

Nicotinic Acid for the Treatment of Alzheimer's Disease: A Phase 1b/2a Study

BIOSPECIMEN COLLECTION AND SHIPMENT TRAINING



National Centralized Repository for
Alzheimer's Disease and Related Dementias

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Nicotinic Acid Biospecimen Collection Schedule

Collection Tube	Visit	Specimen Type	Aliquot Volume	Total Number of Aliquots	Cap Color
2 x EDTA (Purple-Top) Blood Collection Tubes (10 ml)	Day 0, Day 60	Plasma	1.5 ml plasma aliquots	Up to 7	Purple
		Residual Plasma	<1.5 plasma aliquot	1	Blue
		Buffy Coat	~1.0 ml buffy coat aliquots	2	Clear
1 x CSF (Blue-Top) Conical Tube (20 ml)	Day 0, Day 60	Local Lab CSF	1.0-2.0 ml	1	Yellow
		Processed CSF	1.5 ml	11	Clear
		Residual CSF	<1.5 ml	1	Blue

Kit Request Module

www.kits.iu.edu/NicotinicAcid

- ❖ 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


Specimen Collection Kit

Number of blood collection kits needed:

Each Nicotinic Acid blood collection kit contains:

Kit Contents
02 EDTA tube 10 ml [CT001]
06 2ml Cryovial - Purple [CV027]
01 2ml Cryovial - Blue [CV034]
02 2ml Cryovial - Clear [CV014]
01 15ml Centrifuge tube [CV004]
02 Disposable Pipet (3ml) [CV015]
01 Cardboard Cryobox, 25 slot [CV005]
01 Resealable Bag [ST002]

Labels
10 Preprinted Cryovial Labels [LB003]
05 Kit Number Labels [LB003]
03 Participant ID Labels [LB003]
01 2x4 Label [LB006]



Number of CSF collection kits needed:

Each Nicotinic Acid CSF collection kit contains:

Kit Contents
01 LP Tray 22 Gauge Sprotte w Introducer [LP006]
11 2ml Cryovial - Clear [CV014]
01 2ml Cryovial - Yellow [CV037]
01 2ml Cryovial - Blue [CV034]
02 50ml Conical Tube, Individually Wrapped [CV056]
01 Disposable Pipet (3ml) [CV015]
01 Cardboard Cryobox, 25 slot [CV005]
01 Resealable Bag [ST002]

Labels
13 Preprinted Cryovial Labels [LB003]
01 Participant ID Label [LB003]
01 Kit Number Label [LB003]
01 2x4 Label [LB006]

➤ Verify site shipping address and contact information

➤ Enter amount of each kit need

➤ Consider EDTA expiration roughly 3 months when ordering

➤ Allow **2-3 weeks** when placing order for kits to be ready for pick up

Kit Pick Up

- ❖ You will receive a notification via e-mail when your kit contents are ready for pick up.

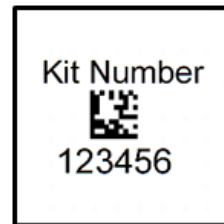
- ❖ Address: 351 W 10th Street Room #316
 1. Enter through the main doors closest to the canal.
 2. Turn left at the first hallway and there will be signs for elevators.
 3. Take the elevator to the 3rd floor.
 4. Pick up ordered kit supplies outside of room #316.

- ❖ Hours of Operation are Monday through Friday 8:00 am – 5:00 pm
 - ❖ Please be aware of our holiday closures found here <https://ncrad.org/contact/holiday-closures>

Specimen Labeling Instruction

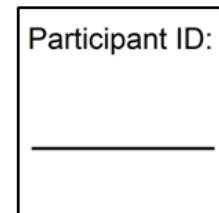
Specimen Labels

Kit Number Label



- Ties all biospecimens and kit content together for each participant
- Placed on EDTA tubes, 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

Aliquot Label



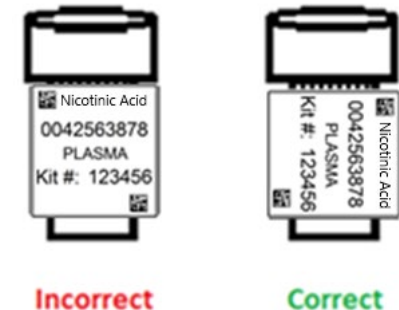
- Specific to type of biospecimen
- Contains unique Specimen# and Kit#
- Place on processed cryovials

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



Collection Tube
Label Diagram



Aliquot
Label Diagram

Specimen Collection and Processing

Nicotinic Acid Biospecimen Samples

NCRAD will provide training and materials for the following biospecimens:

- ❖ Plasma
- ❖ Buffy Coat
- ❖ CSF

PROCESSING PLASMA AND BUFFY COAT

Step One



- ❑ Store tubes at room temp.
- ❑ Each tube should be labeled with Collection Tube and Site and Participant Labels.

Step Two



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

Step Three



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

Step Four



- ❑ Place thoroughly mixed tube on wet ice until centrifugation begins.

Step Five



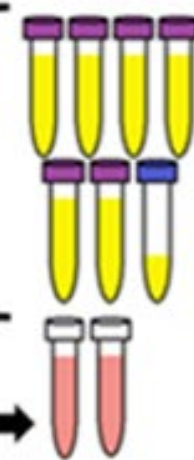
- ❑ Centrifuge samples at 2000 x g for 10 minutes at 4°C.

Step Six



- ❑ Pool all plasma from the 2 EDTA tubes into a 15 ml conical tube and invert gently 3 times to mix the plasma.

Step Seven

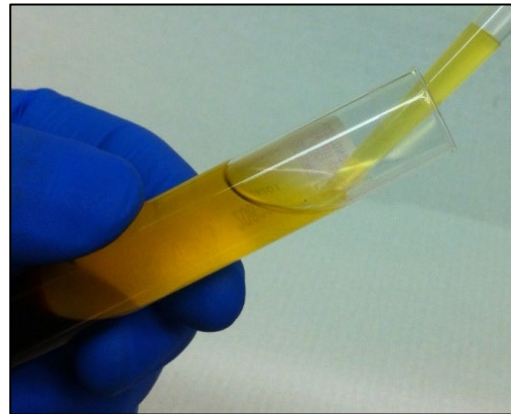
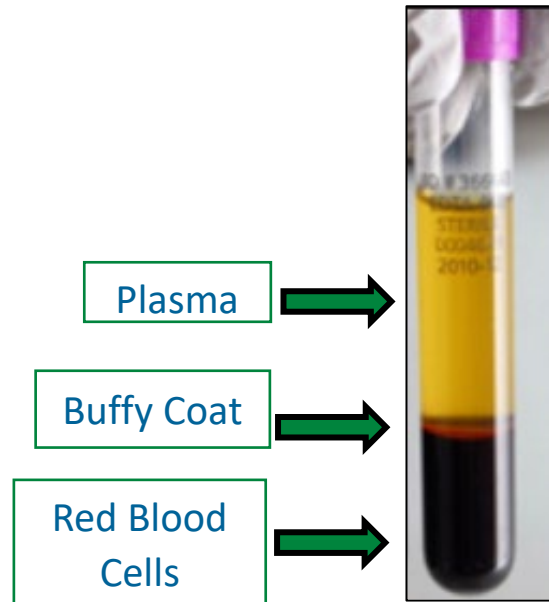


- ❑ Label purple-capped cryovials with "PLASMA" labels. Aliquot 1.5 ml plasma into each cryovial.
- ❑ If residual aliquot is created, document specimen number and volume on Sample Form.
- ❑ Store plasma aliquots upright at -80°C until shipment to NCRAD.

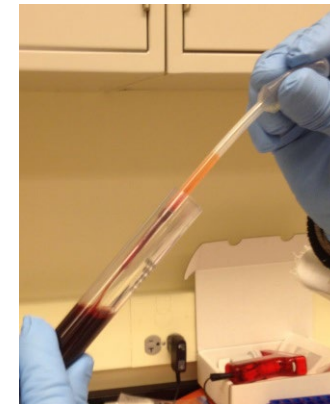
Step Eight

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

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

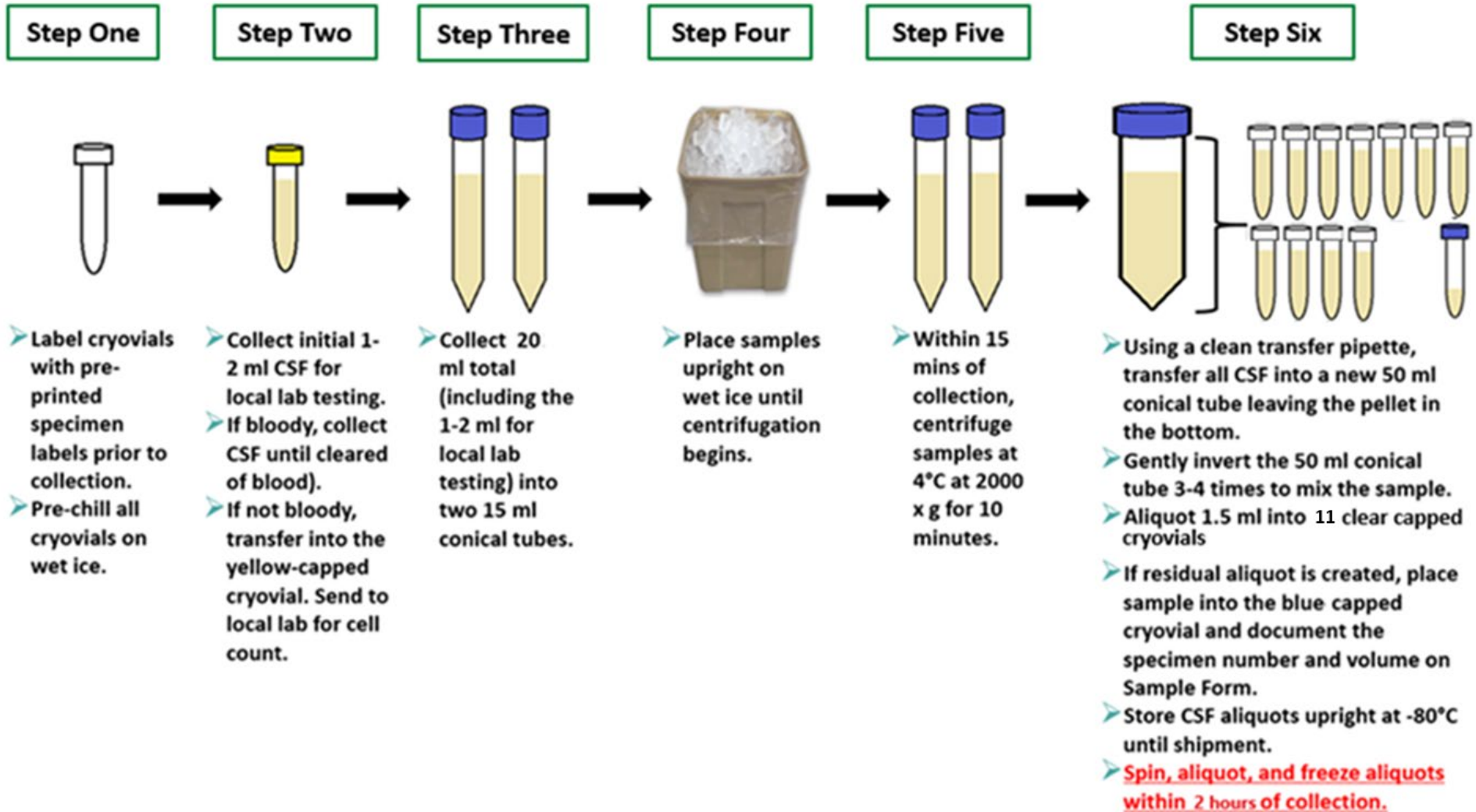


50 ml Conical with
30 ml pooled plasma
after inversion



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

PROCESSING CSF



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



Batch samples together (8 cryoboxes)



Sites provide dry ice for shipments

~45 lbs. per batch shipment

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: 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

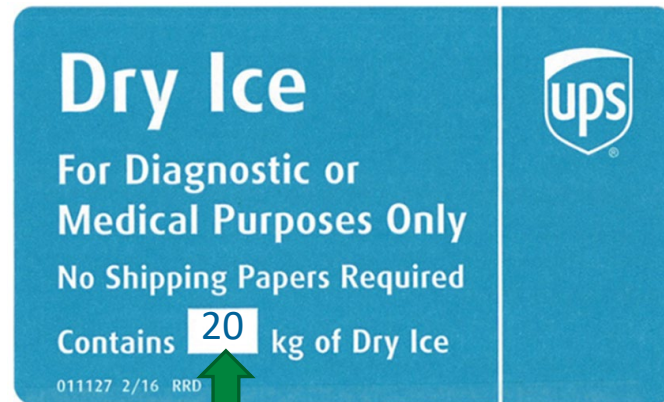
Appendix B: Blood Sample and Shipment Notification Form

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

To: Kelley Faber Email: alzstudy@iu.edu Phone: 1-800-526-2839/317-278-8413			
From: _____		UPS tracking #: 1Z976R8W84	
Phone: _____		Email: _____	
Study: Nicotinic Acid		Participant ID: _____	
Year of Birth: _____		Sex: <input type="checkbox"/> M <input type="checkbox"/> F	
Visit: <input type="checkbox"/> Day 0 <input type="checkbox"/> Day 60		KIT BARCODE	
<i>Blood Collection:</i>			
Date of Draw: _____ [MMDDYY]		Time of Draw: _____ [HHMM]	
Date participant last ate: _____ [MMDDYY]		Time participant last ate: _____ [HHMM]	
<i>Blood Processing:</i>			
Plasma & Buffy Coat (EDTA Tube)			
Original blood volume of EDTA #1: _____		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 (purple 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 6.



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](https://ncrad.org/shipping_address.html)

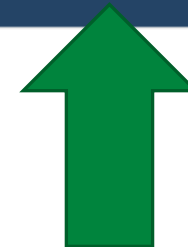
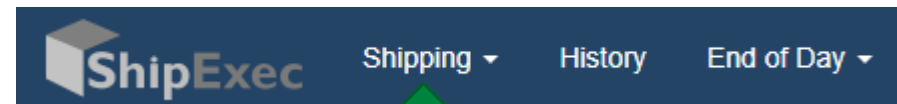
UPS ShipExec™ Thin Client Website



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



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

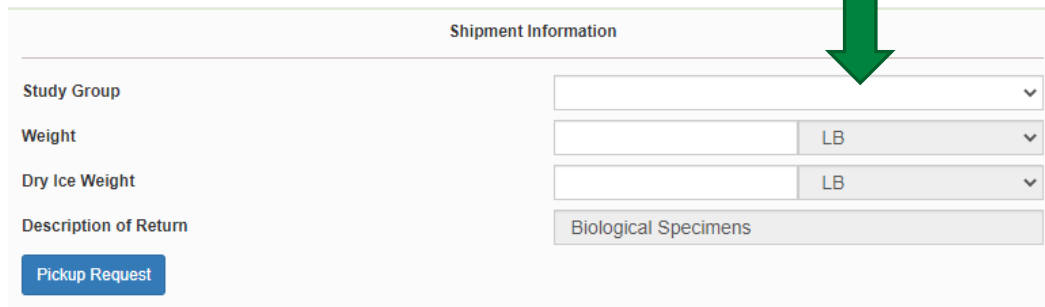


Creating Airbills & Scheduling Pick Ups: Finding your Contact Information

❖ 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*

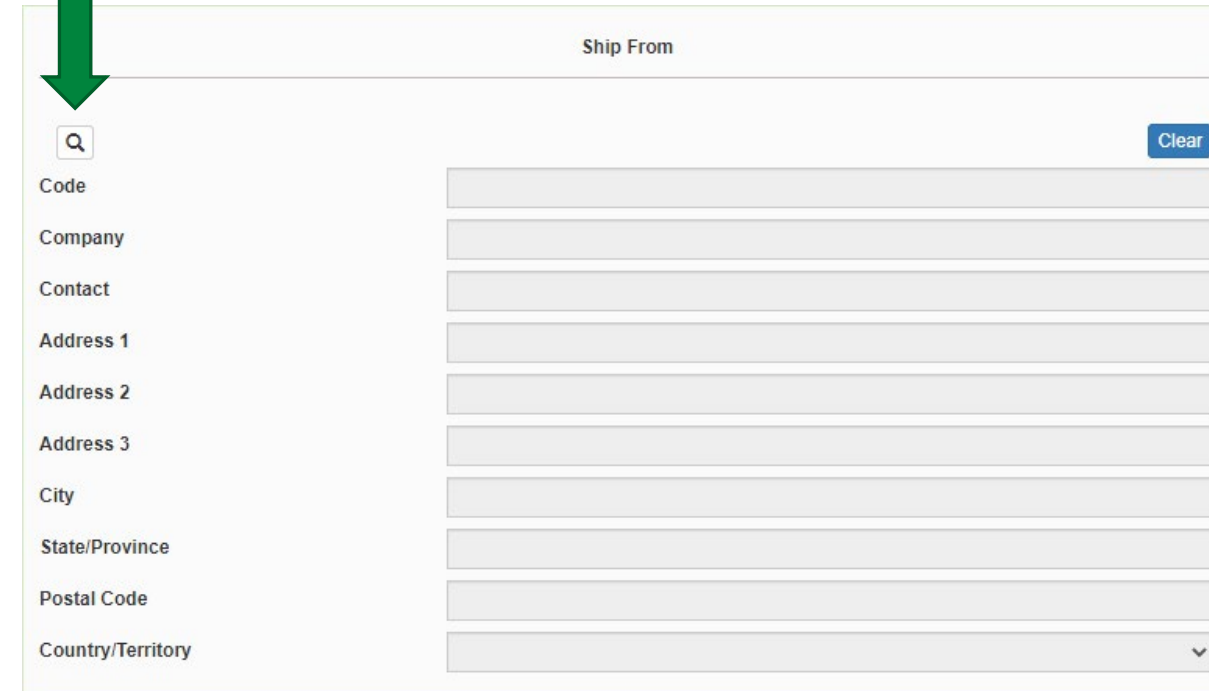
❖ On the left side of the screen, Click on the magnifying glass icon



The screenshot shows a form titled "Shipment Information". It contains the following fields:

- Study Group: A dropdown menu with a downward arrow.
- Weight: A text input field followed by a unit dropdown menu set to "LB".
- Dry Ice Weight: A text input field followed by a unit dropdown menu set to "LB".
- Description of Return: A dropdown menu with "Biological Specimens" selected.

A blue button labeled "Pickup Request" is located at the bottom left. A large green arrow points from the text above to the "Study Group" dropdown menu.



The screenshot shows a form titled "Ship From". It features a search bar with a magnifying glass icon and a "Clear" button. Below the search bar are several input fields:

- Code
- Company
- Contact
- Address 1
- Address 2
- Address 3
- City
- State/Province
- Postal Code
- Country/Territory: A dropdown menu with a downward arrow.

A large green arrow points from the text above to the magnifying glass icon in the search bar.

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

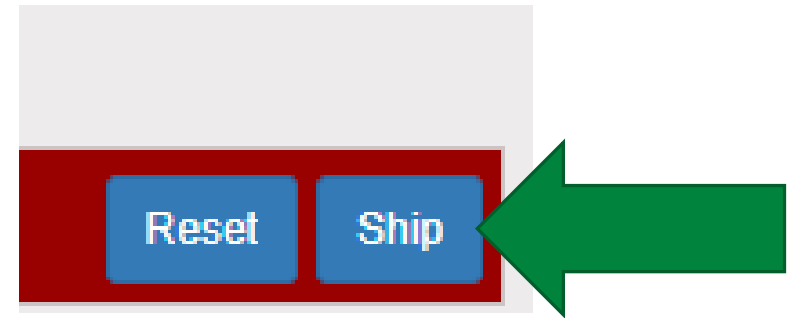
Study Group	<input type="text"/>	▼
Weight	<input type="text"/>	LB ▼
Dry Ice Weight	<input type="text"/>	LB ▼
Description of Return	Biological Specimens	

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

ShipExec Shipping History End of Day

Start Ship Date: 2021-03-15

End Ship Date: 2021-03-15

Site: Select Site...

Shipper: [Dropdown]

Carrier: [Dropdown]

Service: [Dropdown]

Global MSN: [Text]

Global Bundle ID: [Text]

Ship Id: [Text]

Tracking Number: [Text]

Batch Reference: [Text]

Batch Item Reference: [Text]

Shipper Reference: [Text]

Consignee Reference: [Text]

Consignee: [Text]

Show Misc References: [Text]

Search Clear

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	

Reprint

Void

- 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 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 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
- ❖ Nicotinic Acid Coordinator E-mail: eridelan@iu.edu
- ❖ NCRAD General E-mail: alzstudy@iu.edu
- ❖ Website: www.NCRAD.org
- ❖ Study Webpage: www.ncrad.org/coordinate-studies/nicotinic-acid