



# **Study in Parkinson Disease of Exercise Phase 3 Clinical Trial: SPARX3**

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BIOSPECIMEN COLLECTION & PROCESSING

# Overview

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1. Specimen uniformity and quality
2. Site Equipment
3. Procedures
  - Kit Ordering
  - Sample Labels
  - Sample Collection and Processing
  - Shipping Closures
4. Contact Information

# Specimen Uniformity and Quality

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GENERAL REMINDERS

# Specimen Uniformity and Quality

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Most biomarkers are sensitive to *time* and *temperature*

- Standardization of processing across sites is key
- Reference the *BioSEND Specimen Collection, Processing, and Shipment Manual* as needed
- Do not replace or supplement any kit components without first receiving approval from BioSEND/NINDS

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

# Site Equipment

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Sites will need to supply the following items:

## Phlebotomy

- Gloves
- Alcohol wipes
- Butterfly needles
- Tourniquet
- Gauze pads
- Bandages
- Sharps bin and lid



# Site Equipment

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Sites will need to supply the following items:

## Processing

- Crushed ice
- Microcentrifuge tube rack
- Calibrated micropipettes and pipette tips (adjustable or fixed at 200  $\mu$ l and 500  $\mu$ l)
- Centrifuge capable of maintaining 4°C with adapter for microtubes
- -80°C Freezer
- Dry ice




# Collection Protocol

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Visit & Sample Type	BL	6M	12M	18M	24M
Serum aliquots, 1.5ml	6	6	6	6	6
Plasma aliquots, 1.5 ml	6	6	6	6	6
Buffy Coat	2	2	2	2	2
Whole Blood, 3ml	2	2	2	2	2

# Kit Ordering – Biosend.org




Accessing  
Biospecimens

Banking  
Samples


Active Studies

About  
BioSEND

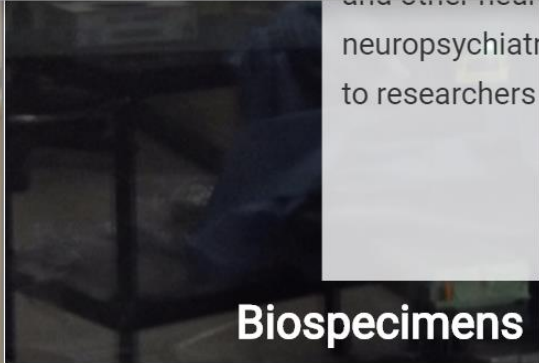
AJPD Study Resources	MBPS Study Resources	SPARX3 Study Resources
CHANGE-HD Study Resources	PBS Study Resources	Udall Study Resources
DLB Study Resources	PHD3 Study Resources	Holiday Closures
DVRP Study Resources	PSP Study Resources	Shipping Information
EpiBioS4Rx Study Resources	SBPD Study Resources	Sample Shipment Form
LBD Study Resources	CRC-SCA Study Resources	
LETBI Study Resources	READISCA Study Resources	



About BioSEND



Banking Samples



Biospecimens



# Kit Ordering

Direct link to kit ordering system:

<http://kits.iu.edu/biosend/sparx3/>

## Study in Parkinson Disease of Exercise Phase 3 Clinical Trial (SPARX3) Study Page



Welcome SPARX3 Study staff, coordinators, and PIs. This section encompasses study specific tools and resources for your reference. If you have any questions, comments, or new ideas please contact [biosend@iu.edu](mailto:biosend@iu.edu) or by phone directly at (317)278-0594.

### Specimen Table

Cohort	Population	Genomic DNA	Plasma	Whole Blood
SPARX3	PD Cases	✓	✓	✓

### Study Resources

#### Kit Request Module

Please follow the below link to access the SPARX3 Kit Request Module. This link will direct you to a REDCap database where study coordinators and staff may request kits, individual supplies, and/or labels. Please allow a total of two weeks for kit requests to be compiled and delivered to your site.

[SPARX3 Kit Request System](#)



# Kit Contents and Ordering

SSBC Kit Request Module

<b>Study Site</b> <small>* must provide value</small>	Indiana University	<div>Select your site from the drop-down list</div>
Indiana University School of Medicine Carolyn Dunifon Dept. of Medical & Molecular Genetics 351 West 10th Street, TK-318 Indianapolis, IN 46202-3002 (317) 274-5751 cdunifon@iu.edu		
<b>Is the contact name above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No	<div>Verify contact information and update if needed</div> <div>reset</div>
<b>New Contact Name</b> <small>* must provide value</small>	Claire Wegel	
<b>Is the shipping address above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	<div>reset</div>
<b>Is the e-mail address above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	<div>reset</div>
<b>Is the phone number above correct?</b> <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No	<div>reset</div>

# Confirm Shipping Info

## Confirm site information:

- Study site
- Shipping address
- Contact name
- Email
- Phone Number

Indiana University

Carolyn Dunifon  
Indiana University School of Medicine  
351 West 10th Street  
TK-217  
Indianapolis, IN 46202  
(317) 274-5751  
biosend@iu.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 Ordering

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**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.

Multiple kit types available

# Kit Ordering

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<b>Kit Type</b> <b>**Please allow two weeks for shipment**</b> <small>* must provide value</small>	<input checked="" type="checkbox"/> Baseline Visit Kit <input type="checkbox"/> Annual Visit Kit <input type="checkbox"/> Supplemental Kit <input type="checkbox"/> Extra Supplies  <small>Please specify in comments if you need kits before the standard two week shipment time.</small>
<b>Baseline Visit Kit Quantity</b> <small>* must provide value</small>	<input type="text"/>



- BioSEND creates ST-Numbers for baseline kits
- ST#s serve as the biorepository subject identifier
- Enter kit quantity

# Kit Ordering

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Please note: the ST-Number provided in a BL kit can be used for any subject's BL visit. **This ST number is a subject identifier** and will need to stay linked to the patient through the entirety of the study.

# Kit Ordering

<b>Kit Type</b> <b>**Please allow two weeks for shipment**</b> <small>* must provide value</small>	<input type="checkbox"/> Baseline Visit Kit <input checked="" type="checkbox"/> Annual Visit Kit <input type="checkbox"/> Supplemental Kit <input type="checkbox"/> Extra Supplies  <small>Please specify in comments if you need kits before the standard two week shipment time.</small>
<b>Annual Visit Kit Quantity</b> <small>* must provide value</small>	<input type="text" value="1"/> <small>If requesting annual kits, you must provide the ST-numbers of all kits needed. Not doing so will cause delay in shipment, as we are unable to complete your request without this information.</small>
<p>If you going to request more than 10 kits/labels 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:  <a href="#">BioSEND_Kit_IDs_Template.xlsx</a> (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> <p> <a href="#">Upload document</a></p>	
<b>1st Kit Visit ID</b> (only if not using file upload option)	<input type="text"/> <small>e.g. ST-00012345</small>
<b>1st Kit Visit Month</b>	<input type="text" value="▼"/>
<b>Comments</b>	<div><div></div><div>Expand</div></div>

Please provide ST# and visit type for follow-up kits. We cannot complete your request without this information.

# Kit Ordering

<b>Kit Type</b> **Please allow two weeks for shipment** <small>* must provide value</small>	<input type="checkbox"/> Baseline Visit Kit <input type="checkbox"/> Annual Visit Kit <input checked="" type="checkbox"/> Supplemental Kit <input type="checkbox"/> Extra Supplies <small>Please specify in comments if you need kits before the standard two week shipment time.</small>
<b>Supplemental Kit Quantity</b> <small>* must provide value</small>	<input type="text" value="1"/>
<b>Comments</b>	<div></div> <div>Expand</div>
<b>Each Supplemental Kit Contains:</b>  10 - Purple-top EDTA tubes (Plastic, 10 ml) 10 - Purple cryogenic vials (2 ml) 10 - Grey cryogenic vials (2 ml) 10 - Disposable transfer pipettes (3ml) 2 - Cryobox, 25-slot 5 - Biohazard bag with absorbent sheet 5 - Shipping label packet (incl. waybill)	

Contains a variety of extra kit components



# Kit Ordering

Allows you to choose specific supplies and particular quantities

<b>Kit Type</b> **Please allow two weeks for shipment** <small>* must provide value</small>		<input type="checkbox"/> Baseline Visit Kit <input type="checkbox"/> Annual Visit Kit <input type="checkbox"/> Supplemental Kit <input checked="" type="checkbox"/> Extra Supplies
<small>Please specify in comments if you need kits before the standard two week shipment time.</small>		
Resealable Tube Pouches	<input type="radio"/> 2 <input type="radio"/> 4	reset
Cryobox	<input type="radio"/> 2 <input type="radio"/> 4	reset
Cryogenic Vial (2 ml) - Grey	<input type="radio"/> 10 <input type="radio"/> 20	reset
Cryogenic Vial (2 ml) - Purple	<input type="radio"/> 10 <input type="radio"/> 20	reset
FedEx® return Airbill	<input type="radio"/> 2 <input type="radio"/> 4	reset
Shipping Container for Dry Ice Shipments (includes shipping labels & airbill)	<input type="radio"/> 2 <input type="radio"/> 4	reset

# Kit Ordering

- Click “Submit” to send order to BioSEND; staff will confirm receipt of your order
- Please allow two week turn-around time for kit shipments
- If urgent request needed, please note date needed by in comments and email BioSEND

**NINDS**  
**BioSEND**

Resize font:  
⊕ | ⊞

NINDS Biosend SPARX3 Kit Request System

Study Site  
\* must provide value

Northwestern University ▼

Northwestern University

Contact Name  
Shipment Address  
Email  
Phone

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  
**\*\*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.

Comments

Expand

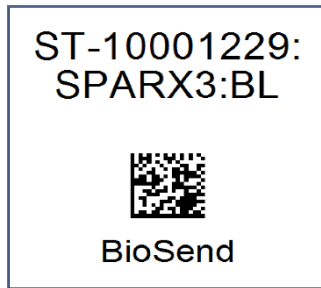
Submit

# Sample Labelling

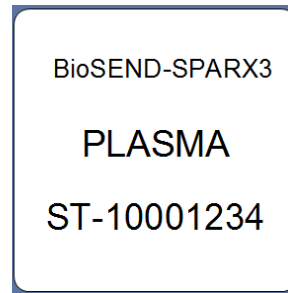
---

## Labels are provided by Indiana University

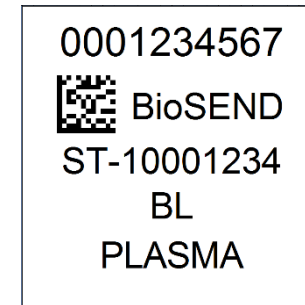
- Please check that all samples are properly labelled with correct specimen type and visit



Case Labels



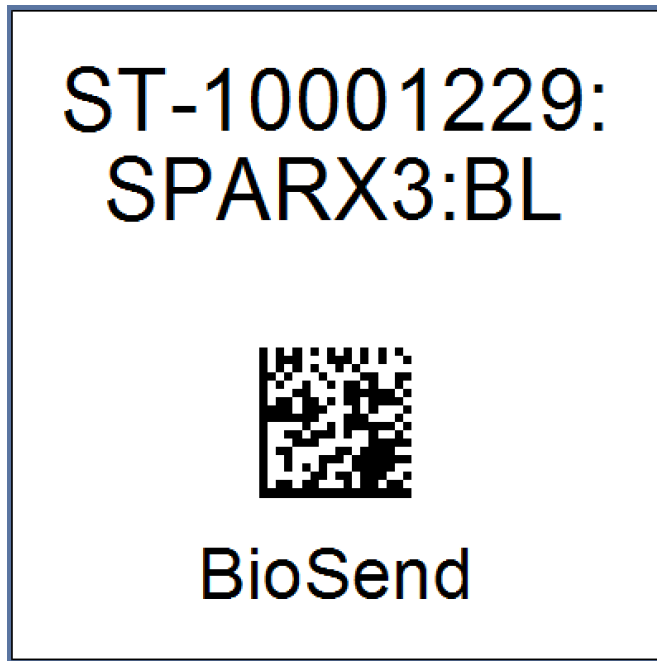
Cryovial Labels



Collection Tube Labels

# Sample Labelling – Case Labels

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← **Subject Number**

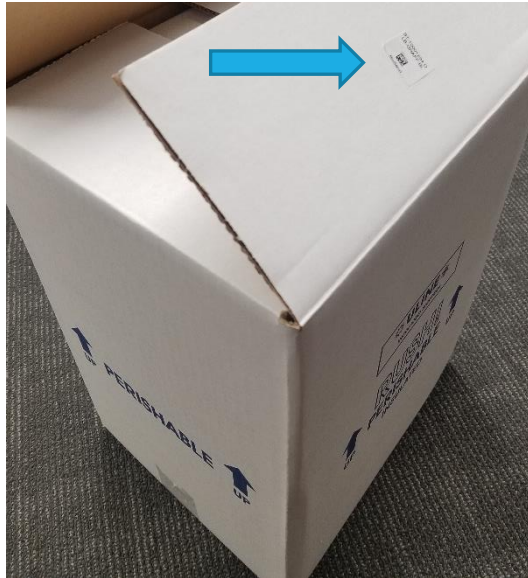
← **Study and Visit**

← **Biorepository Name**

# Sample Labelling – Case Labels

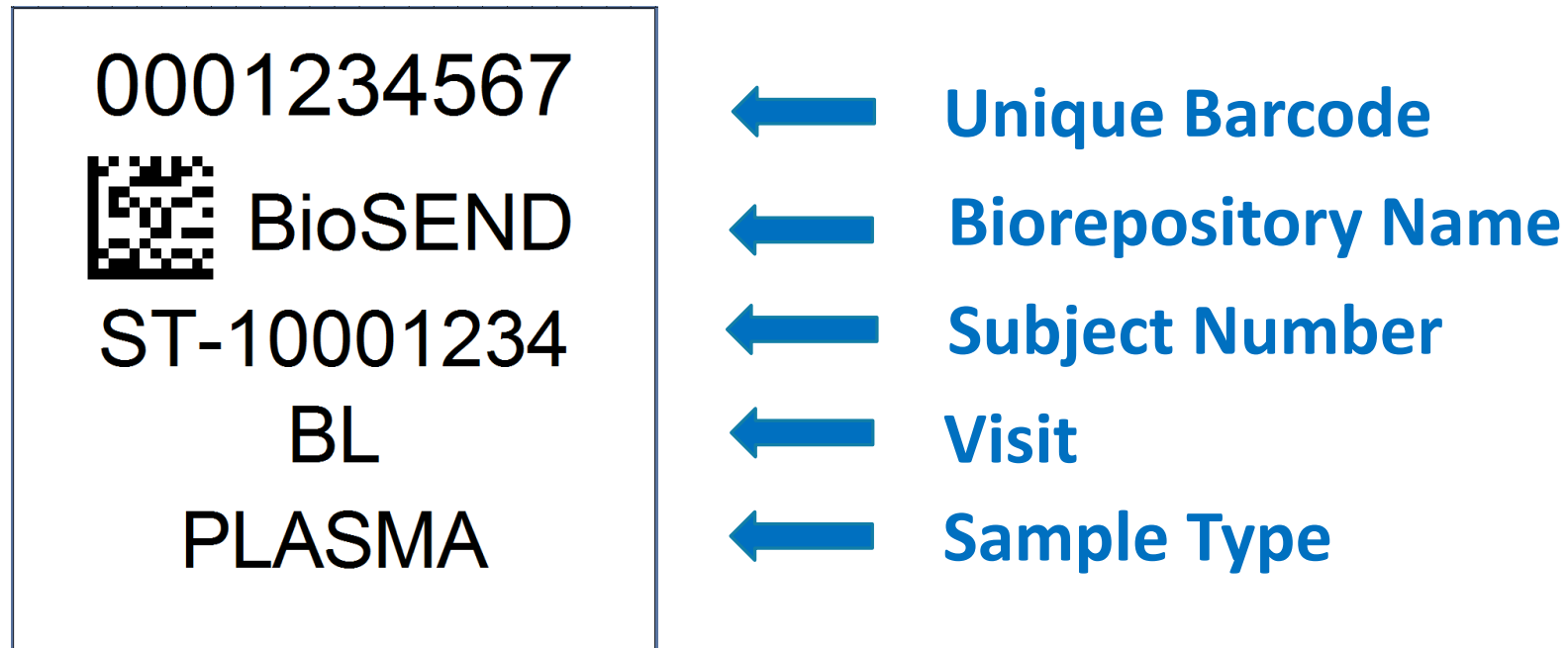
Case labels are placed:

- On the biohazard bag of the cryovial transport box and biohazard bag with EDTA.
- On the lid of frozen shippers



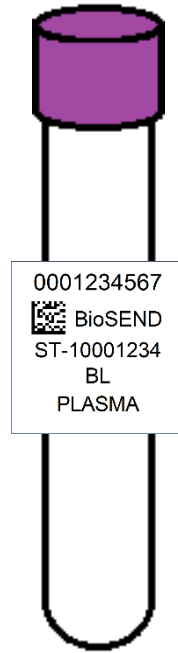
# Sample Labelling – Collection Tube Labels

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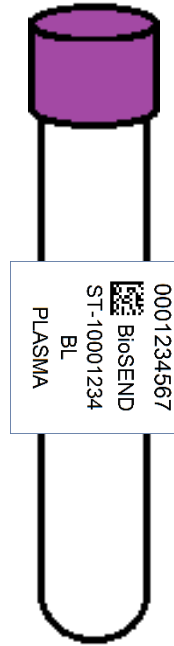


# Sample Labelling – Collection Tube Labels

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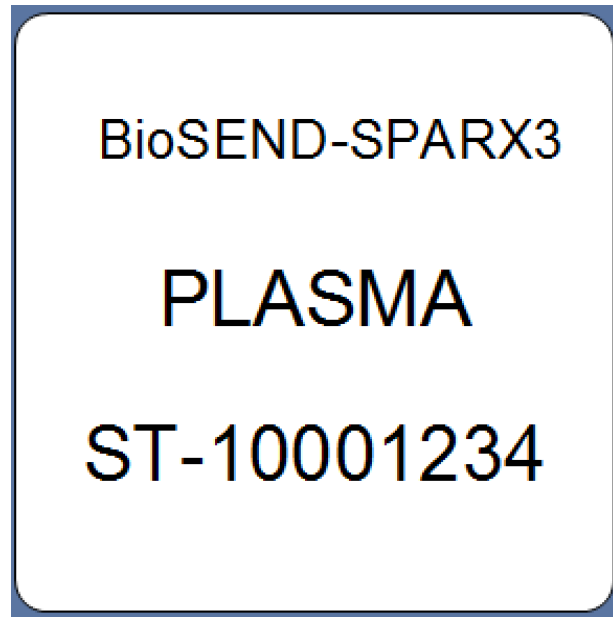
Incorrect



Correct

# Sample Labelling – Cryotube Labels

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**Biorepository/Study**



**Sample Type**



**Subject Number**



# Sample Labelling – Cryotube Labels

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Note: cryotube barcodes are printed on tube, not on the label. Barcodes are tied to the specific kit they arrive in (ie, a specific subject and visit). **Please do not mix the labels from one kit with the cryotubes from another.**

Barcode is in human readable format on side of tube, 2D format on bottom of tube



BioSEND-SPARX3  
BUFFY COAT  
ST-10001234

# Sample Labelling – Cryotube Labels

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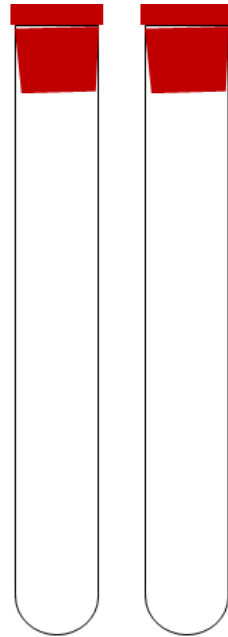
Please verify that you are using the correct cryotube for the correct specimen type

Cap Color	Specimen Type
Purple	Plasma
Grey	Buffy Coat
Red	Serum

# Sample Collection and Processing

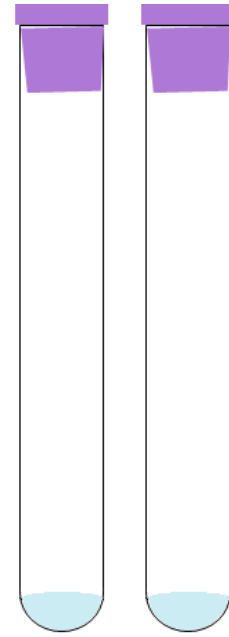
Blood Tube Draw Order

2 x 10ml Serum



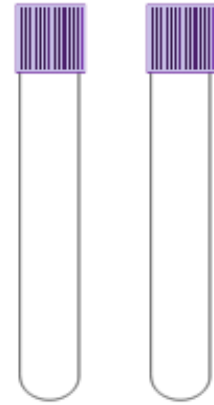
**1**

2 x 10ml EDTA  
for plasma and  
buffy coat



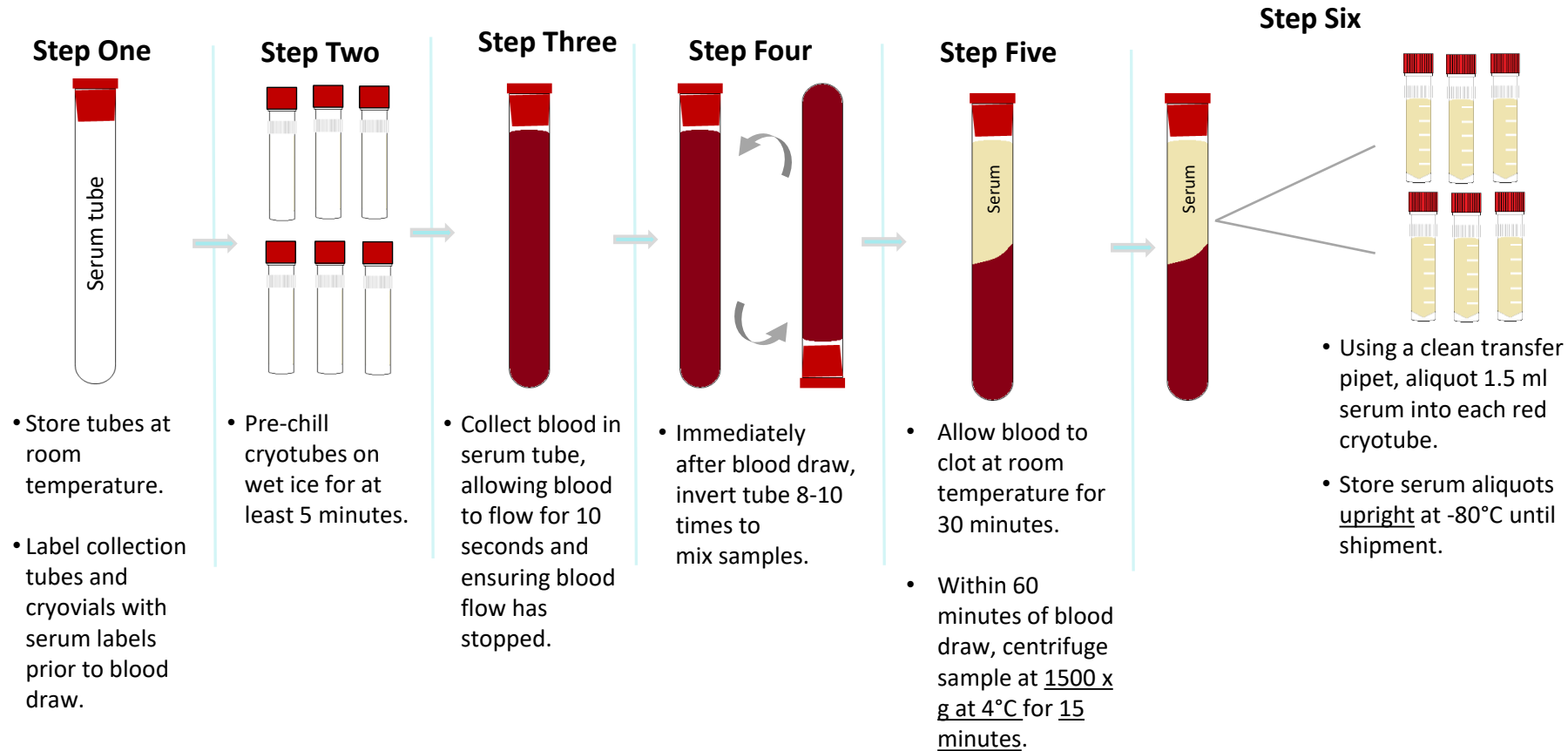
**2**

2 x 3ml EDTA  
for whole  
blood

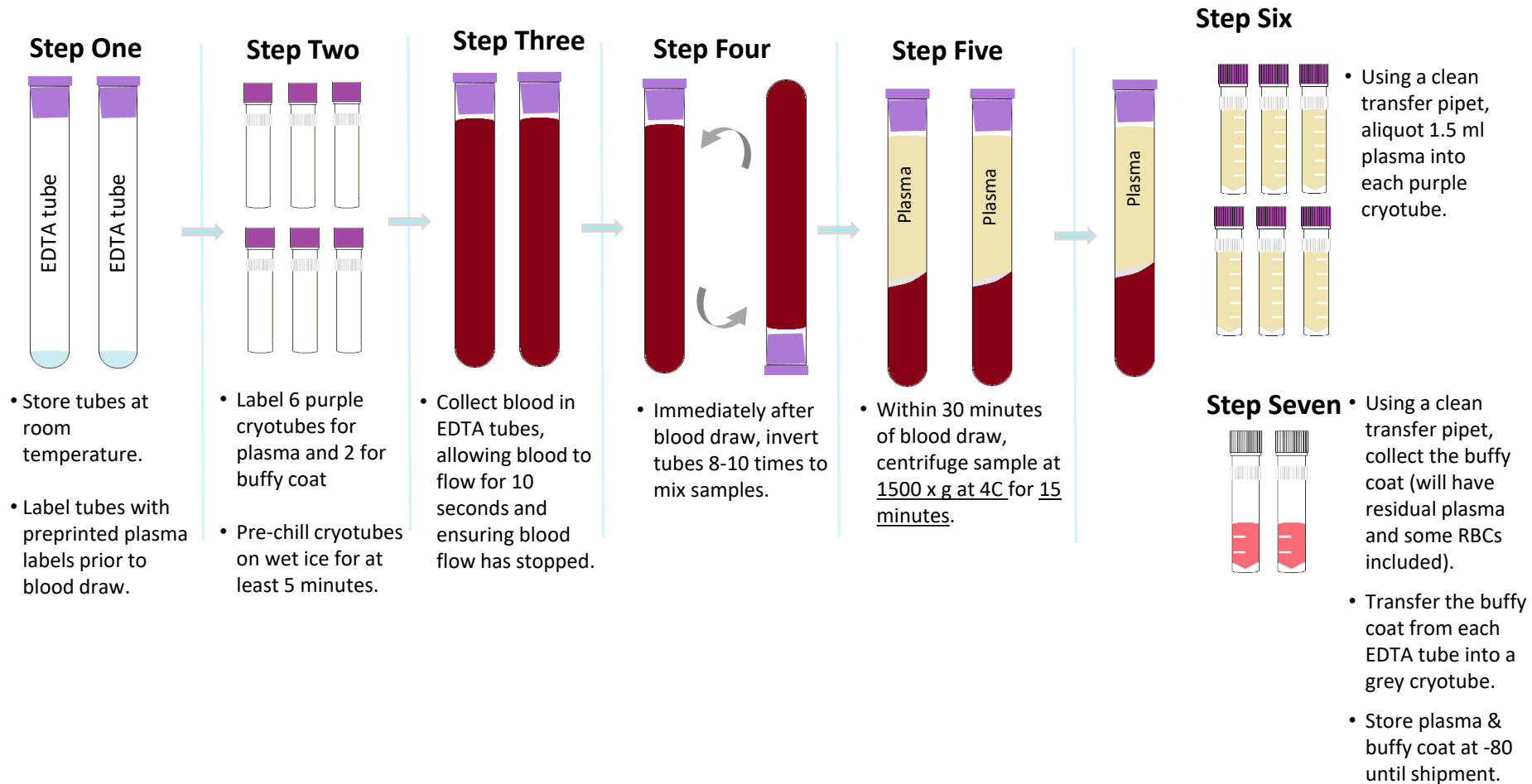


**3**

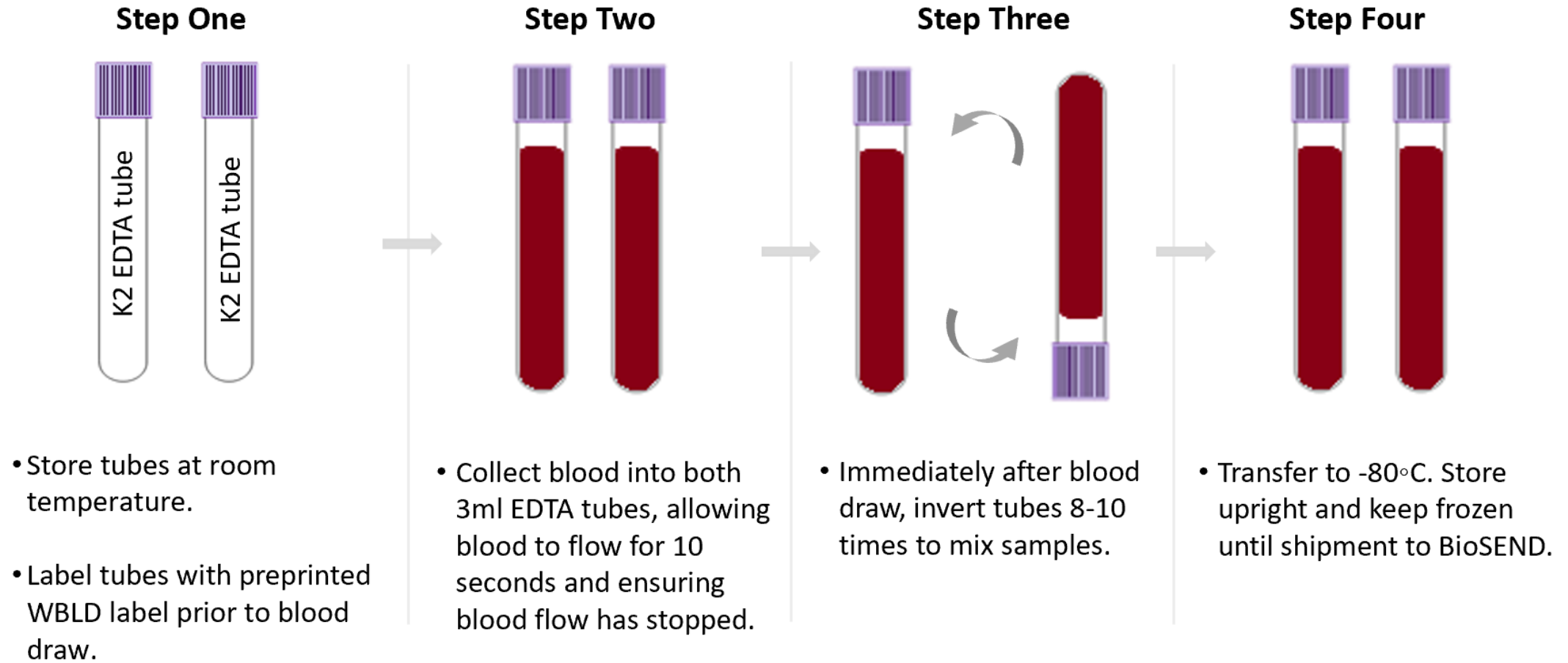
# Sample Collection and Processing: Serum



# Sample Collection and Processing: Plasma & Buffy Coat



# Sample Collection and Processing: Whole Blood

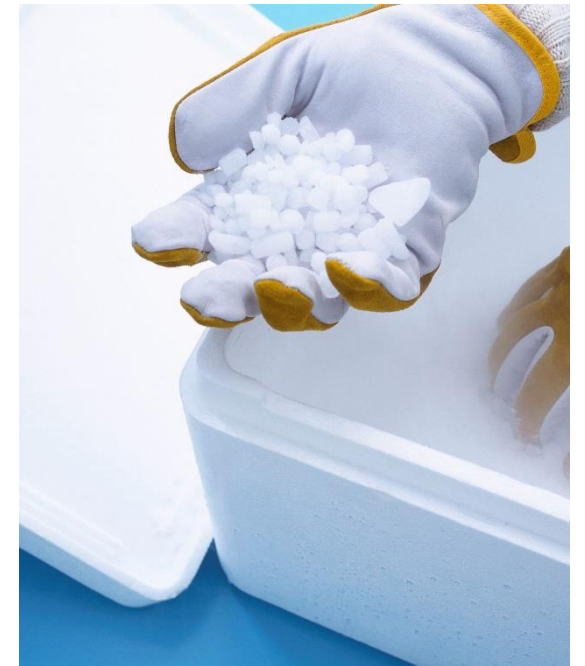


# Shipping Samples: Frozen

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## Packing and Shipping Frozen Samples

- All SPARX3 samples ship frozen
- Ship frozen samples on dry ice
- Frozen samples should be shipped **only** Monday through Wednesday
- Always fill carton to **top** with dry ice
- Do not pack shipment until the day of pickup



# Shipping Samples: Frozen

## Packing and Shipping Frozen Samples

- Shippers use approx. 10lbs of dry ice
- Place layer of dry ice in between cryoboxes





# Shipping Frozen Samples

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Hold packaged samples in a -80°C freezer until pickup.

***Samples should be received at BioSEND within 2 weeks of collection.***



# Shipping Samples

## Packing and Shipping Frozen Samples

Class 9 Dry Ice Label should not be covered with other stickers and must be completed, or courier will reject/return your package!

Shipper's Declaration not Required.

Dry Ice amount must be in kilograms.

Note: 2 lbs. = 1 kg.

Airwaybills / airbills must have the following:  
1. Dry Ice; 9; UN 1845  
2.  $\frac{\text{Number}}{\text{(Number pks)}} \times \frac{\text{wt}}{\text{(wt)}} \text{ Kg}$

Net weight of dry ice in kg

Dry Ice            kg.

Your name & address

Shipper's Name and Address

UN 1845

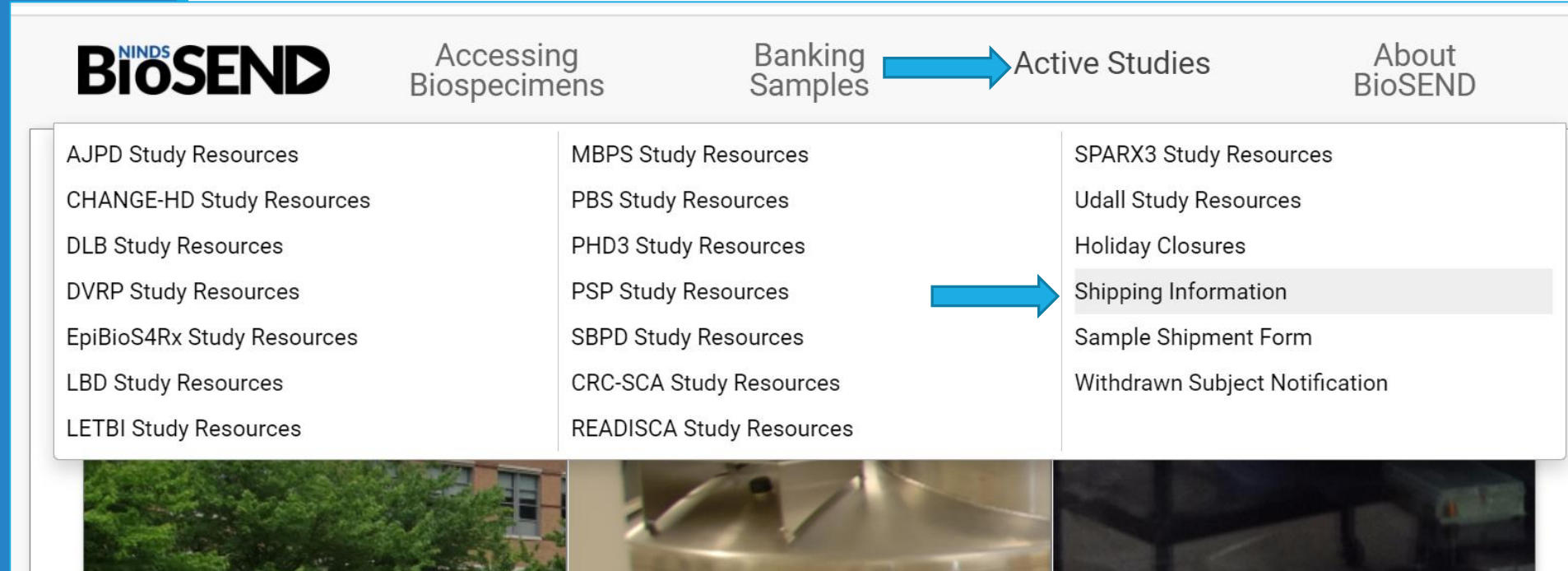
Consignee Name and Address

IU information and address

06426 1/01 RRD

# Shipping Samples

UPS resources available on BioSEND website



The screenshot shows the NINDS BioSEND website navigation menu. The menu is organized into four main categories: Accessing Biospecimens, Banking Samples, Active Studies, and About BioSEND. A blue arrow points from 'Banking Samples' to 'Active Studies'. The 'Active Studies' dropdown menu is open, showing a list of study resources. A blue arrow points from 'PSP Study Resources' to 'Shipping Information', which is highlighted in the list.

**NINDS BioSEND**

Accessing Biospecimens    Banking Samples → Active Studies    About BioSEND

AJPD Study Resources	MBPS Study Resources	SPARX3 Study Resources
CHANGE-HD Study Resources	PBS Study Resources	Udall Study Resources
DLB Study Resources	PHD3 Study Resources	Holiday Closures
DVRP Study Resources	PSP Study Resources → Shipping Information	Sample Shipment Form
EpiBioS4Rx Study Resources	SBPD Study Resources	Withdrawn Subject Notification
LBD Study Resources	CRC-SCA Study Resources	
LETBI Study Resources	READISCA Study Resources	

Below the menu, there are three small images: a green tree, a close-up of a metal surface, and a dark, indistinct image.

## Shipping Information



# Shipping Samples

Links on this page to generate airwaybills, schedule pickups, request account, and view a guide for using the UPS ShipExec Thin Client system.

### Shipping Address

BioSEND  
Indiana University School of Medicine  
351 West 10th Street  
TK-217  
Indianapolis, IN 46202

### UPS Shipping Resources

To generate air waybills and schedule UPS pickups for shipments to BioSEND, please visit the UPS ShipExec™ Thin Client [website](#).

For instructions on how to use the UPS ShipExec™ Thin Client website, please refer to the [BioSEND UPS ShipExec™ Thin Client Guide](#)

To request a new user account for UPS ShipExec™ Thin Client or to request an update to your site's address in the system, please [use this form](#) to submit your request.


### Additional Resources

[Sample Submission Form](#)  
[UPS ShipExec™ Guide](#)

### Contact Us

[biosend@iu.edu](mailto:biosend@iu.edu)  
317-278-0594

# Shipping Samples – UPS: <https://kits.iu.edu/UPS>



**INDIANA UNIVERSITY**  
SCHOOL OF MEDICINE

and Affiliated Biorepositories

Search for address

Code

Company

Contact

Address 1

Address 2

Address 3

City

State/Province

Postal Code

Country/Territory

Ship From

Clear

Icahn School of Medicine - Mt. Sinai

Kenny Persaud

1425 Madison (Icahn Building)

Icahn L4 39

New York

NY

10029

United States

Shipment Information

Study Group

Weight

Dry Ice Weight

Description of Return

Pickup Request

SSBC

20

LB

10

LB

Biologic Specimens

Choose Study

Enter weight

Click "Ship"

Reset

Ship

# Shipping Samples

UPS

- Print out UPS air waybill
- Fold and insert UPS air waybill into clear plastic sleeve on package

JOHN SMITH INDIANA UNIVERSITY 410 WEST 10TH STREET INDIANAPOLIS IN 46202	2 LBS	1 OF 1
RS		
SHIP TO: SCHOOL OF MEDICINE 317-278-2694 INDIANA UNIVERSITY TK 217 351 W 10TH ST INDIANAPOLIS IN 46202		
	IN 461 9-01	
		
UPS NEXT DAY AIR		1
TRACKING #: 1Z 976 R8W 84 3985 8595		
 SAMPLE		
BILLING: P/P DESC: Biological Specimens RETURN SERVICE		
Reference No.1: 4087277		
XOL 20.03.09 NV45 83.0A 12/2019		 TM

# Shipping Samples: Notification


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Please notify BioSEND **ahead** of shipment

- Email [biosend@iu.edu](mailto:biosend@iu.edu) with copy of Sample Form and tracking number
- OR use Online Sample form on biosend.org

# Shipping Samples: Sample Form

## Study in Parkinson Disease of Exercise Phase 3 Clinical Trial (SPARX3) Study Page



Welcome SPARX3 Study staff, coordinators, and PIs. This section encompasses study specific tools and resources for your reference. If you have any questions, comments, or new ideas please contact [biosend@iu.edu](mailto:biosend@iu.edu) or by phone directly at (317)278-0594.

### Specimen Table

Cohort	Population	Genomic DNA	Plasma	Whole Blood
SPARX3	PD Cases	✓	✓	✓

### Study Resources

- Kit Request Module
- Study Specific Sample Notification Forms
- SPARX3 Manual of Procedures
- SPARX3 Training Slides
- SPARX3 Site Listing

### Downloads

- Sample Shipment Form (pdf)
- Sample Shipment Form (xlsx)
- SPARX3 Manual of Procedures
- New Coordinator Training Slides

### Additional Resources

- Online Sample Form


### Contact Us

[biosend@iu.edu](mailto:biosend@iu.edu)  
317-278-0594



# Shipping Samples: Sample Form

## Sample Record and Shipment Notification



Please fill out and submit this form when shipping samples to BioSEND. After submission, please print a copy of the form to include with your submission. If you prefer to not use the online system, you may download a pdf version of this form from the sidebar to the right.

### Contact Information

Site Name/Number

Coordinator

Telephone

Email

### Subject Information

Study

Clinical ID

GUID

Subject ID (ST# from labels)

Gender

Visit Type

### Sample Information

Date Sample(s) Shipped

FedEx Tracking Number

Draw Date	Specimen Type	# of Tubes Sent	Notation of Problems
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

# Shipping Samples: Closures

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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

Please also consider weather when shipping. UPS will post service updates on their webpage. Reach out to BioSEND if you are unsure if it is safe to ship.

# Non-Conformance Reporting

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Most common non-conformance issues:

- Samples shipped for weekend/holiday delivery
- Sample form incomplete/inaccurate
- Unlabeled or mislabeled tube(s)
- Sample hemolysis



# Contacts

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## Indiana University

General Questions/Shipment Notifications:

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

Biorepository Project Manager:

Claire Wegel

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

Tel: 317.278.6158

Biorepository Clinical Research Coordinator:

Carolyn Dunifon

[cdunifon@iu.edu](mailto:cdunifon@iu.edu)

Tel: 317.274.5751