

Preventing Alzheimer's Disease with Cognitive Training: **The PACT Trial**

Biospecimen Collection and Shipment training



National Centralized Repository for
Alzheimer's Disease and Related Dementias

Training Overview

- ❖ Study Specimen Collection Overview
- ❖ NCRAD Kit Request Module
- ❖ Specimen Labeling Instruction
- ❖ Specimen Collection and Processing
- ❖ Specimen Packaging and Shipment Instruction
- ❖ Creating Airbills and Scheduling Pickups
- ❖ Non-Conformance Issues
- ❖ Contact Information

PACT Specimen Collection

Samples will be collected and processed during Baseline Visit and Final Clinical Evaluation.

Plasma and Buffy Coat will be frozen and shipped to NCRAD for both visits

Specimen Type	All Visits
Plasma	X
Buffy Coat (DNA)	X

Kit Request Module

kits.iu.edu/PACT



PACT Kit Request System

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.

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.

Please enter your email address here to receive a confirmation email after completing the survey:

* must provide value

Select your site:

* must provide value

Specimen Collection Kit

Number of PACT Blood Collection Kit(s) needed:

Each PACT Collection Blood Kit Contains:

2 EDTA tube, 10ml [CT001]
6 2ml Cryovial Tubes - PURPLE [CV027]
1 2ml Cryovial Tube - BLUE [CV034]
2 2ml Cryovial Tubes - CLEAR [CV014]
1 Centrifuge tube, 15ml (unwrapped) [CV004]
9 Small Preprinted Cryovial labels (no clear tail) [LB003]
5 Kit Number Labels
3 Participant ID Labels
1 Cryovial box (holds up to 25 cryovials) [CV005]
2 Disposable graduated transfer pipette (3 ml) [CV015]
1 Resealable plastic bag [ST002]
1 4x5 Plastic bag [ST010]

❖ Ordering blood kit supplies

❖ Ordering frozen specimen

shipment supplies

❖ Please allow **two to three weeks** for orders to be processed and delivered to your site



Kit Request Module Instruction

Please enter your email address here to receive a confirmation email after completing the survey:
* must provide value

Select your site:
* must provide value

Do changes need to be made to shipping address or contact information? Yes No reset

University of South Florida
ATTN: Jerri Edwards, Ph.D.
3515 E. Fletcher Avenue
MDT 200
Tampa, Florida 33613
Phone: (813) 974-6703
E-mail: jedwards1@usf.edu

Specimen Collection Kit

Number of PACT Blood Collection Kit(s) needed:

Each PACT Collection Blood Kit Contains:

- 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
- 1 Resealable plastic bag

Our standard shipping time for all orders is 2-3 weeks. If you need any items from this order expedited, please indicate the earliest date you will need these supplies and write which items need expedited in the comment section. Today M-D-Y

Comments
Expand

1. Verify site shipping address and contact information
2. Choose kit order amount
 - Specimen Collection Kit
 - Frozen Shipping Supply Kit
 - Supplemental Kit
 - Extra Supplies
3. Rush order or special comments

*Reminder: allow **two to three weeks** for orders to be processed and delivered to your site

Specimen Labeling Instruction

Specimen Labeling Instructions: Label Type and Placement

Kit Number Label

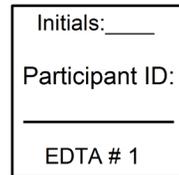


Ties all visit samples and packaging together.

Must be placed on:

1. Blood Sample and Shipment Notification Form
2. Each Cryobox

Participant ID Label

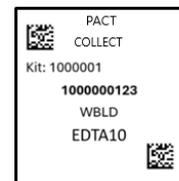


Unique PACT Participant ID written by site and initials of blood processing staff

Must be placed on:

1. Whole-Blood 10 ml EDTA Tube (Purple-Top)

Collection Tube Label



Contains Specimen Number, Specimen Type, and Kit Number.

Must be placed on:

1. Whole-Blood 10 ml EDTA Tube (Purple-Top)

Aliquot Cryovial Label



Contains Specimen Number, Specimen Type, and Kit Number.

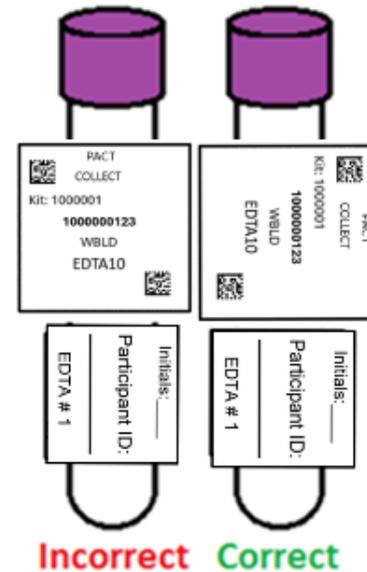
Must be placed on:

1. Aliquoted 2 ml cryovial with corresponding aliquot type

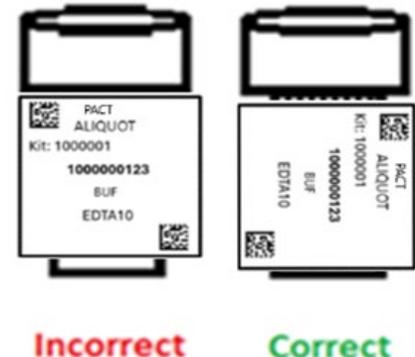
Specimen Labeling Instruction: Label Placement Details

- ❖ Write participant ID and initials 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 subject at a time** in order to avoid mix ups.
- ❖ Wrap labels **horizontally** and adhere **completely** to all tubes

Collection Tube Labeling



Cryovial Labeling

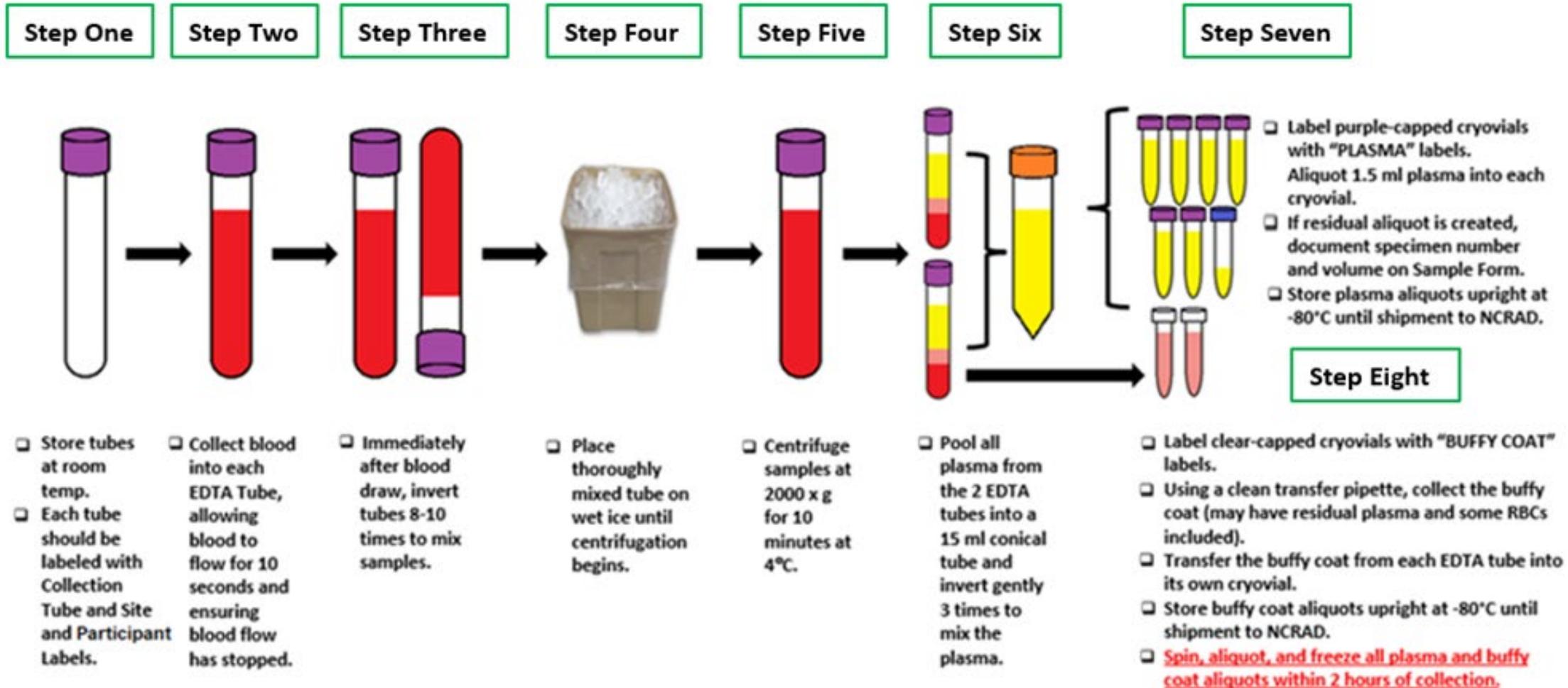


Specimen Collection and Processing

Specimen Collection and Processing: Specimen Tube Types

Type	Cap Color	Size	Purpose	Amount
EDTA Tube	Purple	10 ml	Whole blood collection	2
Conical Tube	Orange	15 ml	Pooling plasma from EDTA tubes	1
Cryovial	Lavender	2 ml	1.5 ml aliquots of plasma from conical tube	Up to 7
Cryovial	Blue	2 ml	Aliquot residual plasma <1.5 ml after filling lavender top cryovials	1
Cryovial	Clear	2 ml	~1.0 ml aliquots of buffy coat from EDTA tubes	2

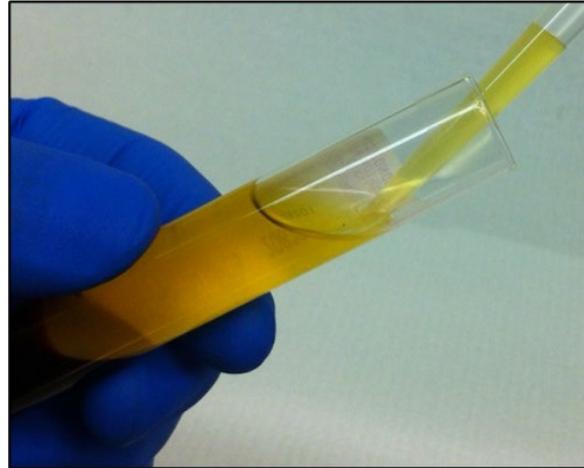
Specimen Collection and Processing: Blood Collection and Specimen Processing



Specimen Collection and Processing: Plasma Collection



10 ml EDTA tubes after centrifuge

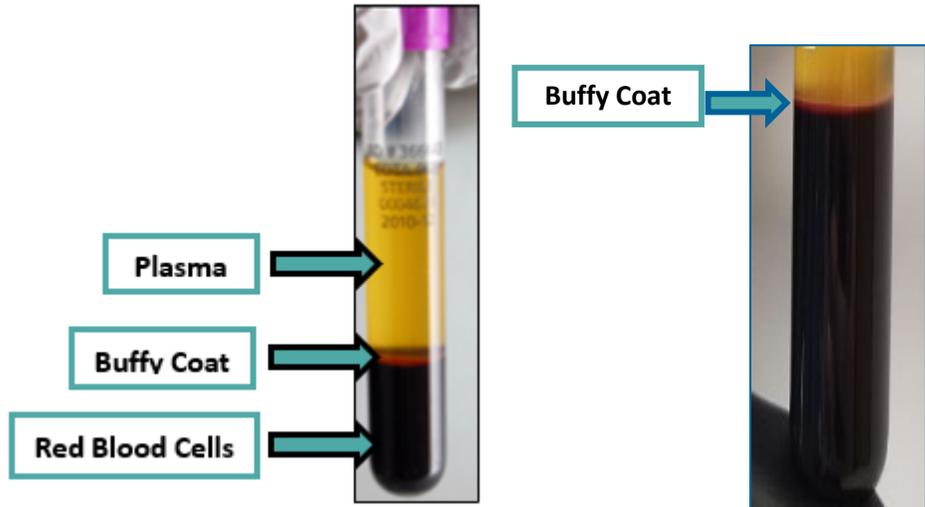


15 ml conical after inversion



- ❖ Processed plasma creates up to seven 1.5 ml aliquots in lavender-top cryovials
- ❖ Residual plasma is placed in blue-top cryovial

Specimen Collection and Processing: Buffy Coat Collection



- ❖ Aliquot ~1.0 buffy coat into two clear-capped cryovials
- ❖ The buffy coat aliquot is expected to have a reddish color from the RBCs

Specimen 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 Shipment and Notification Form



Batch samples together (8 cryoboxes)

Frozen Shipment Tutorial

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
- ❖ Each Styrofoam shipper can contain up to 8 cryoboxes



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 up to 8 cryoboxes with tubes laying upright
- Step 4. Fully cover all cryoboxes with 2 inches of dry ice
- Step 5. Place Styrofoam shipping container into cardboard shipping container



Blood Sample and Shipment Notification Form

Step 6. Include Blood Sample & Shipment Notification Form in Large 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

Appendix B: Blood Sample and Shipment Notification Form

Please email or fax the form on or prior to the date of shipment.

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

From: _____ UPS tracking #: **1Z976R8W**

Phone: _____ Email: _____

Study: PACT Baseline Visit 3-Year Visit

Participant ID: _____

Sex: M F Year of Birth: _____ Training Level: _____

KIT BARCODE

Blood Collection:

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)

Original blood volume of EDTA #1: _____ mL	Original blood volume of EDTA #2: _____ mL	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 (lavender cap, up to 6): _____
If applicable, volume of residual plasma aliquot (less than 1.5 mL in blue cap): _____ mL <input type="checkbox"/> N/A	If applicable, 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): _____	Buffy coat #2 volume: _____ mL	Time aliquots placed in freezer: _____ [HHMM]	Storage temperature of freezer: _____ °C

Notes: _____

Specimen Packaging and Shipment: Cardboard Package Labeling

Step 7.

Number of packages in shipment and dry ice in kg

Shipper's Declaration not Required. Part B is required. Dry Ice amount must be in kilograms. Note: 2 lbs. = 1 kg.

Always bills/Airbills must have the following:
1. "Dangerous Goods Shipper's Declaration Required".
2. Dry Ice: 9, UN1845;
3. _____ X _____ Kg III
(Number of packages) (Net weight)

DRY ICE
kg.

9

UN1845

Shipper's Name and Address

Consignee Name and Address

5-2844 ULINE 1-800-295-5510

Net weight of dry ice in **kg**

Your name & address

Repository name & address

Dry Ice
For Diagnostic or Medical Purposes Only
No Shipping Papers Required
Contains **20** kg of Dry Ice

011127 2/16 RRD

Net weight of dry ice in **kg**



Dangerous Goods Label
Additional Training Required

Creating Airbills & Scheduling Pickups

Navigating UPS ShipExec Tutorial

https://ncrad.org/shipping_address.html

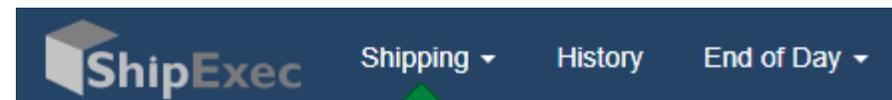
UPS ShipExec™ Thin Client Website



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



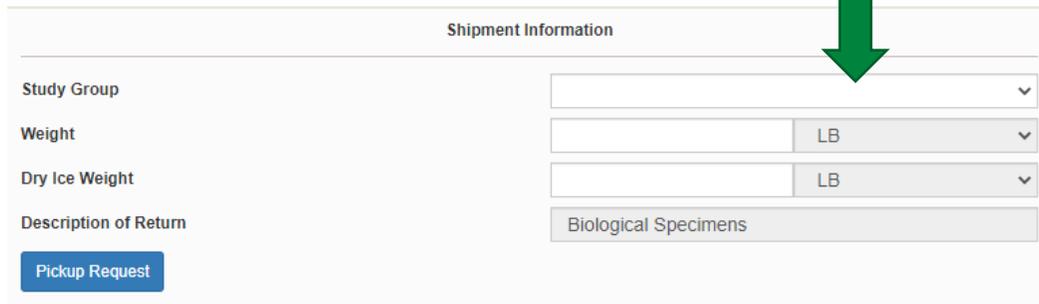
Click on the “Shipping”
dropdown and click on “Shipping
and Rating”



Creating Airbills & Scheduling Pick Ups: Finding your Contact Information

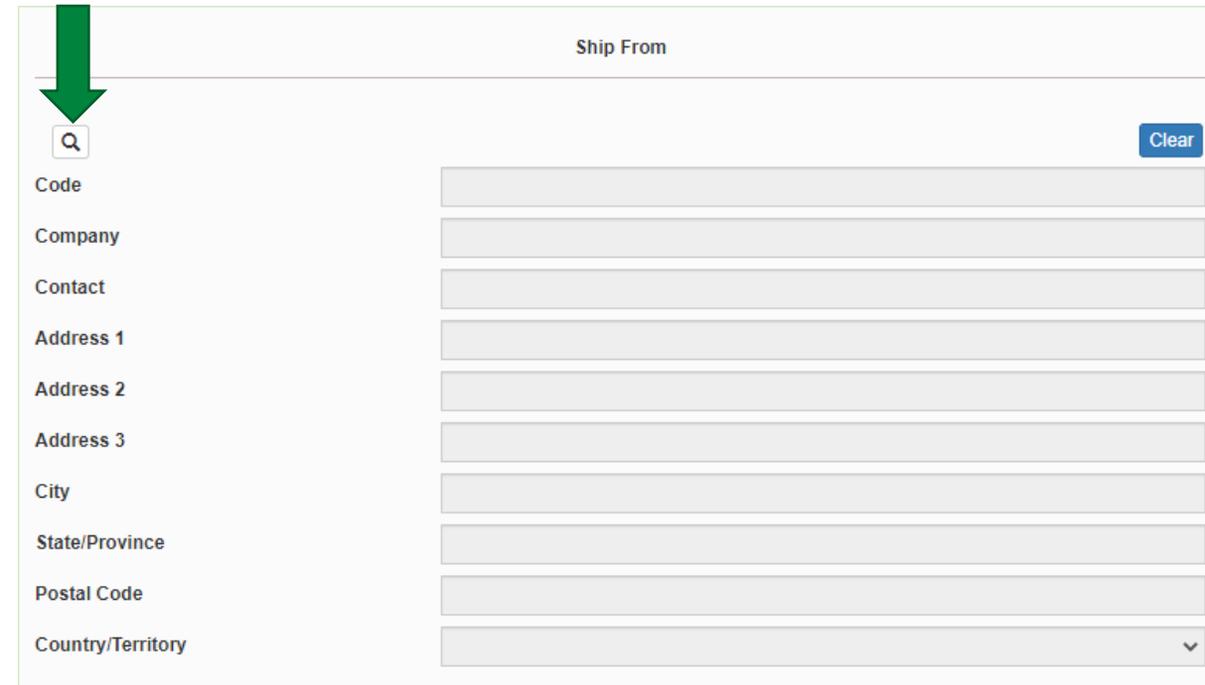
- ❖ On the right side of the screen, choose the name of your study from the “Study Group” drop down menu

❖ *This step must be done 1st*



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.

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



The screenshot shows a form titled "Ship From". It features a search bar at the top left with a magnifying glass icon, and a blue "Clear" button at the top 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

Search Address

Select address book

Address Book	Type
RETURNS	Company

Group: ADCFB (NCRAD)

Code:

Company:

Contact:

Address 1:

Address 2:

Address 3:

City:

State/Province:

Postal Code:

Country/Territory:

Email: Phone Fax: Account / Tax:

Email:

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. Geldy 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
- ❖ 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

Weight LB

Dry Ice Weight LB

Description of Return

Create Pickup Request ×

Pickup Date

Earliest Time Ready

Latest Time Ready

Contact Name

Contact Phone

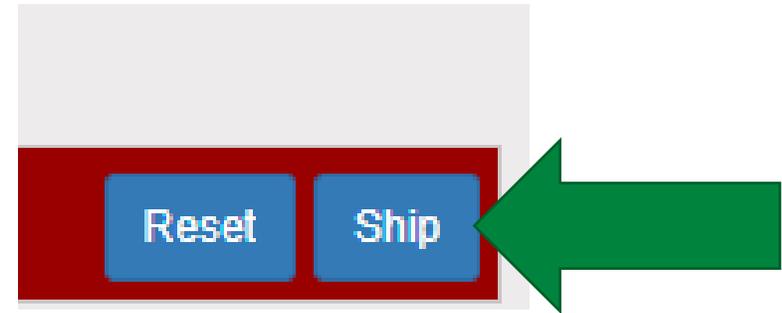
Payment Method

Room Number

Floor

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

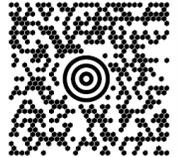


BILLING: P/P
DESC: Biological Specimens
RETURN SERVICE
UN1845, DRY ICE, CLASS 9, 1 x 4.5 KG
AUDIT REQUIRED

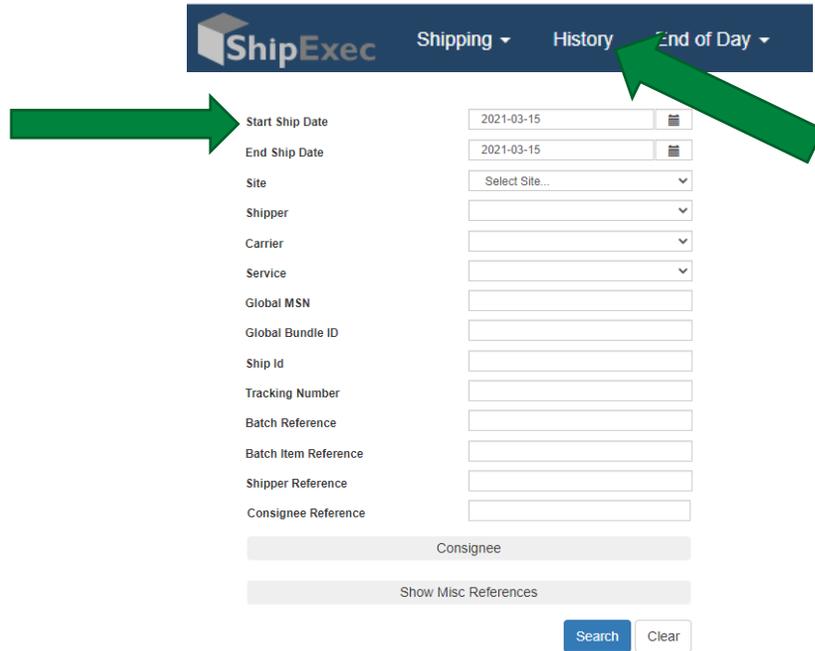
Reference No.1: 6683830

Creating Airbills & Scheduling Pick Ups: Shipping Packages

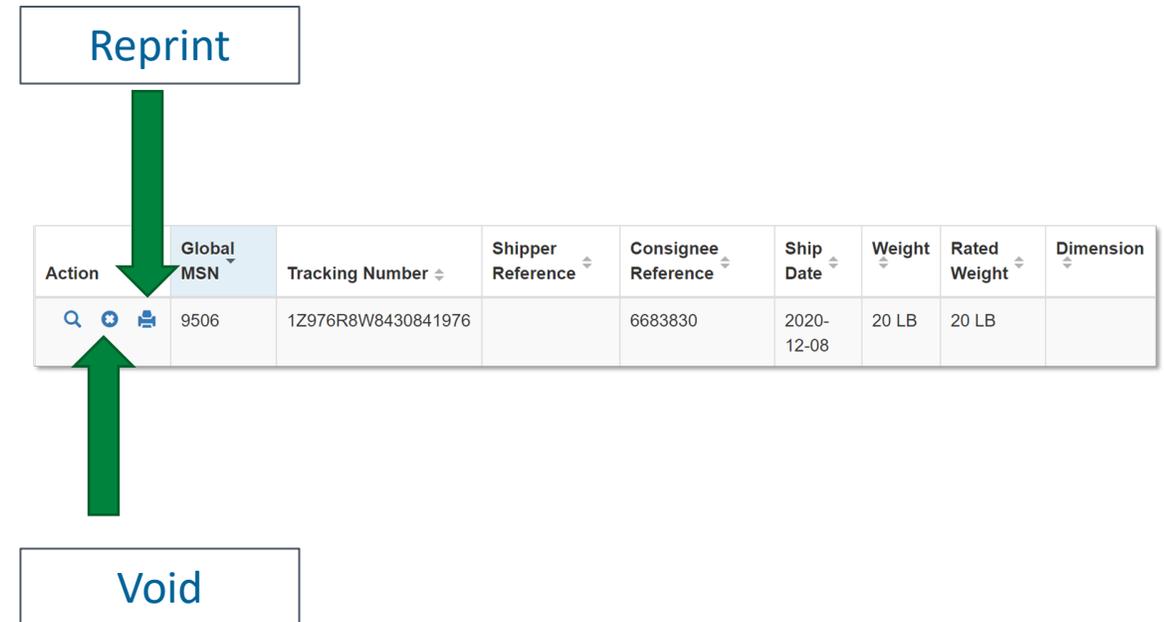
1. Print out the UPS air waybill
2. Fold the UPS Air Waybill and slide it inside the plastic UPS Sleeve (Provided by NCRAD)
3. Peel the back off the plastic UPS sleeve and stick the sleeve to cardboard package
 - ❖ Make sure it is laying as flat as possible along the surface of the package.

JOHN SMITH 317-555-1234 INDIANA UNIVERSITY 980 W. WALNUT STREET INDIANAPOLIS IN 46202	20 LBS RS	1 OF 1
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		
 SAMPLE		
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 screenshot shows a table of shipment records. A green arrow points from a 'Reprint' button above to the 'Action' column of the table. Another green arrow points from a 'Void' button below to the same 'Action' column. The table has the following columns: Action, Global MSN, Tracking Number, Shipper Reference, Consignee Reference, Ship Date, Weight, Rated Weight, and Dimension. The first row of data contains: Action (with search, refresh, and print icons), Global MSN (9506), Tracking Number (1Z976R8W8430841976), Shipper Reference, Consignee Reference (6683830), Ship Date (2020-12-08), Weight (20 LB), Rated Weight (20 LB), and Dimension.

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”

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 subjects together. Use one cryobox per subject

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 or faxed to NCRAD before shipment arrives

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

Contact Information

• Questions?

- Please Contact NCRAD Coordinator at:
 - ❖ Phone: 1-800-526-2839
 - ❖ PACT Coordinator E-mail: eridelan@iu.edu
 - ❖ NCRAD General E-mail: alzstudy@iu.edu
 - ❖ Website: www.NCRAD.org
 - ❖ PACT Webpage: <https://ncrad.org/coordinate-studies/pact>