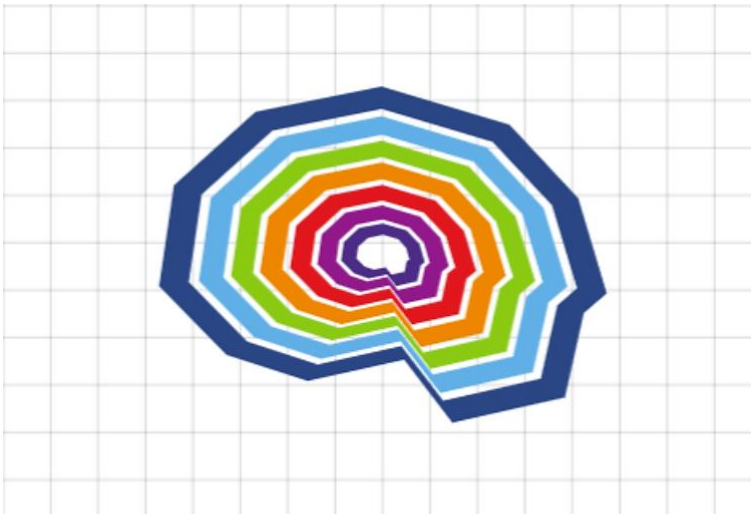


The STEP Biobank

A Platform for Discovery across
the Stroke Continuum





STEP Biobank

STEP Biobank Team

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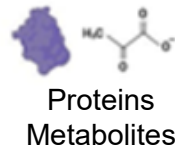
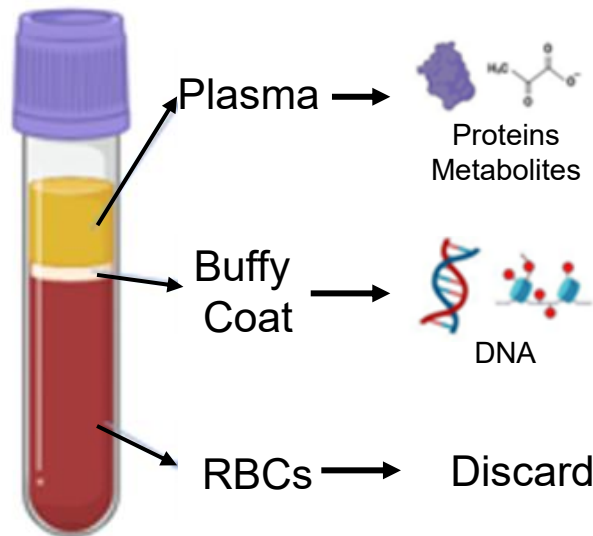
StrokeNet Prog Director, NINDS

Agenda

- Introduction to the STEP Biobank
 - Unique resource for multi-omic studies
 - Accessing biosamples
- STEP Biosample Training
 - Lab kits
 - Blood draws
 - Blood processing
 - Shipping

STEP Biobank

- Blood will be collected in all patients enrolled in STEP assets
 - 2 tubes of blood at 24 hours time-point (or any time during hospitalization)
 - No new phenotyping will be added (only blood collection)
- Banked at the WashU Neurogenomics & Informatics Center
 - Isolation and storage of DNA, RNA, and plasma
- Enables multi-omic studies in stroke patients

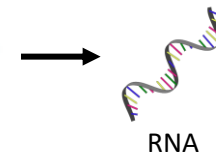


**Proteomics
Metabolomics**



**Genomics
Epigenomics**

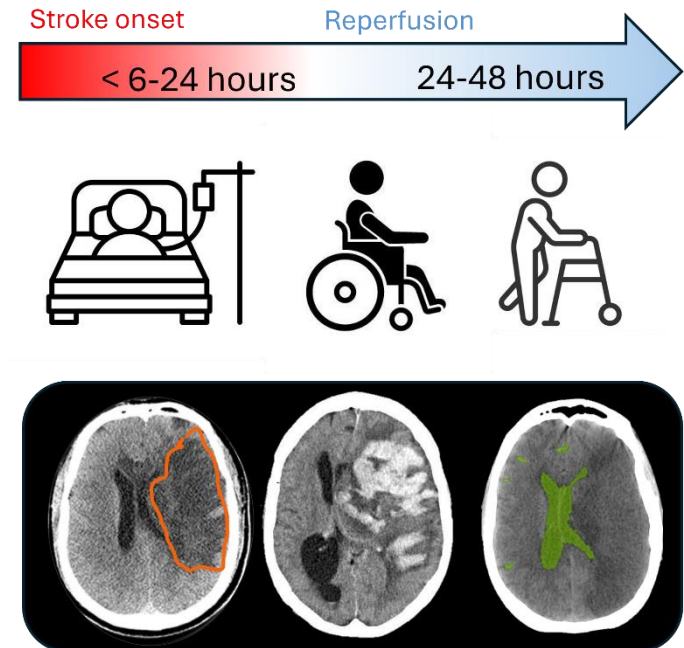
RBCs → Discard



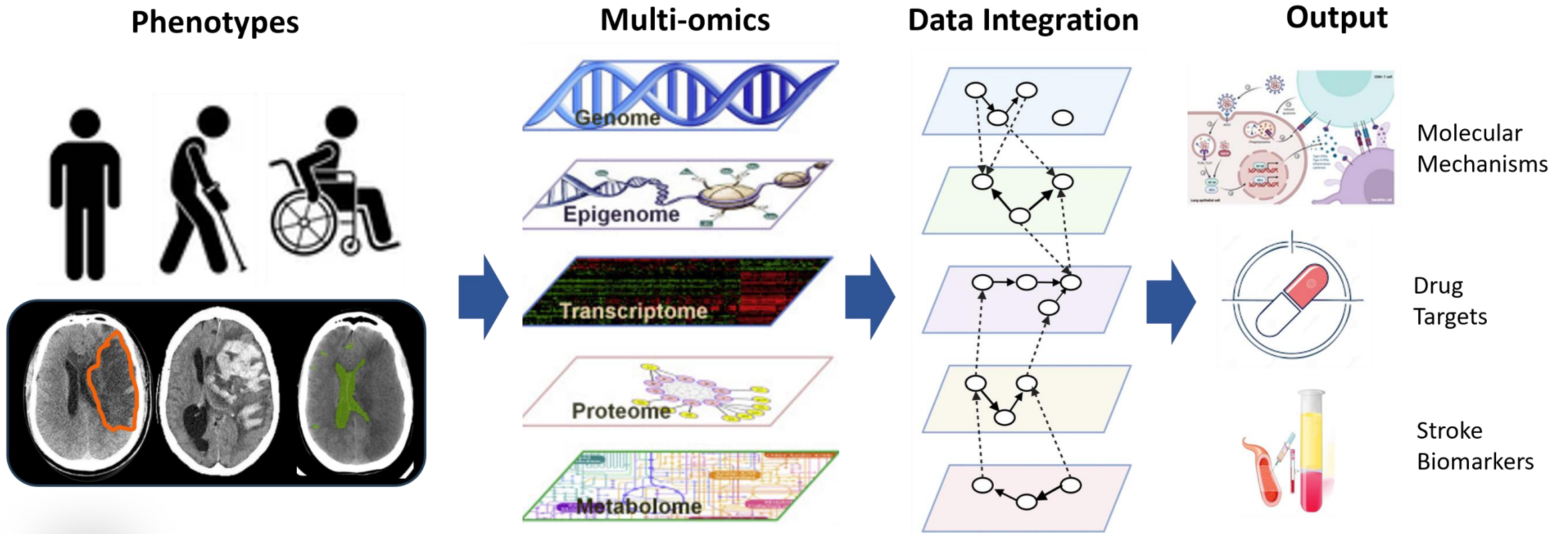
Transcriptomics

What Makes the STEP Biobank Unique?

- Deep phenotyping of LVO AIS
 - Serial neurological assessments
 - Anatomic & physiological neuroimaging
 - Serial neuroimaging (CTs, MRIs)
 - Vascular imaging (CTA, cerebral angiograms)
 - Physiological imaging (CTP)
 - Standardized baseline & outcome measures
- Cerebral ischemia coupled with reperfusion
 - Understand pathobiology of acute brain ischemia and reperfusion injury
- Extraction of DNA, RNA, and Protein
 - Genomics, Transcriptomics, and Proteomics
 - Mechanistic studies to identify potential drug targets



From Phenotypes to Multi-omics to Mechanisms to Biomarkers & Drug Targets



Sharing STEP Biosamples

- STEP biosamples can support a wide range of future research, and will be **widely shared**.
- A **STEP Biobank Committee** will oversee access to these biosamples.
- The **Committee** consists of (one representative from each group):
 - **STEP PIs:** Eva Mistry, Jordan Elm, Pooja Khatri
 - **Biobank Directors:** Carlos Cruchaga, Jin-Moo Lee
 - **NINDS Leadership:** Carlos Faraco or designee
 - **Director of another Biobank**
 - **STEP Site PI's (2)**
 - **Stroke Survivor**



Sharing STEP Biosamples

- All requests for biosamples will undergo review by the **STEP Biobank Committee**, based on:
 - Responsible use of biosample resources
 - Scientific merit / potential impact
- Approved projects will require:
 - Material Transfer Agreements (MTA)
 - Data Use Agreements (DUA)
- **For grant submissions:**
 - Committee approval is not required
 - Director will provide letter of support if the request is feasible
 - If the grant is funded, the committee will then be engaged (some assets have already requested biosamples)



Training

Training Materials

Training:

- All site staff involved in the blood collection process should read the Biobank Instructions.
- All site staff can watch this training video at:

Link for Training Folder:

<https://dcu.musc.edu/campus/>

Equipment:

- Centrifuge should be in working order and tested as required by manufacturer.
- -80°C freezer
 - Temperature monitoring system is advisable.

**If any samples have been compromised for any reason,
please inform the coordinators at the Biobank**

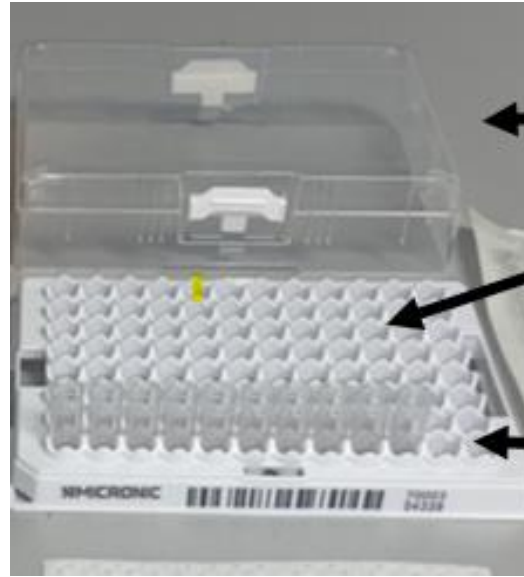
Collection Kits

- The **initial shipment** from the STEP Biobank will **include 5 of each different kits.**

Buffy Coat Kit



Plasma Kit



1-96 Well Plate
with Lid

10x 0.75ml
Microtube Plasma
Tubes



PAXgene Kit

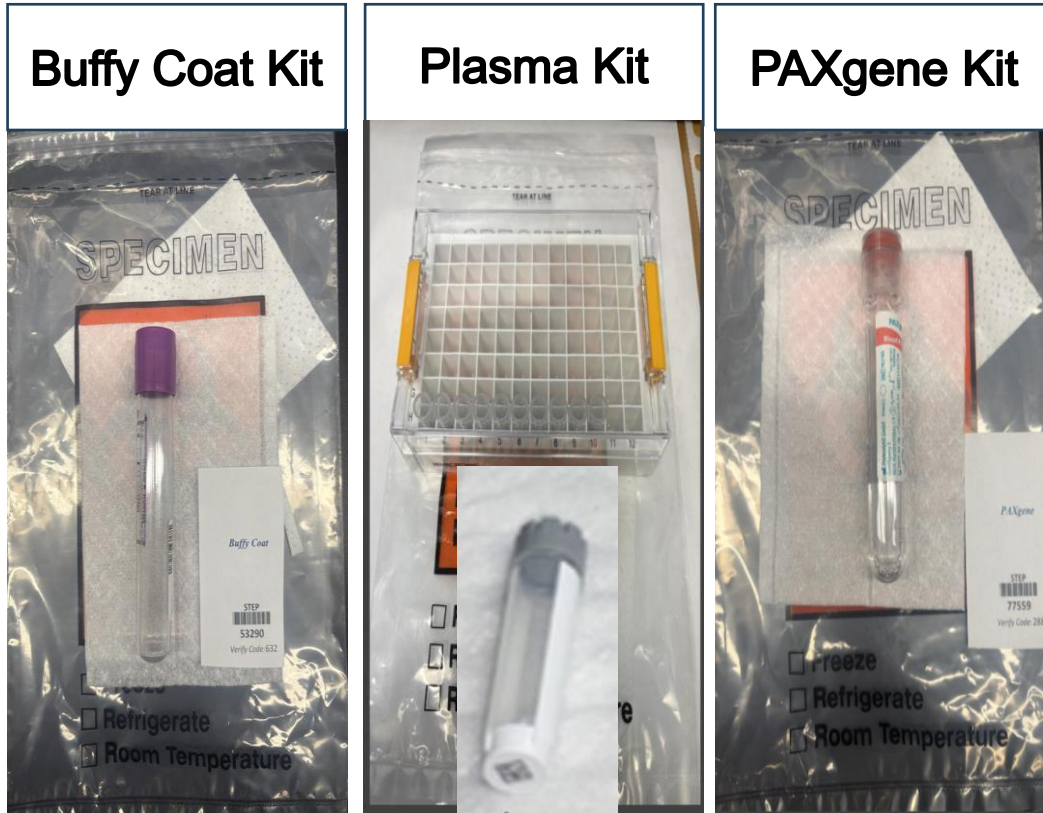


Supplying & Resupplying Kits

- WebDCU™ will automatically track the number of kits each site has remaining.
- When sites have 3 of each kits left in their inventory, WebDCU™ will alert the STEP Biobank to create and ship more kits to a specific site.
- Supplies will arrive at sites within 1-2 weeks of the WebDCU™ automated alert.
- Sites will be notified by WebDCU™ when the shipment is sent.
- Samples will be shipped and stored at STEP Biobank at Washington University in St. Louis.

If you have any other Biobank questions/comments/concerns, please contact the NGL Coordinators (contact information on Slide 27).

Preparation for Blood Draw



Step Biobank Provides:

Buffy Coat Kit: 10mL Purple-top EDTA Tube (prelabeled)

Plasma Kit: Plasma Aliquots, 10× 0.75ml Microtubes in a 96- Well Plate (prelabeled)
1 Plasma 3ml Screwcap Microtube (prelabeled)

PAXgene Kit:
2.5mL PAXgene RNA Blood Tube (prelabeled)

Preparation for Patient Blood Draw

Extra Material (provided by STEP Biobank)

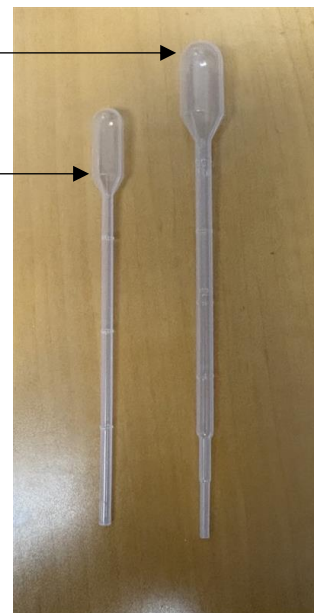
1 × 3ml Disposable Sterile Transfer Pipette

1 × 0.3ml Disposable Sterile Transfer Pipette

1 × Slotted Absorbent Material

1 × Biohazard Transport Bag

1 × FedEx label



Suggested Blood Collection Supplies

(not provided by STEP Biobank)



After consent is obtained, gather blood drawing tools available on site, including:

- Gloves
- Tourniquet
- Alcohol prep pad
- Vacutainer holder
- Blood draw needle
- 2x2 gauze pad
- Bandages
- Biobank provided draw tubes (EDTA & PAXgene).
- Male Luer-Lok™ Vacutainer Adaptors (only needed for IV or central line blood draw)

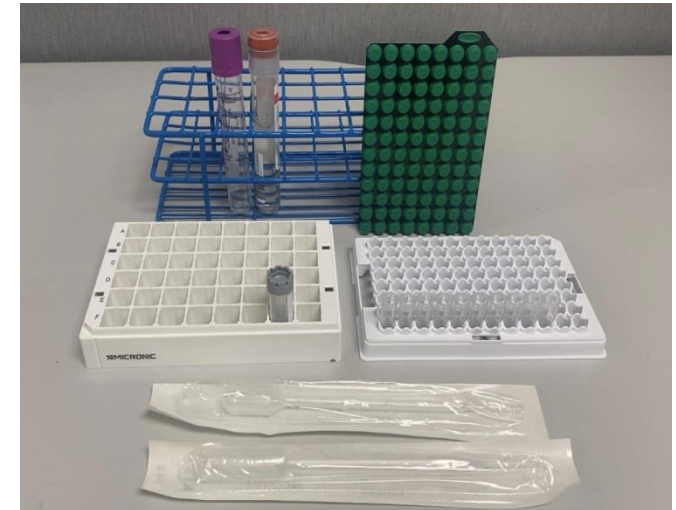
NOTE: If sample has an infectious blood disease, please mark the sample labels with “INF.”

Blood processing supplies should be gathered in the lab area, including:

- 10 – 0.75ml Microtubes with pushcaps in Empty Rack
- 1 – 3ml Grey lid Microtube
- 1 – 0.3ml Pipette
- 1 – 3ml Pipette
- 1 – Standard Sized Tube Rack

Wet ice placed in container may be used if transporting the EDTA tube for processing.

Always handle microtubes with gloves on.



Labels

Tubes will be sent pre-labeled. **It is critical not to mix components across kits.** If a kit is damaged, contact us for proper instructions.

1. Buffy Coat Kit

- Step biobank unique sample code assigned to the sample
- Verify code is a secondary confirmation code that is entered into WebDCU when confirming receipt of lab kits.

2. Plasma Kit

- Primary Sample Code affixed to the plate
- Verify code is a secondary confirmation code that is entered into WebDCU when confirming receipt of lab kits.
- Aliquot tubes labels (11 individual labels per aliquot, derived from the primary sample code, affixed to each vial)

3. PAXgene Kit

- STEP unique sample code, assigned to the sample.
- Verify code is a secondary confirmation code that is entered into WebDCU when confirming receipt of lab kits.



Buffy Coat Kit



53290

Verify Code: 632



Plasma Kit



PAXgene Kit



77559

Verify Code: 288

The Blood Draw

- Universal Participation
 - We expect every site to participate in the STEP Biobank.
 - Sites will approach all patients enrolled in STEP to participate.
 - Patients will have the opportunity to consent or decline the biobank component of the study.
- A STEP Biobank Informed Consent will be obtained.
- Blood will be collected in:
 - 10mL Purple top EDTA tube
 - PAXgene tube
- Fill tubes as completely as possible.



Buffy Coat Kit Processing

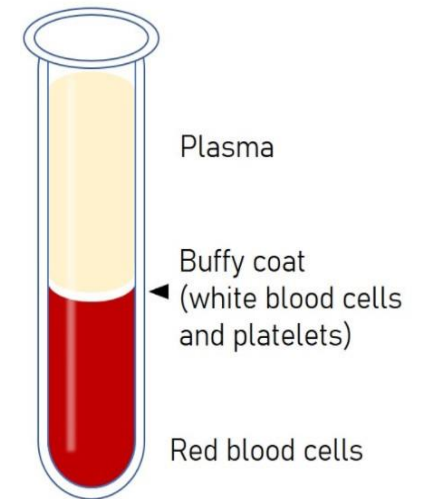
Centrifugation

1. The purple-top EDTA tube is then spun in a tabletop centrifuge *within 20 minutes after blood draw*.

- Centrifuge for 10 minutes at 1500g at room temperature.

2. Three layers will form in the tube:

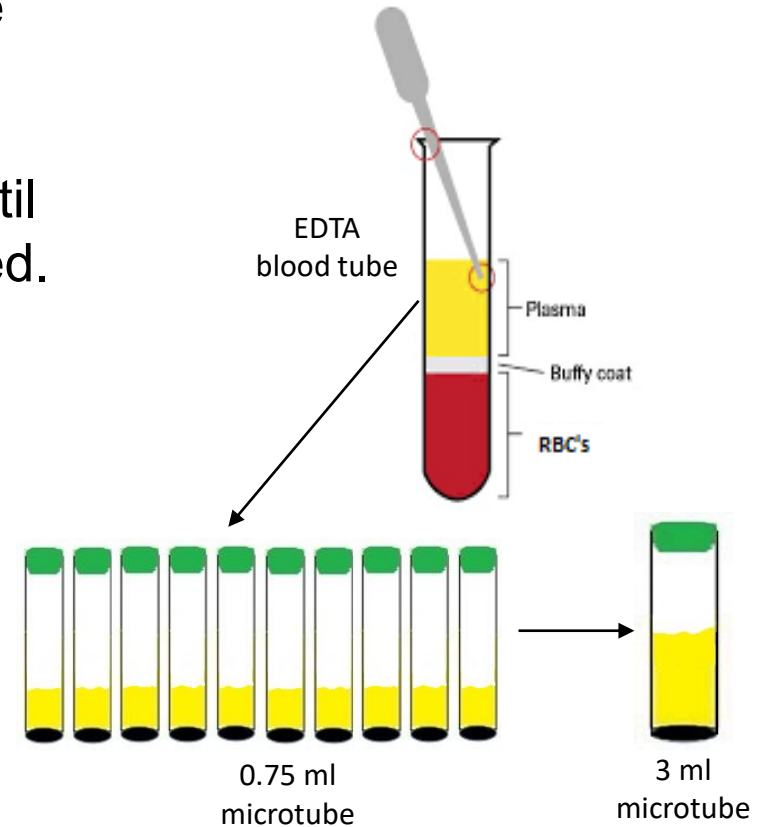
- The top may be a yellowish translucent fluid known as **plasma**.
- The thin, middle, whitish layer is made up of white blood cells and is called the **buffy coat**.
- The bottom layer is made up of red blood cells (**RBCs**).



Buffy Coat Kit Processing

Plasma Aliquots

1. Use the **0.3ml** disposable pipette to extract **0.2ml** (middle line on pipette) of the plasma from the EDTA blood tube, and release into the first **0.75ml** microtube.
2. Repeat up to **9** times into the other **0.75ml** microtubes until all the plasma is aliquoted or all of the microtubes are filled.
3. Dispose of pipette appropriately.
4. Place plasma aliquot pushcaps on each vial.
5. Use the **3ml** pipette to extract the remaining plasma (***be careful not to disturb the buffy coat and RBCs***).
6. Release the plasma into the **3ml** microtube.
7. Dispose of pipette appropriately.
8. Replace lids on microtube and purple-top EDTA blood tube.



PAXgene Kit Processing

PAXgene Tube:

1 – 2.5ml* PAXgene®



1. Immediately after blood collection, gently invert the PAXgene Blood RNA tube 8-10 times.
2. Set aside PAXgene blood tube at room temperature for at least 2 hours, but no more than 72 hours.
3. After at least 2 hours, the PAXgene blood tube can be placed into its assigned kit's slotted absorbent material and be put back into the -80°C freezer, preferably freezing with the sample away from the cap.
4. Without proper handling RNA yield is lower.
5. If you would like more detailed information about PAXgene processing, you can reference the website:

https://www.bdbiosciences.com/content/dam/bdb/products/global/blood-collection/blood-collection-tubes/762xxx/7621xx/762165_base/pdf/VDP40400.pdf

Biosample Handling and Storage

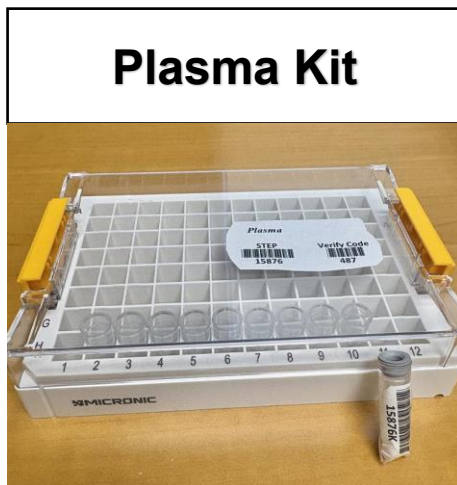
Buffy Coat Kit



53290

Verify Code: 632

Plasma Kit



PAXgene Kit



77559

Verify Code: 288

- If possible, biosamples should be frozen in a position that will prevent the liquid from freezing near the caps of the blood tubes/microtubes.
- Blood tubes and/or microtubes containing bio samples can be placed upright in the freezer prior to storing them in the biohazard transport bag to ensure the liquid freezes at the bottom.

Shipping Biosamples

1. For sites that have the recommended -80°C freezer, biosamples are ready to be shipped to the STEP Biobank when either 10 kits have been collected or every three months, whichever occurs first. If sites only have access to a -20°C freezer, samples need to be shipped to the STEP Biobank within two weeks of draw.
2. Place each participant's biohazard transport bag into the larger kit bag and seal when all the shipment's samples are in the bag.
3. Place the airway bill pouch on the box and insert the folded FedEx airway bill.
4. Place the shipping labels on the outside of the package (UN1845, Biohazard and Exempt Human Specimen) and fill out the UN1845 (dry ice) label appropriately.
5. Call FedEx at 1 (800) 463-3339 to schedule a pickup or coordinate with site's shipping dock.
6. Enter tracking number and shipping details in WebDCU™.

Additional Information

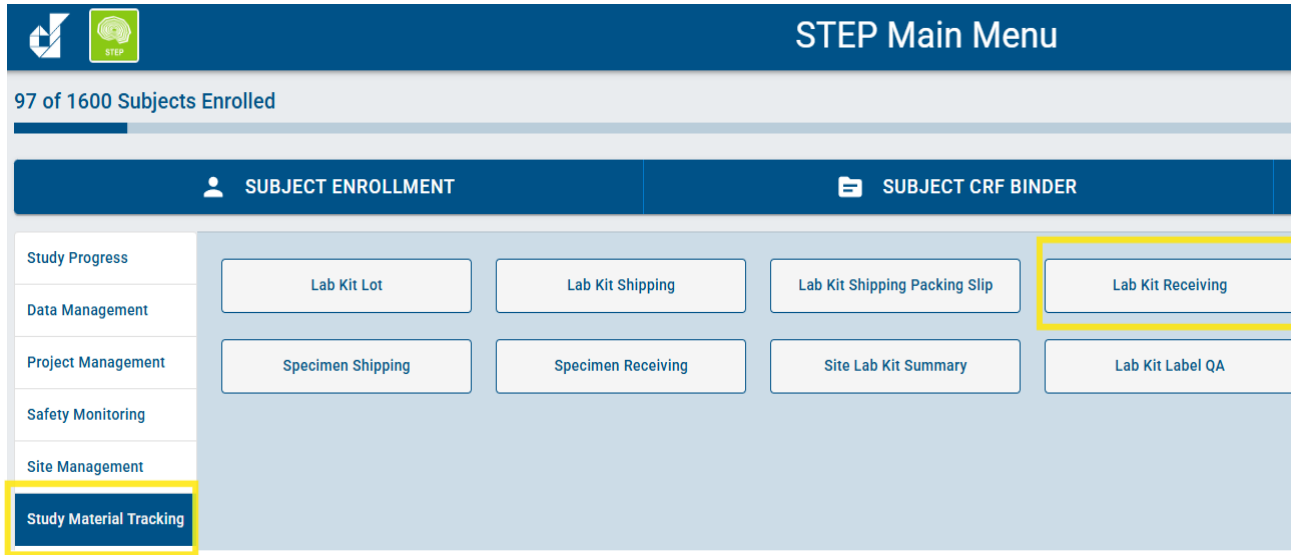
- Please let the Biobank know if the site needs more training, supplies or information. NGICoordinators@wustl.edu, franco.eileen@wustl.edu are available for questions.
- For additional assistance, please contact the STEP Biobank at 1-800-747-2979 or through the link below
<https://wustl-hipaa.zoom.us/j/94094214905>
(Monday – Friday 12pm-2pm CST)

Thank you for participating!

STEP Biobank

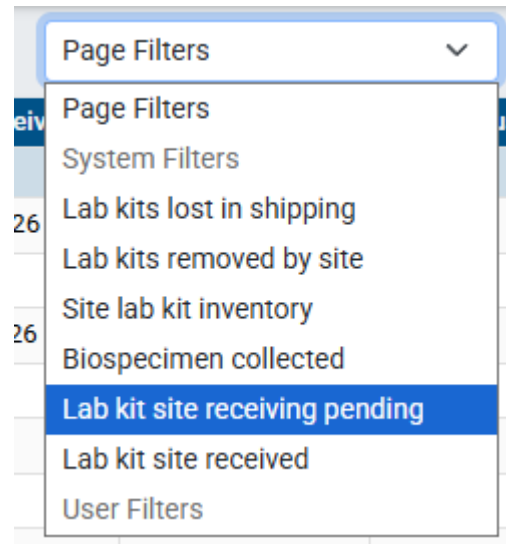
WebDCU™ Interface

Confirmation of Receipt



Once lab kits are received:

1. Log into WebDCU™ and click on [Study Material Tracking].
2. Click on [Lab Kit Receiving].
3. In the upper right-hand corner of the Lab Kit Receiving table, click on [Page Actions].
4. Page Filters drop-down menu for [Lab Kits site receiving pending].



Biosample Kit Receiving

Each site must confirm receipt to ensure you have lab kits in hand. To confirm receipt, please follow these steps:

1. Click on [Site name]
2. Enter kit type
3. Provide Lab Kit code from label
4. Confirm status
5. Enter verify code from label.



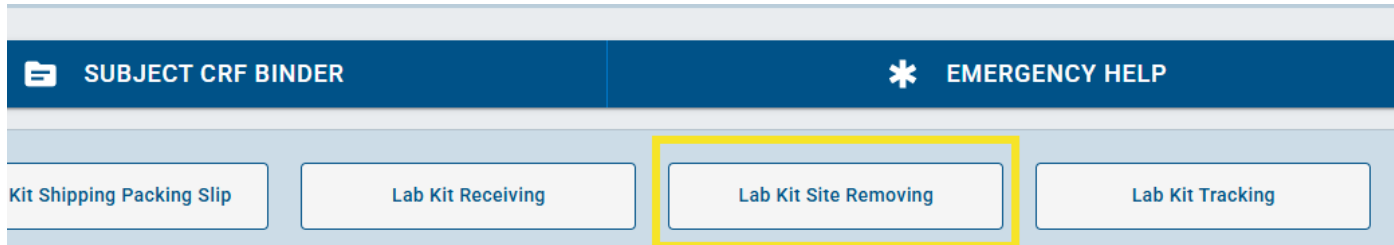
Editing: Lab Kit Receiving



2	Site Name	Medical City Plano, Plano, TX
17	Lab kit type	Buffy Coat
3	Lab kit code	40193
6	Date shipped	29-May-2026
7	Tracking number	654789123
9	Receiving status	☐ Pending ☒ Confirm received ☐ Lost in shipping
18	Verify code	 Expected format:
10	Date received	 Clear Date Today
11	Receiving notes	

Unused Lab Kits

Performed if a site has an unused kit and it needs to be removed from inventory (e.g. expired kit, damaged, etc.).



1. Log into WebDCU™ and click on [Study Material Tracking].

2. Click on [Lab Kit Removing].

3. In the upper right-hand corner of the Lab Kit Removing table, click on [Page Actions].

4. From the Page Filters drop-down menu, select [Lab kits expired, removing pending].

The screenshot shows the 'Lab Kit Site Removing' table. The table has columns for Lab kit type, Lab kit code, Lot ID, Expiration date, Date received, and Removing confirm. There are 15 rows in the table. The 'Page Filters' dropdown menu is open in the upper right-hand corner, showing options for Page Filters, System Filters, Lab kits expired, removing pending (which is selected), Lab kits removed by site, and User Filters.

Lab kit type	Lab kit code	Lot ID	Expiration date	Date received	Removing confirm
Plasma Kit	15876	1	31-Dec-2050	30-Mar-2026	Yes
PAXGene	71732	4	07-Apr-2026	04-Jun-2026	No
PAXGene	70960	2	31-Dec-2027	29-May-2026	Yes

Unused Lab Kits

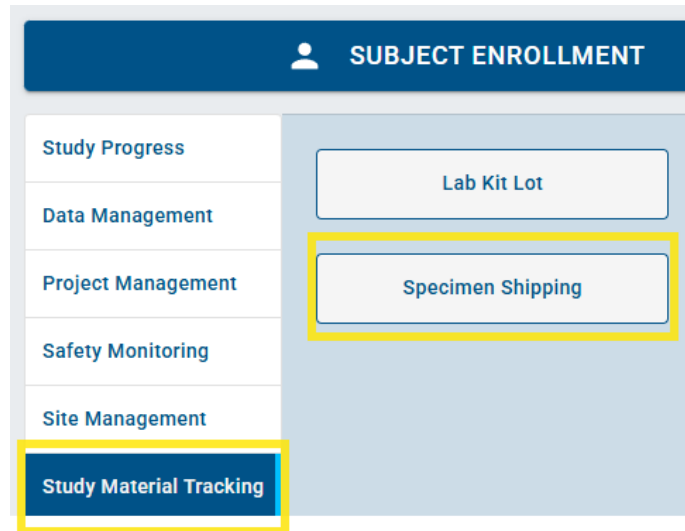
Lab Kit Site Removing						
#	Site ID	Site Name	Lab kit type	Lab kit code	Lot ID	Expiration date
1	1035	Grady Memorial Hospital, Atlanta, GA	Plasma Kit	15876	1	31-Dec-2050
2	1496	Brigham and Women's Hospital, Boston, MA	PAXGene	71732	4	07-Apr-2026

4	Lab kit type	Plasma Kit
3	Lab kit code	15876
5	Expiration date	31-Dec-2050
6	Date received	30-Mar-2026
Important Instruction: Lab kits can be removed from site inventory due to any reason that makes the lab kit not available for subject use.		
7	Removing confirm	☐ No ☒ Yes
9	Date removed	07-Apr-2026  Clear Date Today
8	Removing type	☐ Expired ☐ Damaged ☒ Missing ☐ Returned ☐ Recall ☐ Quarantined ☐ Temperature excursion ☐ Site closing ☐ Other

- Find the correct lab kit code that needs to be removed and click on the blue hyperlink # next to that code.
- Click and confirm [Yes] for removing. This will remove the kit from inventory.
- Once step 6 is completed, the remaining fields on the form can be edited.
- Enter the:
 - date removed
 - reason for removal
- Click on [Save Record].

Shipping Biosamples

When preparing samples to be shipped, log into WebDCU™ and follow the steps on the following slides



1. Click on [Study Material Tracking] and then [Specimen Shipping].
2. Find the lab kit code for the specimen that is being shipped and click the blue hyperlink # next to the code.

#	Site ID	Site Name	Lab kit code	Lab kit expiration Date	Subject ID	Specimen collection date	Specimen shipping date	Specimen shipment tracking number
1	1382	UVA Medical Center, Charlottesville, VA	70755	31-Dec-2027	1034	29-May-2026	05-Jun-2026	36952147
2	1382	UVA Medical Center, Charlottesville, VA	10114	31-Dec-2050	1034	29-May-2026	08-Jun-2026	963852741
3	1382	UVA Medical Center, Charlottesville, VA	10114	31-Dec-2050	1034	29-May-2026	08-Jun-2026	963852741

Shipping Biosamples

2	Site Name	UVA Medical Center, Charlottesville, VA
3	Lab kit code	10379
5	Subject ID	1024
6	CRF ID	4295
7	Specimen collection date	02-Jun-2026
8	Specimen shipping confirm	☐ No ☒ Yes
9	Specimen shipping date	 Clear Date Today
10	Specimen shipment tracking number	
11	Specimen shipping notes	

- Click “Edit Record” and select “Yes” for [Specimen shipping confirm]. Enter the:
 - shipping date
 - FedEx tracking number
 - shipping notes (if needed)

Click on [Save Record] when information is entered.

- To print the Lab Kit Packing Slip:
 - navigate to the [Specimen Shipping] list table
 - click on the green link  icon within the “Specimen Packing Slip” column for the specific specimen lab kit(s) ID in the shipment
 - print the Lab Kit Packing Slip for each specimen Lab Kit

Shipping Biosamples

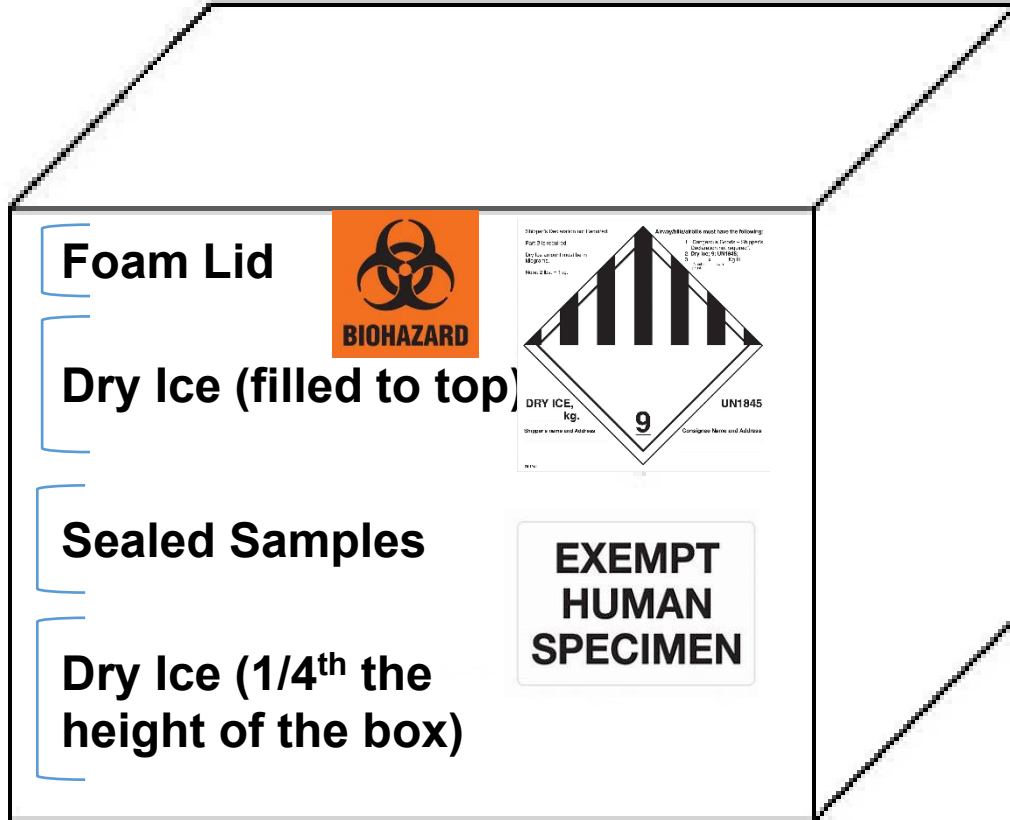
Important Shipping Reminders:

- Box in which supplies were received should be retained to ship bio samples to biobank.
- Check the accuracy of the package prior to shipping
 - Ensure that all biosamples collected are included in the biohazard transport bag for that participant.
 - Verify that all the Lab Kit IDs listed on the packing slip match what is in the shipment.
- The study team member preparing the shipment needs to sign and date the packing slip
 - For Collection site's study records, retain the original packing slip as a source document in a secure location.

**Only 5 samples shipped if
box is 11x9x10,
10 samples can be shipped if the box is 15x13x12.
Please call if unsure about dry ice/samples ratio**

Bulk Shipment

**** Dry Ice is considered a dangerous good and specialized training is required for bulk shipments.****



1. Fill the bottom of the foam shipping box with dry ice until about 1/4th the way up the sides.
2. Place sealed and frozen transport bags with the biosamples on the dry ice layer.
3. Fill the box to the top with more dry ice.
4. Replace foam lid.
5. Always, fill box completely with dry ice to keep samples frozen for transit.

*****Per IATA Regulations, packages containing dry ice must be labelled as a hazardous material with a UN1845/Class 9 sticker, regardless of what other hazardous materials may also be inside.**

Please affix appropriate labels provided by the Biobank prior to shipping.



Bulk Shipment

**** Dry Ice is considered a dangerous good and specialized training is required for bulk shipments.****

6. Seal the shipment box with packing tape down the center but leave the sides open for proper Carbon Dioxide venting.
7. The biobank will email each site a pre-made airbill for shipping.

Packing tape
down the
middle but
not on
the sides.



****DO NOT SEAL COMPLETELY****

Bulk Shipment

- If your institution has a dock, please verify that the shipment has been picked up on the scheduled date.
- If it has not been picked up, it may need to be taken to a FedEx location for same-day shipping, or the shipment may have to be postponed. Take back the shipment and place the samples back into the freezer.

Holiday Closures (avoid these dates for shipping):

Severe Weather: Please email NGICoordinators@wustl.edu before shipping any samples to confirm they can be received appropriately (e.g., in case STEP Biobank is experiencing severe weather).

New Year's Eve & Day
Martin King Jr Day
Memorial Day
Independence Day
Labor Day
Thanksgiving & Friday after
Christmas Eve & Day

Training for Biosample Collection

- Training session was given to STEP Steering Committee on 6/18/26
- A training video and Biobank Instructions can be accessed at:

<https://dcu.musc.edu/campus/>

STEP Biobank Team



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STEP Biobank



Jin-Moo Lee
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