

Multicultural Community Dementia Screening (MCS)

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

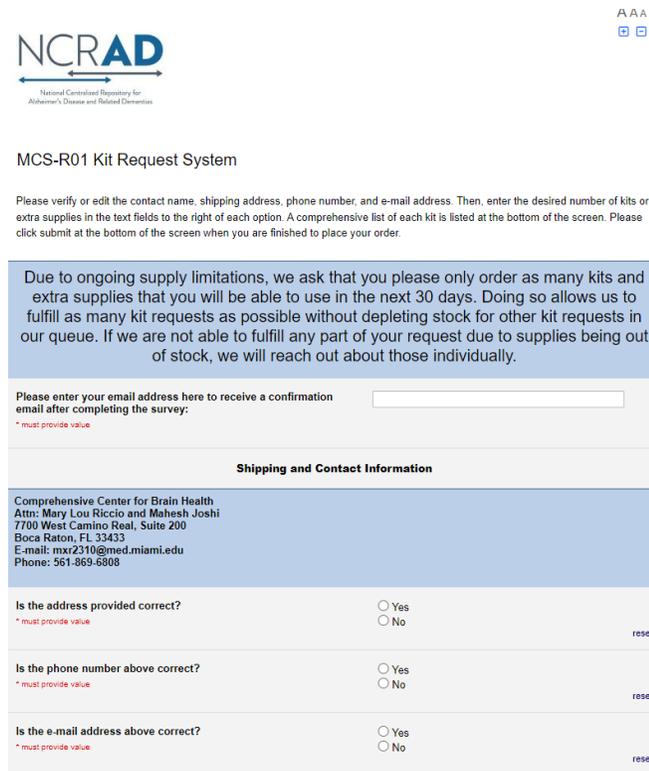
MCS Specimen Collection

- Samples will be collected and processed during Baseline Visit and during annual visit for 5-years.
- Plasma and Buffy Coat will be frozen and shipped to NCRAD for all visits

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

Kit Request Module

www.kits.iu.edu/MCS



The screenshot shows the NCRAD MCS-R01 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". To the right of the logo are three small square icons. Below the logo, the text "MCS-R01 Kit Request System" is displayed. 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 indicating it is required. The "Shipping and Contact Information" section includes contact details for the Comprehensive Center for Brain Health, Attn: Mary Lou Riccio and Mahesh Joshi, located at 7700 West Camino Real, Suite 200, Boca Raton, FL 33433. It also provides an email address (mxr2310@med.miami.edu) and a phone number (561-869-6808). Three validation questions are listed: "Is the address provided correct?", "Is the phone number above correct?", and "Is the e-mail address above correct?". Each question has radio buttons for "Yes" and "No", a red asterisk indicating it is required, and a "reset" link.

❖ 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

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

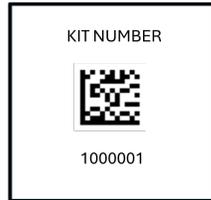
*Reminder: allow **two to three weeks** for orders to be processed and delivered to your site

Specimen Collection Kit	
Number of MCS Blood Collection Kit(s) needed:	<input type="text"/>
Each MCS 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 [CV004] 11 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] 3 Disposable graduated transfer pipette (3ml) [CV015] 1 Resealable plastic bag [ST002] 1 Resealable small poly bag (4"x6") [ST010]	
Frozen Shipping Supply Kit	
Number of MCS Frozen Shipping Kit(s) needed: (for up to 8 subjects)	<input type="text"/>
Each MCS Frozen Shipping Supply Kit Contains:	
8 Plastic Biohazard bag with absorbent sheet (small) [SH015] 1 UPS return airbill and pouch [SH002] 1 Shipping box/Styrofoam container [SH003] 1 Warning label packet with dry ice sticker [LB016] 1 Resealable Bag [ST002]	
Supplemental Kit	
Number of MCS Blood Supplemental Supply Kit(s) needed:	<input type="text"/>
Each MCS Supplemental Supply Kit Contains:	
04 EDTA tube, 10ml [CT001] 12 2ml Cryovial Tubes - PURPLE [CV027] 02 2ml Cryovial Tubes - BLUE [CV034] 04 2ml Cryovial Tubes - CLEAR [CV014] 02 50 ml Conical Tube [CV019] 05 Participant ID labels [LB003] 02 Cryovial box (holds up to 25 cryovials) [CV005] 06 Disposable graduated transfer pipette [CV015] 01 Resealable plastic bag [ST002] 06 Resealable small poly bag (4" x 6") [ST010]	

Specimen Labeling Instruction

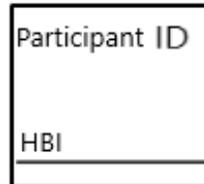
Specimen Labels

Kit Number Label



- Ties all biospecimens and kit content together for each participant
- Placed on each cryobox and blood sample notification form

Participant ID Label



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

Collection Tube Label



- Specific to type of specimen. Contains unique specimen ID, barcodes, and kit number.
- Place on each collection tube

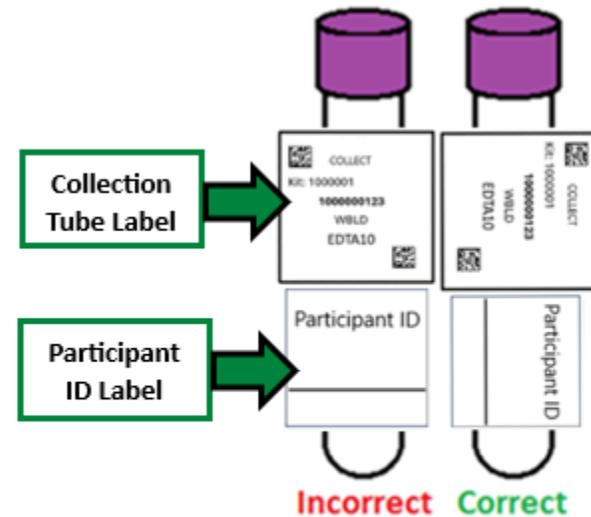
Aliquot Cryovial Label



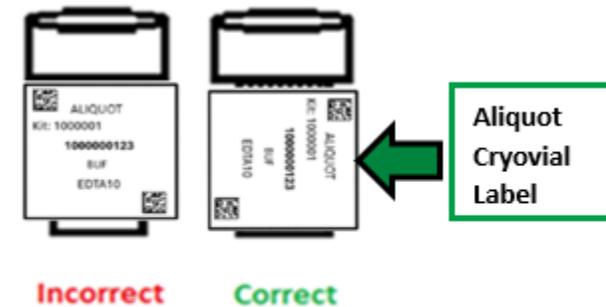
- Specific to type of specimen. Contains unique specimen ID, barcodes, and kit number.
- Place on each collection tube

Specimen Labeling Instruction: Label Placement Details

- ❖ Write participant ID with fine-point marker prior to label placement
- ❖ Place **all** labels on specimen specific collection tubes 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



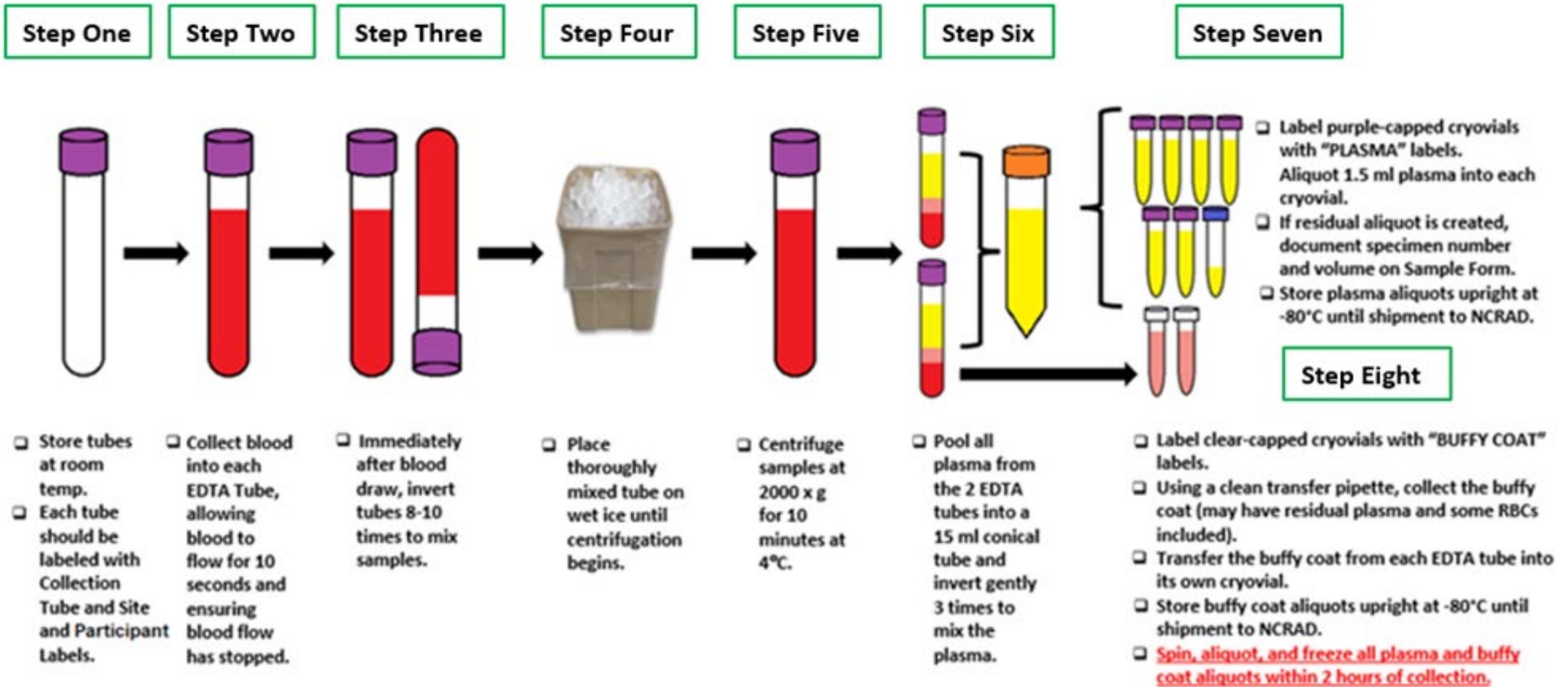
Aliquot Cryovial Label Diagram

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
Centrifuge Tube	Orange	15 ml	Pooling plasma from EDTA tubes	1
Cryovial	Lavender	2 ml	1.5 ml aliquots of plasma from Centrifuge 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



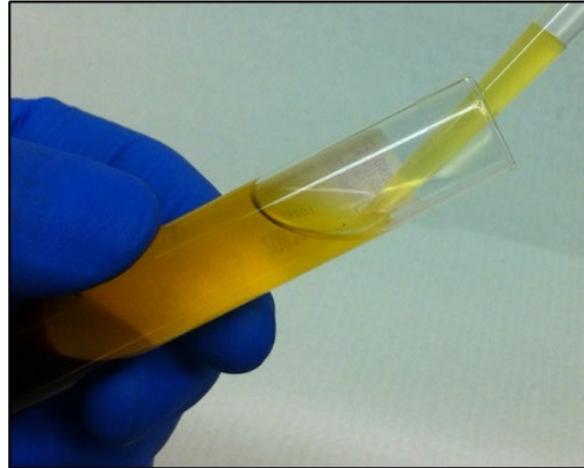
Specimen Collection and Processing: Plasma Collection



10 ml EDTA tubes after centrifuge

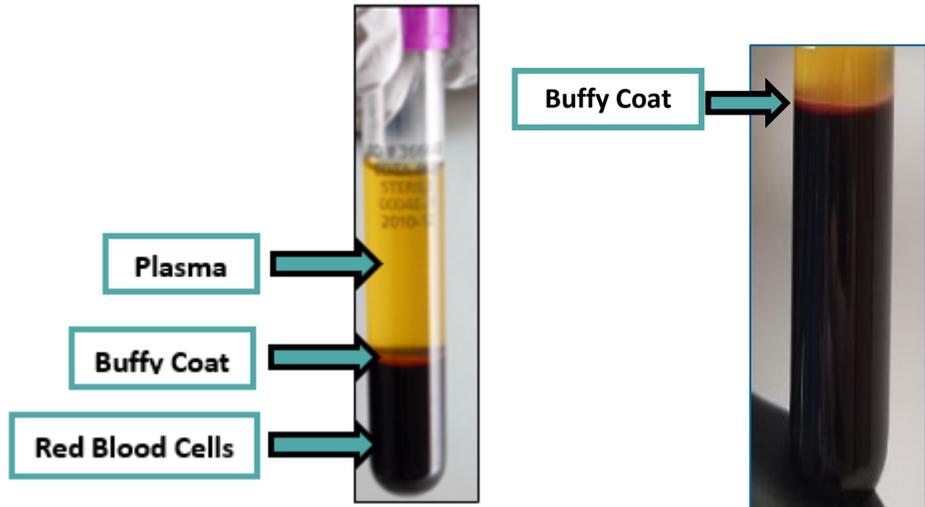


15 ml conical after inversion



- ❖ 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



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

- Each Styrofoam shipper must contain 45 lbs. (20 kg) of dry ice
- Important: Fill shipper to the top with dry ice



Blood Sample and Shipment Notification Form

- ✓ 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
- ✓ Include Blood Sample and Shipment Notification Form in Large Cardboard Shipper

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: <u> Mahesh Joshi, PhD </u>		UPS tracking #: <u> 1Z976R8W84 </u>	
Phone: <u> 561-869-6827 </u>		Email: <u> maj145@med.miami.edu </u>	
Study: Multicultural Community Dementia Screening			
Visit: <input type="checkbox"/> Baseline <input type="checkbox"/> 1-Year <input type="checkbox"/> 2-Year <input type="checkbox"/> 3-Year <input type="checkbox"/> 4-Year <input type="checkbox"/> 5-Year			
Sex: <input type="checkbox"/> M <input type="checkbox"/> F		Year of Birth: _____	
Participant ID: HBI _____		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: Federal Shipping Regulations and Training

- Important: It is the sites' responsibility to ensure all study personnel responsible for shipping has received the appropriate IATA training for certification in biospecimen shipping

International Air Transport Association (IATA) Training

DGI Training Center 800-338-2291 DGItraining.com Provides IATA Certified Air Seminars and online courses	IATA Training Schools North America 1(514)390-6726 Europe, Africa & Middle East 41 (22) 799 2751 Asia, Australia & the Pacific 65 239 7232 www.iata.org Training schools located in 30 countries
Saf-T Pak Inc. www.saftpak.com Provides dangerous goods training via CD or on-site instruction for North America and Europe	Aiconsult Email: Airconsult@wanadoo.fr www.airconsult-bf.com
Bureau of Dangerous Goods LTD., TIANJIN Addr.: No.3 Yingshui road, Nankai district, Tianjin China Tel: 022-23495890 83326960 83326854 / Fax: 022-83326959 Email: cadmin@bdg-china.com.cn www.bdg-china.com.cn	

Specimen Packaging and Shipment: UN3373 Biological Substance-Category B Training Resources

- ❖ Training for UN3373 Biological Substance-Category B being transported for investigational purposes is recommended for study personnel
- ❖ Find training information and further resources on the Department of Transportation website <http://hasmat.dot.gov>

Creating Airbills & Scheduling Pickups

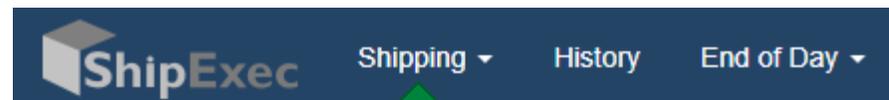
UPS ShipExec™ Thin Client Website



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



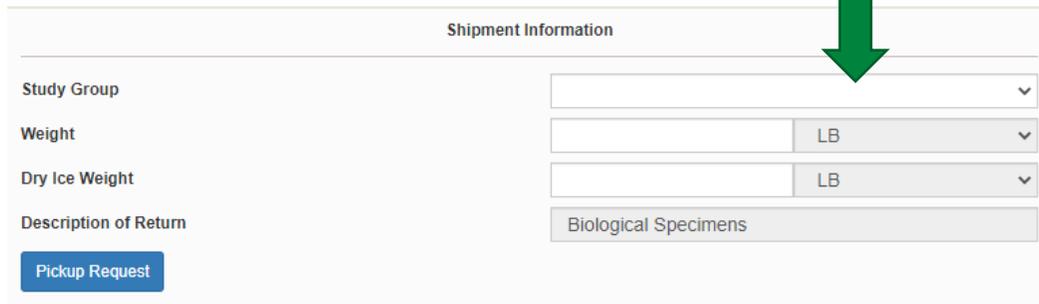
Click on the “Shipping”
dropdown and click on “Shipping
and Rating”



Creating Airbills & Scheduling Pick Ups: Finding your Contact Information

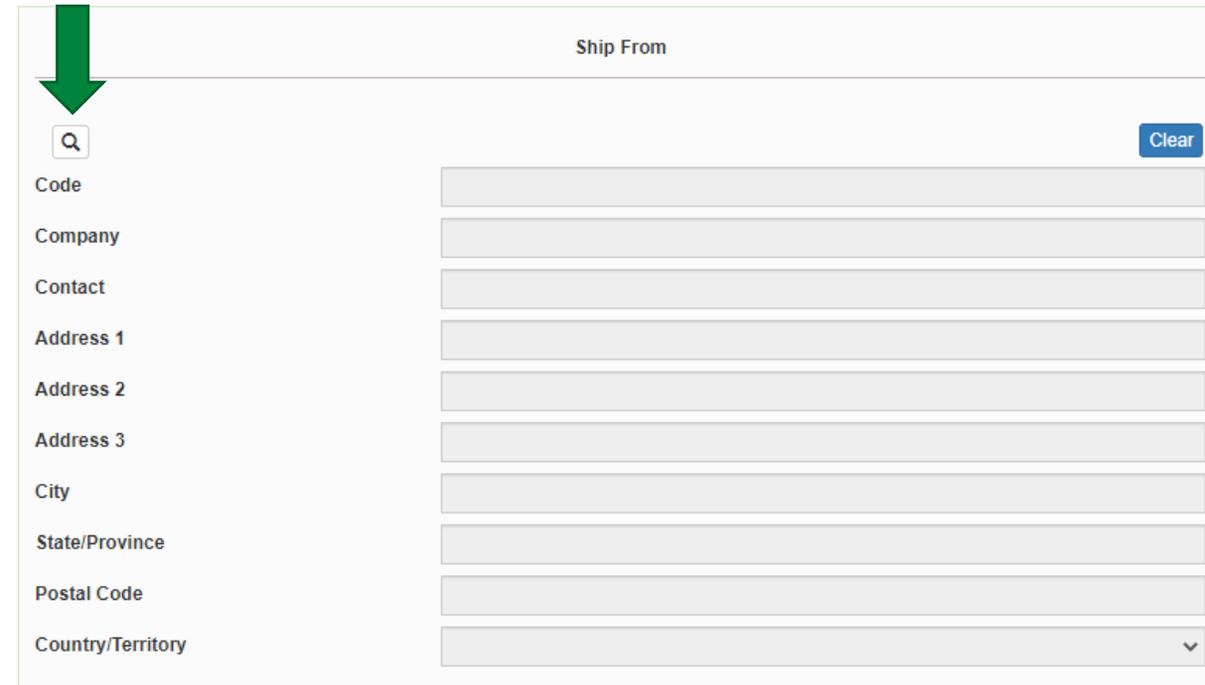
- ❖ On the right side of the screen, choose the name of your study from the “Study Group” drop down menu

❖ *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 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
- ❖ Click “Search” when ready.
- ❖ Once you have found your site address, click on the “Select” button to the left of the address
- ❖ 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: Verify your Contact Information

- ❖ Please verify that both the shipping information AND study reference are correct for this shipment

The screenshot displays a web-based shipping form with two main sections: 'Ship From' and 'Shipment Information'.

Ship From Section:

- Code:** ACFB NYU
- Company:** NYU Langone Medical Center
- Contact:** Ashley Clayton
- Address 1:** 145 East 32nd Street-2nd floor
- Address 2:** (empty)
- Address 3:** (empty)
- City:** NEW YORK
- State/Province:** NY
- Postal Code:** 10016
- Country/Territory:** United States

Shipment Information Section:

- Study Group:** ACFB (NCRAD)
- Weight:** (empty) LB
- Dry Ice Weight:** (empty) LB
- Description of Return:** Biological Specimens

A 'Pickup Request' button is visible below the 'Description of Return' field.

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

The screenshot shows a web application interface for creating a pickup request. It is divided into two main sections: 'Shipment Information' and 'Create Pickup Request'.

Shipment Information:

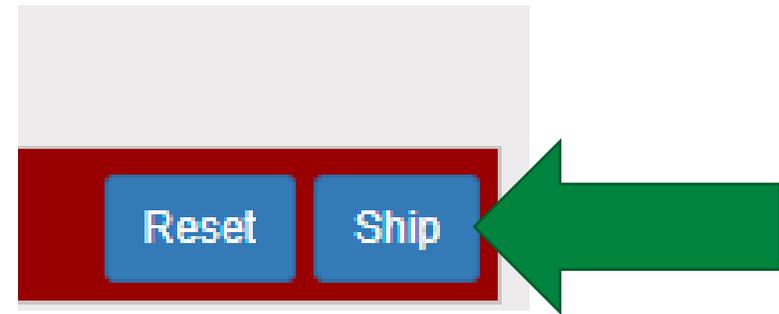
- Study Group:** A dropdown menu.
- Weight:** A text input field followed by a dropdown menu set to 'LB'.
- Dry Ice Weight:** A text input field followed by a dropdown menu set to 'LB'.
- Description of Return:** A text input field containing 'Biological Specimens'.
- Pickup Request:** A blue button.

Create Pickup Request:

- Pickup Date:** A text input field with '2021-03-15' and a calendar icon.
- Earliest Time Ready:** A text input field with 'HH:MM (24 hours format)'.
- Latest Time Ready:** A text input field with 'HH:MM (24 hours format)'.
- Contact Name:** A text input field.
- Contact Phone:** A text input field.
- Payment Method:** A dropdown menu set to 'Pay by shipper account'.
- Room Number:** A text input field.
- Floor:** A text input field.
- Buttons:** 'Save' and 'Cancel' buttons at the bottom right.

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	

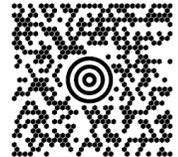
Reprint

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”

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		

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
- ❖ Study Coordinator E-mail: eridelan@iu.edu
- ❖ NCRAD General E-mail: alzstudy@iu.edu
- ❖ Website: www.NCRAD.org
- ❖ Study webpage: ncrad.iu.edu/coordinate-studies/mcs