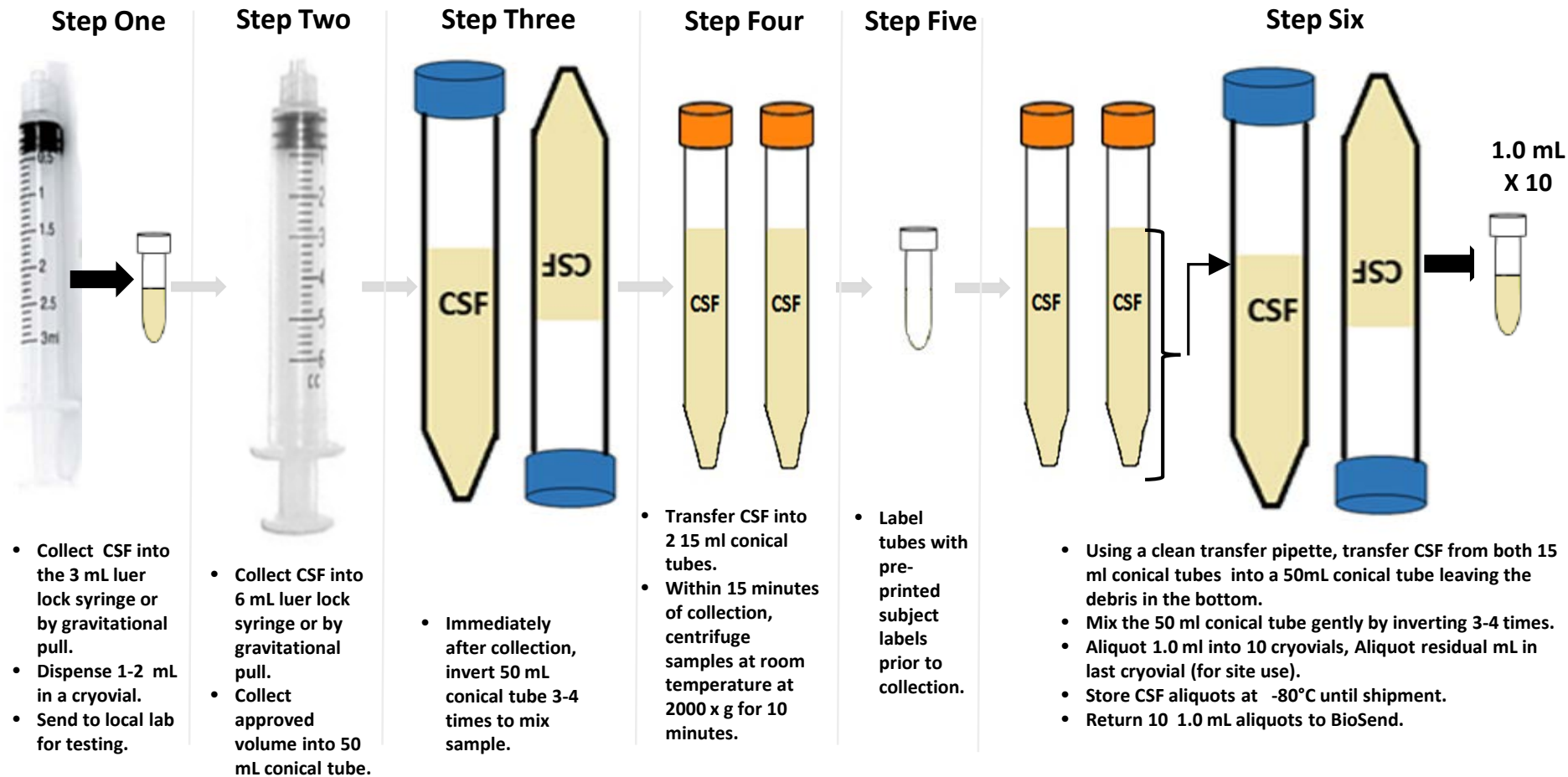


Order of Specimen Collection

1. Serum (red top) blood collection for serum (if applicable)
2. PAXgene™ tube for RNA
3. EDTA **6 ml (purple top)** blood collection for DNA (usually only at baseline)
4. EDTA **10 ml (lavender top)** blood collection for plasma
5. EDTA **6 ml (purple top)** blood collection for whole blood



CSF Preparation Processing



Combine the CSF in two-15 ml conical tubes into a single 50 ml conical tube to ensure complete mixing and reduce possible batch effects in CSF aliquots generated from different conical tubes

Sample Shipments to BioSEND

Sample Record and Shipment Notification

PDBP Sample Record and Shipment Notification

Site Name/Number: Principal Investigator:
 Coordinator: Telephone: Email:

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

GUID: Subject ID (ST# from pre-printed labels):
 Gender: Visit Type:
 Age in Years: Date Sample(s) Shipped:
 Plus Months: FedEx Tracking Number:
 Subject Indicator: Subject's Diagnosis:

Instructions: Ship Frozen Shipments Monday- Wednesday ONLY! Ambient Shipments (purple-top EDTA tube) may be shipped Monday- Friday (preferably Monday- Thursday) provided they are received at Indiana University within five days of collection. This form must be completed for shipment of all research samples. Notify Indiana University (email preferred) and the DMR in advance of shipment using contact information below. Place a copy in the shipment box and file a copy of the completed form in the study binder. Ensure all frozen shipments are filled with dry ice.

In the table below, please indicate the date of specimen collection and the Tube ID

Completed by Submitter/Site				Completed by Repository
Dates of Draw	Specimen Type	Number of Tubes/ Aliquots sent to BioSEND	Volume of Draw (mL)	Notation of Problems
	DNA			
	RNA			
	Plasma			
	Serum			
	CSF			
	WB			

Contact Information: Indiana University; Email: biosend@iu.edu Ph: 317-278-0495
 Data Management Resource (DMR); Email: PDBP-OPS@mail.nih.gov

- **PDBP and Udall sites must complete this form**
- **FTLD and PredictHD will also complete this form**
- **ALL sites must send form to:**
 - Casey Bales at biosend@iu.edu
- **PDBP and Udall sites ONLY must send form to:**
 - Jenna Linde at jenna.linde@nih.gov

Ambient Sample Shipment

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

Packaging Ambient Sample



- Insert tube into the tube sleeve.
- Insert the sleeve into the canister.
- Seal the canister tightly.
- Place case label on canister.
- Wrap the canister in the enclosed bubble wrap.
- Place canister into the cardboard box.

Labeling Ambient Sample Shipments

- Apply the UN3373 label to the outside of the cardboard box.
- Place the box and a copy of the PDBP 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.

A photograph of a FedEx air waybill form. The 'From' section is circled in red, indicating where to enter the sender's information. The form includes fields for name, address, city, state, zip, and phone number. The 'To' section is also visible, showing the recipient's information.

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.***

Frozen Samples

- **All other samples are shipped frozen**
 - Plasma, serum, CSF, PAXgene™ and whole blood
- **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**



Shipping Frozen Samples

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



Bulk Shipping

- Bulk shipping is available, with NINDS approval
 - Options include:
 - Samples from 2 subjects can be shipped together
 - Samples from up to 10 subjects can be shipped together
- Appropriate for high volume sites



Summary of Protocol Changes

- Changed tube for DNA



- Label appearance



- Labels included with kits

- Order of Specimen Collection



- CSF – combine contents of 2 conical tubes prior to aliquoting

Repository Transition

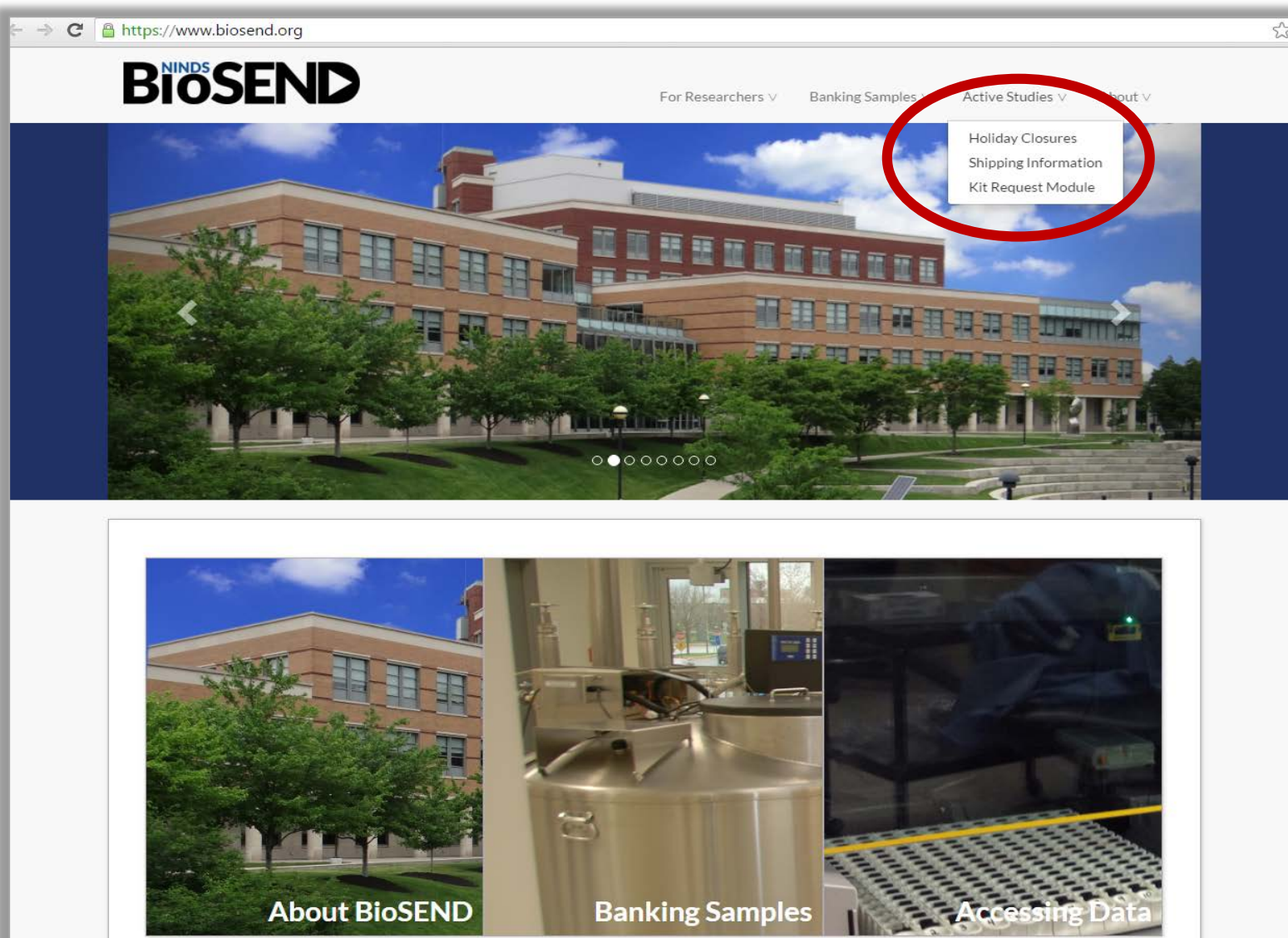
- **November 30, 2015:**
 - This is the LAST day that sites can ship previously collected samples to Coriell. All samples collected using a Coriell kit must be shipped by the end of this day.
- **November 30, 2015:**
 - Sites begin using kits and labels provided by BioSEND. The contents of these kits are to be shipped to BioSEND at Indiana University.

BioSEND Website

- Basic information now but will be expanding to include more information

<https://www.biosend.org>

NINDS BioSEND Website



<https://www.biosend.org/>

Holiday Closures

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

BioSEND Contact Information

- Questions?

Please contact Casey Bales:

- Phone: 317-278-0495
- Email: biosend@iu.edu