

A Seamless Phase 2A-Phase 2B Multi-Center Trial
to test the Benefits of Benfotiamine on the
Progression of Alzheimer's disease
(BENFOTEAM)

BIOSPECIMEN COLLECTION AND SHIPMENT TRAINING



National Centralized Repository for
Alzheimer's Disease and Related Dementias

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- ❖ Non-Conformance Issues
- ❖ NCRAD Resources and Contact

Benfotiamine Biospecimen Collection Schedule

	Pre-Dose				Post Dose				Optional
	Whole Blood	Plasma	Buffy Coat	Washed Erythrocyte	Whole Blood	Plasma	Buffy Coat	Washed Erythrocyte	CSF
Screening		X	X						
Baseline	X	X	X	X	X	X	X	X	X
Week 8	X	X	X	X	X	X	X	X	
Week 72	X	X	X	X					X

Kit Request Module

The screenshot shows the NCRAD Kit Request System interface. At the top left is the NCRAD logo with the text "National Centralized Repository for Alzheimer's Disease and Related Dementias". Below the logo is the title "Kit Request System". A paragraph of instructions follows: "Please verify or edit the contact name, shipping address, phone number, and e-mail address. Then enter the desired number of kits or extra supplies in the text fields to the right of each option. A comprehensive list of each kit is listed at the bottom of the screen. Please click submit at the bottom of the screen when you are finished to place your order." A blue box contains a notice: "Due to ongoing supply limitations, we ask that you please only order as many kits and extra supplies that you will be able to use in the next 30 days. Doing so allows us to fulfill as many kit requests as possible without depleting stock for other kit requests in our queue. If we are not able to fulfill any part of your request due to supplies being out of stock, we will reach out about those individually." Below this is a form field for an email address with the label "Please enter your email address here to receive a confirmation email after completing the survey:" and a red asterisk note "* must provide value". A green box contains a "Select your site:" dropdown menu with a red asterisk note "* must provide value". A blue box contains the "Specimen Collection Kit" section with a label "Number of Blood Collection Kit(s) needed:" and a text input field. At the bottom, a list titled "Each PACT Collection Blood Kit Contains:" includes: 2 EDTA tube, 10ml; 6 2ml Cryovial Tubes - PURPLE; 1 2ml Cryovial Tube - BLUE; 2 2ml Cryovial Tubes - CLEAR; 1 Centrifuge tube, 15ml; 9 Small Preprinted Cryovial labels (no clear tail); 5 Kit Number Labels; 3 Participant ID Labels; 1 Cryovial box (holds up to 25 cryovials); 2 Disposable graduated transfer pipette; and 1 Resealable plastic bag.

❖ Ordering Blood Kit Supplies

❖ Ex: tubes, pipettes, labels, cryobox

❖ Ordering Frozen Shipment Supplies

❖ Ex: styrofoam container, cardboard shipper, shipping stickers

❖ Allow for **three weeks** from time of order to receipt of supplies

❖ Initial order should be received prior to site start date

Kit Request Module Instruction

www.kits.iu/BENFO

Specimen Collection Kits	
Number of Screening Blood Collection Kit(s) needed:	<input type="text" value="3"/>
Record screening visit information at https://redcap.uits.iu.edu/surveys/?s=NT74734AWTF7Y8FC	
Each BENFO Screening Collection Blood Kit Contains:	
03 EDTA tube, 10ml [CT001] 24 2ml Cryovial Tubes - PURPLE [CV027] 01 2ml Cryovial Tube - BLUE [CV034] 03 2ml Cryovial Tubes - CLEAR [CV014] 01 Conical Tube, 50ml (unwrapped) [CV019] 31 Collection Tube/Aliquot Labels[LB003] 04 Kit Number Labels [LB003] 04 Participant ID Labels [LB003] 02 Cryovial box (holds up to 25 cryovials) [CV005] 05 Disposable graduated transfer pipette (3 ml) [CV015] 01 Resealable plastic bag [ST002] 01 4x5 Plastic bag [ST010]	
Number of Baseline Blood Collection Kit(s) needed:	<input type="text"/> <small>(account for pre dose and post dose)</small>
Number of Week 8 Blood Collection Kit(s) needed:	<input type="text"/> <small>(account for pre dose and post dose)</small>
Number of Week 72 Blood Collection Kit(s) needed:	<input type="text"/>
Each BENFO Baseline, Week 8, Week 72 Collection Blood Kit Contains:	
03 EDTA tube, 10ml [CT001] 24 2ml Cryovial Tubes - PURPLE [CV027] 01 2ml Cryovial Tube - BLUE [CV034] 03 2ml Cryovial Tubes - CLEAR [CV014] 01 2 ml Cryovial Tube - YELLOW [CV037] 01 2ML Cryovial Tube - RED [CV028] 01 Conical Tube, 50ml (unwrapped) [CV019] 01 Centrifuge Tube, 15 ml [CV004] 34 Collection Tube/Aliquot Labels[LB003] 04 Kit Number Labels [LB003] 04 Participant ID Labels [LB003] 02 Cryovial box (holds up to 25 cryovials) [CV005] 05 Disposable graduated transfer pipette (3 ml) [CV015] 01 Resealable plastic bag [ST002] 01 4x5 Plastic bag [ST010]	

➤ Verify site shipping address and contact information

➤ Enter kit order amount

- Screening Kit->Screening Shipping Kit
- Baseline, Week 8, Week 72->Batch Shipping Kit
- All screening visits **must** be entered into screening tracker prior to shipping. Reminder in kit request module
- Supplemental kit will be sent with initial order. This kit contains the saline needed for washed RBCs. Only one supplemental kit should be order per year.

* Allow for **3 weeks** for kits to arrive when placing order

BENFO Screening Reporter

www.kits.iu.edu/BENFOScreening

BenfoTeam Screening Sample Shipment

Please select the weeks screening samples are expected to ship this month:
* must provide value

First week of the month
 Second week of the month
 Third week of the month
 Fourth week of the month

Reminder: Ship samples **Mon-Wed only**

Estimated date of shipment:  Today M-D-Y

Number of participants' screening samples expected to ship the first week of the month:

If available, please enter kit number(s) and participant ID(s) associated with screening shipments:
(Example: Kit#052416 BENFO9990001)

Expand

if only kit number is available, please enter kit number

- Screening visits must be reported using the screening reporter.
- Crucial step in receiving and distributing samples for eligibility test results.

GUID (Globally Unique Identifier)

The GUID is a participant ID that allows researchers to share data specific to a study participant, without exposing personally identifiable information.

Participation is optional. If a patient chooses to participate:

1. Create an account:

<https://bricsguid.nia.nih.gov/portal/jsp/login.jsp>

2. Once you have an account, go to the GUID Tool—Create GUID

3. To open the ‘Launch GUID Tool’ you will need to have Java installed on your device

4. In order to generate a GUID, the following PHI is required on the Appendix A.



Biospecimen Collection, Processing, and Shipment Manual
Appendix A: GUID Demographics Form

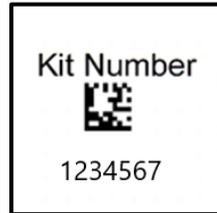
Please be certain to collect the following demographic information to generate a Global Unique Identifier. **Do NOT** return this information to NCRAD. Only send the GUID to NCRAD.

1. Complete legal given (first) name of subject at birth: _____
2. Complete additional (middle) name or names at birth: _____
3. Complete legal family (last) name of subject at birth: _____
4. Suffix: _____
5. Date of Birth: _____
6. Name of city/municipality in which subject was born: _____
7. Country of birth: _____

Specimen Labeling Instruction

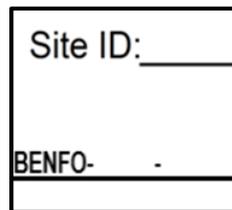
Specimen Labels

Kit Number Label



- Ties all biospecimens and kit contents together for each participant
- Placed on Cryobox and Blood Sample and Shipment Notification Form

Participant ID Label



- Handwritten by sites according to unique study ID
- Placed on blood collection EDTA tubes

Collection Tube Label and Aliquot Label



- Specific to type of biospecimen
- Contains unique Specimen# and Kit#
- Place on corresponding EDTA collection tube and processed aliquot cryovials

Collection tube and Aliquot Labels

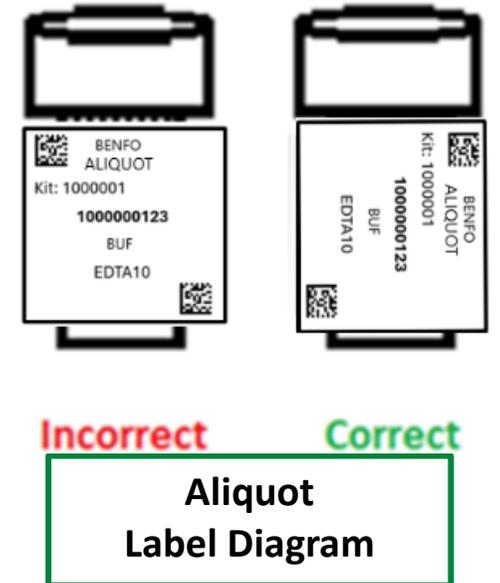
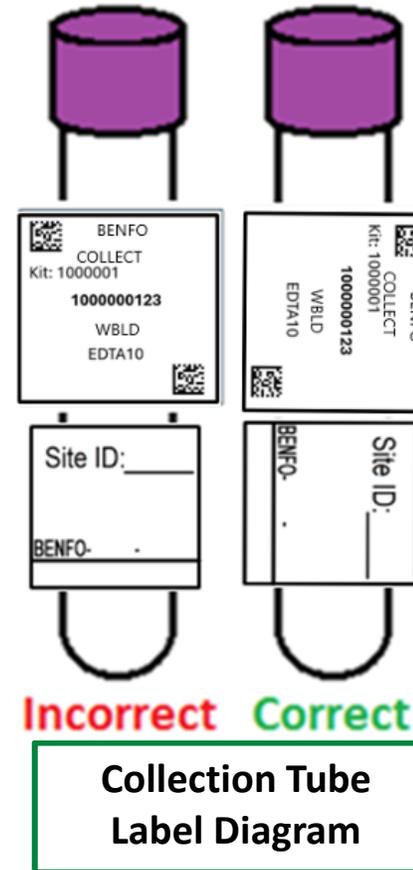


Specimen Type Abbreviations

- WBLD - Whole Blood
- PLA - Plasma
- BC - Buffy Coat
- RBC- Washed RBC
- CSF - Cerebrospinal Fluid

Specimen Labeling Instruction: Label Placement Details

- ❖ Write site ID and participant ID with fine-point marker prior to label placement
- ❖ Place **all** labels on Whole-Blood EDTA 10 ml tube and Cryovial 2 ml **before** blood collection, processing, or freezing
- ❖ Label collection tubes and cryovials for **one participant at a time** to avoid mix ups.
- ❖ Wrap labels **horizontally** and adhere **completely** to all tubes



Specimen Collection and Processing

Benfotiamine Biospecimen Samples

NCRAD will provide training and materials for the following biospecimens collected:

- ❖ Whole Blood
- ❖ Plasma
- ❖ Buffy Coat
- ❖ Washed RBCs
- ❖ CSF (Optional)

Sample Type	Cryovial Cap Color	Example:
Whole Blood	Yellow	
Plasma	Purple	
Residual Plasma	Blue	
Buffy Coat	Clear	
Washed RBC	Red	
Local Lab CSF	Yellow	
Processed CSF	Clear	
Residual CSF	Blue	

SCREENING VISIT- PROCESSING PLASMA AND BUFFY COAT ONLY

Step One



- ❑ Store tubes at room temperature
- ❑ Label each tube with appropriate pre-printed labels prior to blood draw

Step Two



- ❑ Collect 10 ml of blood into each EDTA tube, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



- ❑ Immediately after blood draw, gently invert tubes 8-10 times to mix samples.

Step Four



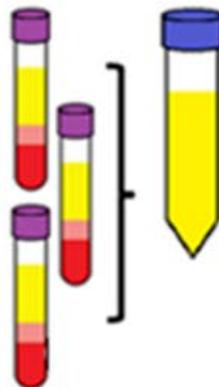
- ❑ Placed thoroughly mixed tubes on wet ice until centrifuge begins

Step Five



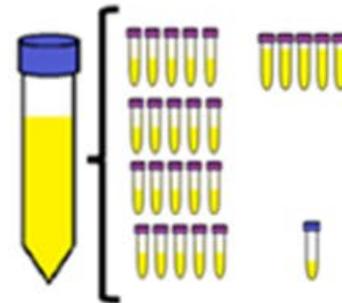
- ❑ Replace caps to all 3 EDTA's prior to centrifuge.
- ❑ Centrifuge samples at 2000 x g for 10 minutes at 4° C

Step Six



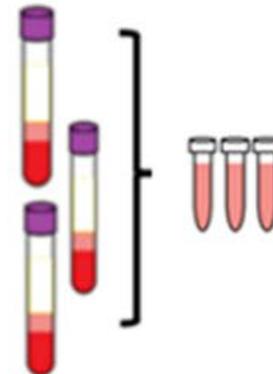
- ❑ Pool all plasma from 3 EDTA tubes into a 50 ml Conical tube
- ❑ Gently invert conical tube 3 times to mix the plasma

Step Seven



- ❑ Label purple top cryovials with "PLASMA" labels.
- ❑ Aliquot 1.0 ml of plasma from conical tube into 5 purple top cryovials
- ❑ Aliquot 0.5 ml of plasma from conical tube into 20 purple top cryovials
- ❑ Aliquot any residual plasma of <0.5 ml into the blue top cryovial
- ❑ Document specimen number and volume of residual plasma on Sample form.
- ❑ Store all plasma aliquots upright at -80° C until shipment to NCRAD

Step Eight



- ❑ Label clear top cryovials with "BUFFY COAT" labels
- ❑ Using a clean transfer pipette, collect the buffy coat from EDTA tubes (may have some residual plasma and some RBC's included)
- ❑ Transfer the buffy coat from each EDTA tube into its own cryovial
- ❑ Store all buffy coat aliquots upright at -80° C until shipment to NCRAD
- ***Note: spin, aliquot and freeze all samples within 2 hours of collection**

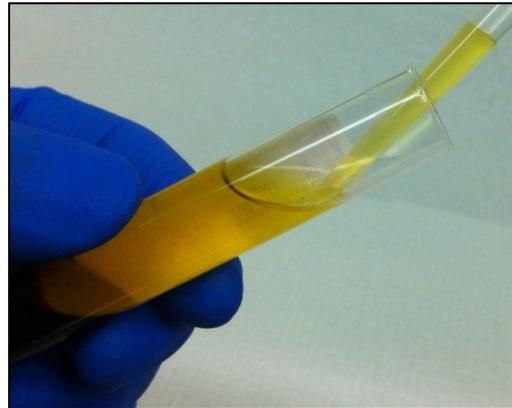
Specimen Collection and Processing: Plasma and Buffy Coat Collection (Screening)



Plasma

Buffy Coat

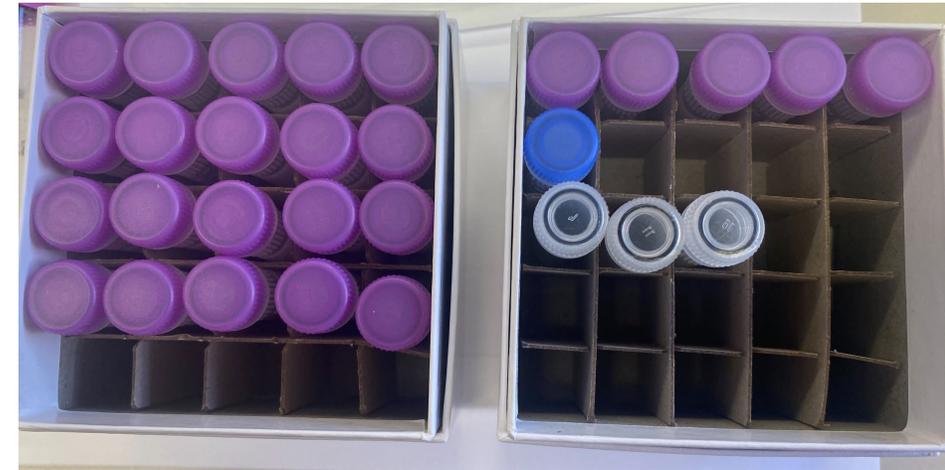
Red Blood
Cells



50 ml Conical with
30 ml pooled plasma
after inversion



Retrieve buffy coat
from each EDTA
(expected to have reddish
color from RBCs)



Cryobox #1

- 20 purple-capped - 0.5 ml of plasma

Cryobox #2

- 5 purple-capped – 1.0 ml of plasma
- 1 blue-capped – <0.5 ml residual plasma
- 3 clear-capped – ~1.0 ml buffy coat

BASELINE, WEEK 8, WEEK 72

Processing Whole-Blood, Plasma, Buffy Coat, and Washed RBCs

Processing Whole-Blood, Plasma, Buffy Coat and Washed RBCs from EDTA Purple-Top Tube (3x10ml)

Step One



- Store tubes at room temperature
- Label each tube with appropriate pre-printed labels prior to blood draw

Step Two



- Collect 10 ml of blood into each EDTA tube, allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



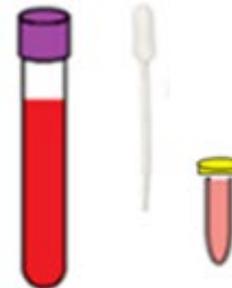
- Immediately after blood draw, gently invert tubes 8-10 times to mix samples.

Step Four



- Placed thoroughly mixed tubes on wet ice until centrifuge begins

Step Five



- Prior to processing for plasma and buffy coat, aliquot 1.0 ml of whole blood from ONE of the EDTA blood collections into one yellow capped cryovial labeled "WHOLE-BLOOD".
- Store whole blood aliquot at -80° C freezer until shipment to NCRAD

Step Six



- Replace caps to all 3 EDTA's prior to centrifuge.
- Centrifuge samples at 2000 x g for 10 minutes at 4° C

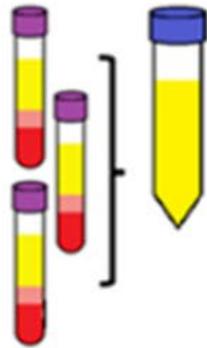
Continue for Next Steps

BASELINE, WEEK 8, WEEK 72

Processing Whole-Blood, Plasma, Buffy Coat, and Washed RBCs

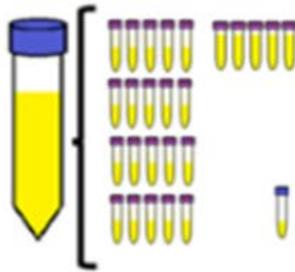
Processing Whole-Blood, Plasma, Buffy Coat and Washed RBCs from EDTA Purple-Top Tube (3x10ml)

Step Seven



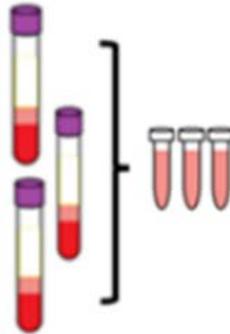
- Pool all plasma from 3 EDTA tubes into a 50 ml Conical tube
- Gently invert conical tube 3 times to mix the plasma

Step Eight



- Label purple top cryovials with "PLASMA" labels.
- Aliquot 1.0 ml of plasma from conical tube into 5 purple top cryovials
- Aliquot 0.5 ml of plasma from conical tube into 20 purple top cryovials
- Aliquot any residual plasma of <0.5 ml into the blue top cryovial
- Document specimen number and volume of residual plasma on Sample form.
- Store all plasma aliquots upright at -80° C until shipment to NCRAD

Step Nine



- Label clear top cryovials with "BUFFY COAT" labels
- Using a clean transfer pipette, collect the buffy coat from EDTA tubes (may have some residual plasma and some RBC's included)
- Transfer the buffy coat from each EDTA tube into its own cryovial
- Store all buffy coat aliquots upright at -80° C until shipment to NCRAD

Step Ten



- To the remaining RBCs in **ONE** of the EDTA tubes; add normal saline (0.9% w/v NaCl solution) to equal the approximate volume of whole blood previously collected during Step Two (~10 ml)

Step Eleven



- Gently invert the tube 10 times to mix saline and RBCs.
- Centrifuge the EDTA tube containing saline and RBCs at **2000 x g for 5 minutes** at 4° C

Step Twelve



- Using a clean transfer pipette, remove and discard the saline supernatant
- Repeat Steps 10-12 for a total of **two washes** (or until the supernatant is clear and not red).
- Ensure complete removal of the final saline supernatant. (*Note: it is better to remove a mm of RBCs with the saline rather than leaving any saline in the sample.)

Step Thirteen



- Label clear top cryovial with "WASHED RBC" label
- Aliquot 1.5 ml of washed RBCs to one labeled red capped cryovial
- Store washed RBC aliquot at -80 °C until shipment to NCRAD
 - ***Note: spin, aliquot and freeze all samples within 2 hours of collection**

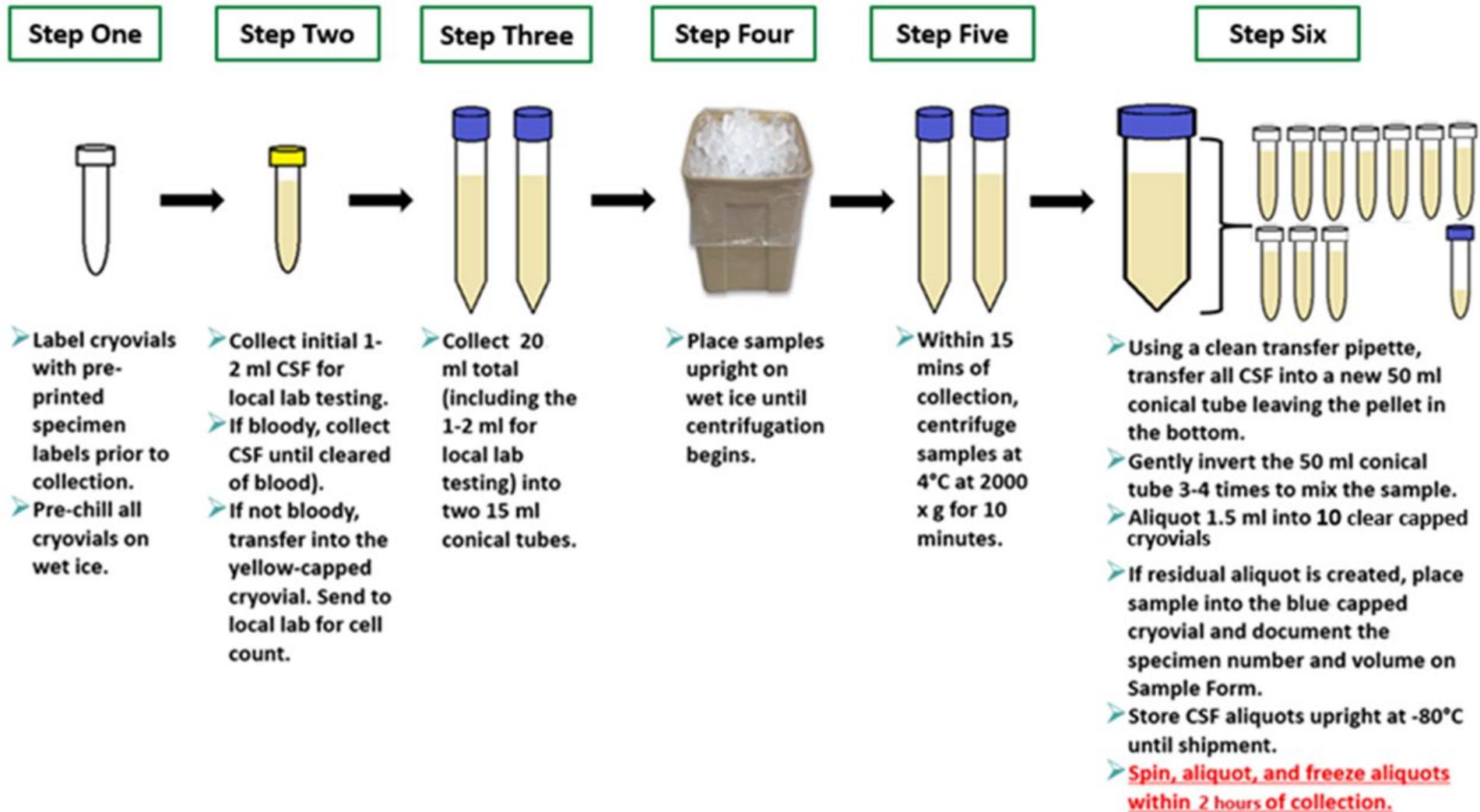
Visit	Pre-Dose	Post-Dose
Baseline	X	X
Week 8	X	X
Week 72	X	



Cryobox #1
20 purple-capped - 0.5 ml of plasma

Cryobox #2
5 purple-capped – 1.0 ml of plasma
1 blue-capped – >1.0 ml residual plasma
3 clear-capped – ~1.0 ml of buffy coat
1 yellow-capped – 1.0 ml of whole blood
1 red-capped – 1.5 ml of washed RBCs

Optional Baseline and Week 72 CSF Preparation



Shipment Packaging, Labeling, & Forms

Frozen Shipment Packaging



All samples shipped frozen to NCRAD **Monday-Wednesday ONLY**



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



Include copy of Blood Sample and Shipment Notification Form in shipper



E-mail electronic copy of Blood Sample and Shipment Notification Form to alzstudy@iu.edu



Screening visit-ship quickly & individually (2 cryoboxes)
All other visits-batch samples together (8 cryoboxes)



Sites provide dry ice for shipments
~10 lbs. per single shipper (screening). ~45 lbs. per batch shipment (visits)

Frozen Shipment Tutorial

[HTTPS://NCRAD.ORG/SHIPPING_ADDRESS.HTML](https://ncrad.org/shipping_address.html)

Specimen Packaging and Shipment: Frozen Specimen Packaging

Step 1. Place frozen cryobox in biohazard bag with absorbent sheet

❖ Important: Confirm kit number label has been placed on the outside of cryobox



Specimen Packaging and Shipment: Frozen Specimen Packaging

Step 2. Place 2-3 inches of dry ice in the bottom of the styrofoam shipping container

Step 3. Insert cryoboxes with tubes upright

Step 4. Fully cover all cryoboxes with 2 inches of dry ice

Reminder:

Screening Shipper holds 2 cryoboxes

Batch Shipper holds 8 cryoboxes



Blood Sample and Shipment Notification Form

Step 5. Include Blood Sample & Shipment Notification Form in Cardboard Shipper

- ✓ Fill out completely during study visit
- ✓ Include Kit Number Label on Form
- ✓ Take a copy of each form prior to shipment. E-mail or fax NCRAD for notification
 - Email: alzstudy@iu.edu
 - Fax: 317-321-2003

To: Kelley Faber Email: alzstudy@iu.edu Phone: 1-800-526-2839

From: _____ UPS tracking #: **1Z976R8W84**

Phone: _____ Email: _____

Study: BENFOTEAM Site ID: _____ BENFO- _____ - _____ Sex: M F Year of Birth: _____

GUID: _____

Visit: Screening Baseline Week 8 Week 72

Dose: Pre-dose Post-dose Time of Dose: _____ (24-hour format)

KIT BARCODE

Blood Collection: (24-hour format)

Date of Draw: _____ [MMDDYY]	Time of Draw: _____ [HHMM]
Date subject last ate: _____ [MMDDYY]	Time subject last ate: _____ [HHMM]

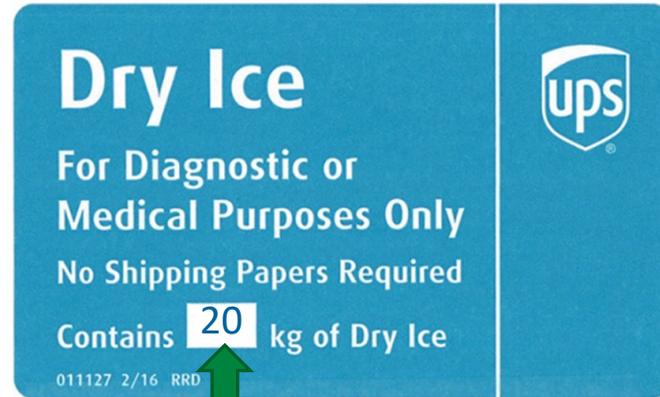
Blood Processing:

Plasma & Buffy Coat (EDTA Tube)			
EDTA #1 specimen number (Last four digits): _____		Original blood volume of EDTA #1: _____ mL	
EDTA #2 specimen number (Last four digits): _____ <input type="checkbox"/> N/A		Original blood volume of EDTA #2: _____ mL <input type="checkbox"/> N/A	
EDTA #3 specimen number (Last four digits): _____ <input type="checkbox"/> N/A		Original blood volume of EDTA #3: _____ mL <input type="checkbox"/> N/A	
Time spin started: _____ [HHMM]		Duration of centrifuge: _____ mins	
Temp of centrifuge: _____ °C		Rate of centrifuge: _____ x g	
Time aliquoted: _____ [HHMM]		Number of 1.5 mL plasma aliquots created (purple cap): _____	
Volume of residual plasma aliquot (less than 1.5 mL in blue cap): _____ mL <input type="checkbox"/> N/A		Specimen number of residual plasma aliquot (Last four digits): _____ <input type="checkbox"/> N/A	
Buffy coat #1 specimen number (Last four digits): _____		Buffy coat #1 volume: _____ mL	
Buffy coat #2 specimen number (Last four digits): _____ <input type="checkbox"/> N/A		Buffy coat #2 volume: _____ mL <input type="checkbox"/> N/A	
Buffy coat #3 specimen number (Last four digits): _____ <input type="checkbox"/> N/A		Buffy coat #3 volume: _____ mL <input type="checkbox"/> N/A	
Time aliquots frozen: _____ [HHMM]		Storage temperature of freezer: _____ °C	
Complete following fields for Baseline, Week 8, and Week 72 Visits Only:		Number of 1.0 mL whole blood aliquots created (yellow cap): _____	
Number of 1.5 mL washed RBC aliquots created (red cap): _____		Duration of centrifuge: _____ mins	
Temp of centrifuge: _____ °C		Rate of centrifuge: _____ x g	
Time aliquoted: _____ [HHMM]		Time spin started _____ [HHMM]	

Notes: _____

Specimen Packaging and Shipment: Cardboard Package Labeling

Step 6.



Net weight of dry ice in **kg**



Dangerous Goods Label
Additional Training Required

Creating Airbills & Scheduling Pickups

Shipping Accounts

<https://redcap.link/BENFOaccountsurvey>

One person from each site must fill out this survey to set up accounts with NCRAD.

Navigating UPS ShipExec Tutorial

[HTTPS://NCRAD.ORG/SHIPPING_ADDRESS.HTML](https://ncrad.org/shipping_address.html)

UPS ShipExec™ Thin Client Website



Log into the ShipExec Thin Client:
<https://kits.iu.edu/UPS>



Click on the “Shipping”
dropdown and click on “Shipping
and Rating”

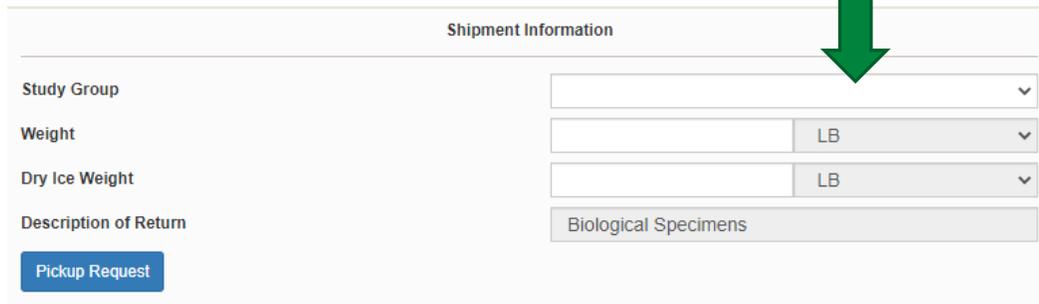


Creating Airbills & Scheduling Pick Ups: Finding your Contact Information

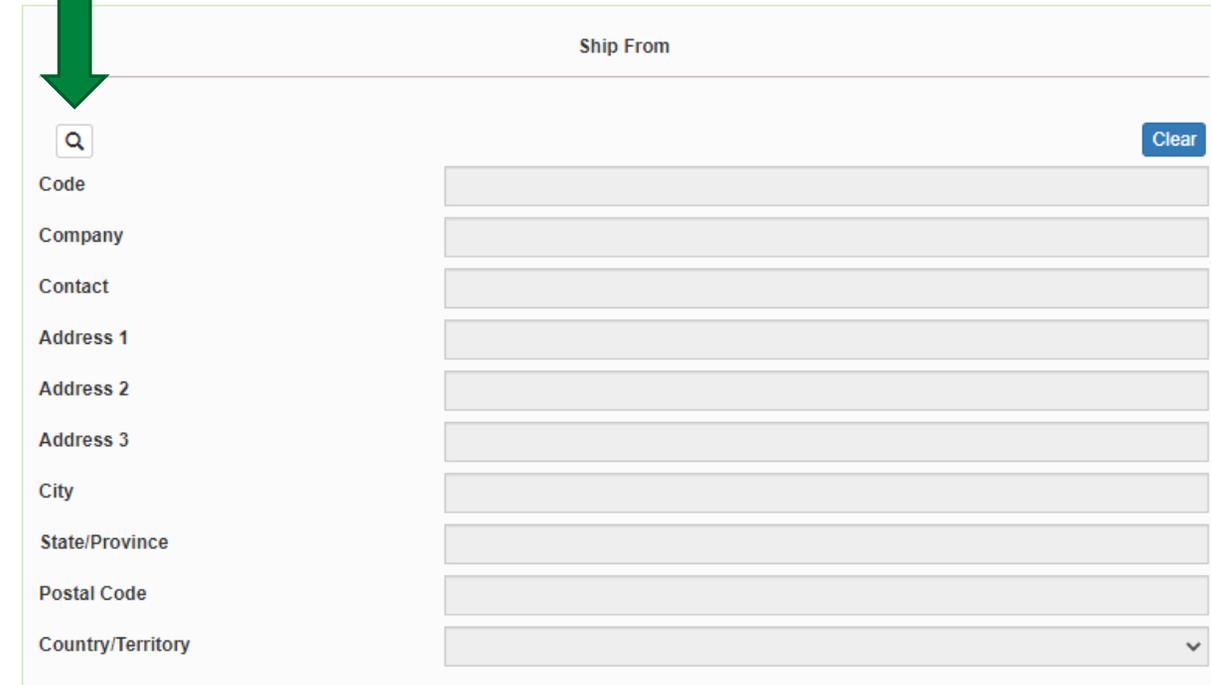
❖ On the right side of the screen, choose the name of your study from the “Study Group” drop down menu

❖ *This step must be done 1st*

❖ On the left side of the screen, Click on the magnifying glass icon



The screenshot shows a form titled "Shipment Information". It contains several fields: "Study Group" (a dropdown menu), "Weight" (a text input field with a unit dropdown set to "LB"), "Dry Ice Weight" (a text input field with a unit dropdown set to "LB"), and "Description of Return" (a text input field containing "Biological Specimens"). A blue button labeled "Pickup Request" is located at the bottom left. A large green arrow points down to the "Study Group" dropdown menu.



The screenshot shows a form titled "Ship From". It features a search bar with a magnifying glass icon on the left and a "Clear" button on the right. Below the search bar are several input fields: "Code", "Company", "Contact", "Address 1", "Address 2", "Address 3", "City", "State/Province", "Postal Code", and "Country/Territory" (a dropdown menu). A large green arrow points down to the magnifying glass icon.

Creating Airbills & Scheduling Pick Ups: Finding your Contact Information

- ❖ On the right side of the screen, a list of all the site addresses within the study you selected should populate
- ❖ User can filter the search for their address further by filling in the “Company”, “Contact”, or “Address 1” fields
- ❖ Please verify that both the shipping information AND study reference are correct for this shipment
- ❖ If any information needs to be updated, please reach out to the NCRAD Coordinator of your study

Select address book

Address Book	Type
RETURNS	Company

Group	ADCFB (NCRAD) ▼
Code	<input type="text"/>
Company	<input type="text"/>
Contact	<input type="text"/>
Address 1	<input type="text"/>
Address 2	<input type="text"/>
Address 3	<input type="text"/>
City	<input type="text"/>
State/Province	<input type="text"/>
Postal Code	<input type="text"/>
Country/Territory	<input type="text" value=""/>
<input type="checkbox"/> Email <input type="checkbox"/> Phone Fax <input type="checkbox"/> Account / Tax	
Email	<input type="text"/>
<input type="button" value="✕Clear"/> <input type="button" value="🔍Search"/>	

Action	Code	Company	Contact
<input type="button" value="Select"/>	ADCFB ARIZONA BARROW	Barrow ADCFB	Angelica Garcia
<input type="button" value="Select"/>	ADCFB ARIZONA BSHRI	Arizona Alzheimer's Center: BSHRI	Dr. Geidy Serrano
<input type="button" value="Select"/>	ADCFB BOSTON	Boston University ADRC	Eric Steinberg
<input type="button" value="Select"/>	ADCFB JOHNS HOPKINS	John Hopkins ADRC	Carol Gogel
<input type="button" value="Select"/>	ADCFB KANSAS	University of Kansas	Kayla Meyer
<input type="button" value="Select"/>	ADCFB MGH	Massachusetts General Hospital	Raya Kumar
<input type="button" value="Select"/>	ADCFB MICHIGAN	University Of Michigan	Matthew Perkins
<input type="button" value="Select"/>	ADCFB NYU	NYU Langone Medical Center	Ashley Clayton

Creating Airbills & Scheduling Pick Ups: Entering Shipment Information

- ❖ Enter the total weight of your package in the “Weight” field
- ❖ Enter the dry ice weight in the “Dry Ice Weight” field
 - The “Dry Ice Weight” field cannot be higher than the “Weight” field (will receive an error message)

Shipment Information

Study Group	<input type="text"/>	▼
Weight	<input type="text"/>	LB ▼
Dry Ice Weight	<input type="text"/>	LB ▼
Description of Return	Biological Specimens	

[Pickup Request](#)

Creating Airbills & Scheduling Pick Ups: Scheduling Pickup Request

- ❖ Click on the “Pickup Request” button
- ❖ Fill out all fields for the pickup request
- ❖ Enter in the “Earliest Time Ready” and “Latest Time Ready” in 24-hour format separated by colon.
- ❖ Choose a name and number that is the best to contact if the UPS driver has questions related to picking up your package
- ❖ Entering the Room Number and Floor will help the UPS driver locate your package
- ❖ Hit “Save” when done

Shipment Information

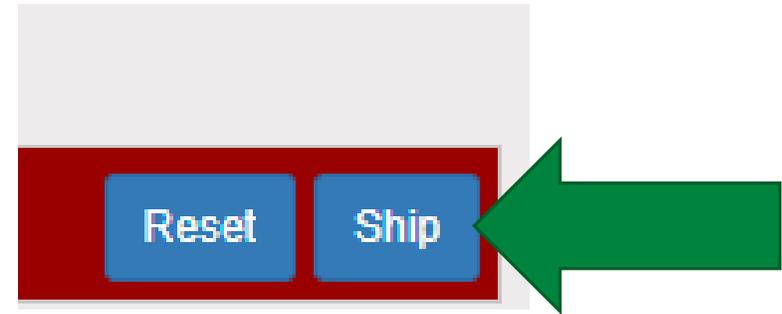
Study Group	<input type="text"/>	▼
Weight	<input type="text"/>	LB ▼
Dry Ice Weight	<input type="text"/>	LB ▼
Description of Return	Biological Specimens	

Create Pickup Request

Pickup Date	<input type="text" value="2021-03-15"/>	
Earliest Time Ready	<input type="text" value="HH:MM (24 hours format)"/>	
Latest Time Ready	<input type="text" value="HH:MM (24 hours format)"/>	
Contact Name	<input type="text"/>	
Contact Phone	<input type="text"/>	
Payment Method	Pay by shipper account ▼	
Room Number	<input type="text"/>	
Floor	<input type="text"/>	

Creating Airbills & Scheduling Pick Ups: Shipping Packages

- ❖ If all fields in “Ship From” and “Shipment Information” fields are completed, and pickup request is completed (if necessary) then click “Ship” in the bottom right corner of the page



Shipment Receipt

ShipExec™ Shipment Receipt

Transaction Date: Tuesday, December 8, 2020

Pickup No: 2929602E9CP

Address Information

Ship To:
John Smith
Indiana University
980 W. Walnut Street
Indianapolis, IN 46202

Shipper:
lugb
Iu School Of Medicine
351 W 10Th St
Indianapolis, IN 46202

Ship From:
lugb
Iu School Of Medicine
351 W 10Th St
Indianapolis, IN 46202

Shipment Information

Service: UPS Next Day Air (UPS Adapter)

Package Information

Pkg No	Tracking No	Packaging Type	Actual Wt	Billable Wt	Insured Value
1	1Z976R8W8430841976	Customer Packaging	20.0	20	0.00

- ❖ Check Pickup Status by going to [UPS.com](https://www.ups.com), click on the Shipping, select Schedule a Pickup, and look on the right side of screen to click on "Pickup Request Status". Enter in the Pickup No. listed on receipt into PRN field and submit

Airbill

JOHN SMITH
317-555-1234
INDIANA UNIVERSITY
980 W. WALNUT STREET
INDIANAPOLIS IN 46202

20 LBS

1 OF 1

RS

SHIP TO:
IUGB
317-278-6158
IU SCHOOL OF MEDICINE
TK 217
351 W 10TH ST
INDIANAPOLIS IN 46202



IN 461 9-01



UPS NEXT DAY AIR

1

TRACKING #: 1Z 976 R8W 84 3084 1976



BILLING: P/P
DESC: Biological Specimens
RETURN SERVICE
UN1845, DRY ICE, CLASS 9, 1 x 4.5 KG
AUDIT REQUIRED

Reference No.1: 6683830

Creating Airbills & Scheduling Pick Ups: Reprinting/Voiding Airbills

The screenshot shows the ShipExec Thin Client portal interface. At the top, there is a navigation bar with the ShipExec logo and three tabs: 'Shipping', 'History', and 'End of Day'. A green arrow points to the 'History' tab. Below the navigation bar, there is a search filter section with various input fields: 'Start Ship Date' (2021-03-15), 'End Ship Date' (2021-03-15), 'Site' (Select Site...), 'Shipper', 'Carrier', 'Service', 'Global MSN', 'Global Bundle ID', 'Ship Id', 'Tracking Number', 'Batch Reference', 'Batch Item Reference', 'Shipper Reference', and 'Consignee Reference'. There are also buttons for 'Consignee', 'Show Misc References', 'Search', and 'Clear'.

The diagram illustrates the process of reprinting or voiding an airbill. A box labeled 'Reprint' has a green arrow pointing down to a table. A box labeled 'Void' has a green arrow pointing up to the same table. The table contains one shipment record with the following data:

Action	Global MSN	Tracking Number	Shipper Reference	Consignee Reference	Ship Date	Weight	Rated Weight	Dimension
  	9506	1Z976R8W8430841976		6683830	2020-12-08	20 LB	20 LB	

- To reprint airbill or void a shipment, click “History” at the top of the ShipExec Thin Client portal
- If your shipment doesn’t automatically pop up, enter in the date of shipment and then click “Search”

Requirements Prior to Collections:

MATERIAL TRANSFER AGREEMENT

- Master Material Transfer Agreement must be in place with Institution prior to receiving kits from NCRAD
- Appendix A for BenfoTeam study must be completed by Investigator prior to receiving kits from NCRAD

IATA BIOSPECIMEN SHIPMENT TRAINING

- All study personnel responsible for shipping should be certified in biospecimen shipping
- It is the sites responsibility to provide additional training according to federal regulations including UN3373 Biological Substance Category B
- Resources:
 - International Air Transport Association Training (IATA) www.iata.org
 - UN3373 <http://hasmat.dot.gov>

Non-Conformance Issues

Non-Conformance

Solution

Low volume aliquots

Put cryovials in a row, aliquoting in order until sample is depleted

Tubes received frozen at an angle/inverted

Carefully place tubes upright in freezer and in shipper

Aliquots are not labeled or labeled incorrectly

Refer to training or MOP for correct label placement. Save all labels until samples are packed for shipping.

All frozen samples for one participant are not sent within one shipment box

Keep plasma and buffy coat for individual participants together. Use one cryobox per participant

Fields on Blood Sample and Shipment Form left blank or incorrect data is given

Complete Blood Sample and Shipment Form during participant's study visit while samples are processed

Blood Sample and Shipment Forms are not e-mailed to NCRAD or included in physical shipment.

Make copy of participants completed form after visit and save until shipment.

Resources

- Kit Request Module: www.kits.iu/BENFO
- Screening Visit Reporter: www.kits.iu.edu/BENFOscreening
- BENFO Webpage: <https://www.ncrad.org/coordinate-studies/benfoteam>
- Training and Account Survey: <https://redcap.link/BENFOaccountsurvey>

Contact Information

Questions?

Please Contact NCRAD Coordinator at:

- ❖ Phone: 1-800-526-2839
- ❖ Benfo Coordinator E-mail: eridelan@iu.edu
- ❖ NCRAD General E-mail: alzstudy@iu.edu
- ❖ Website: www.ncrad.org/coordinate-studies/benfoteam