Risk Factors for Future Cognitive Decline and Alzheimer's Disease in Older African Americans (Pathways) Study and

The National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD)

**Biofluids Collection Training Slides** 



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#### **Contact Information**

• Questions?

Please contact NCRAD Coordinators at:

• Phone: 1-800-526-2839 or 317-278-1133

• E-mail: alzstudy@iu.edu or agericks@iu.edu

• Website: www.ncrad.org



## **Training Overview**

- Specimen Collection Schedule
- Kit Request Module
- Specimen Labels
- Handling/Processing Study Specimens
- Sample Shipping
- NCRAD Website
- Questions



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## Specimen Collection Schedule

Collection Tube	Drawn At	Specimen Type	Aliquot Volume	Total Number of Aliquots	Shipping Temperature
3 EDTA (Purple-Top) Blood Collection Tubes (10 ml)	All Visits	Plasma	1.5 ml plasma aliquots	Up to 10	Frozen
1 EDTA (Purple-Top) Blood Collection Tube (6 ml)	All Visits	Whole Blood (for DNA)	N/A	N/A	Frozen





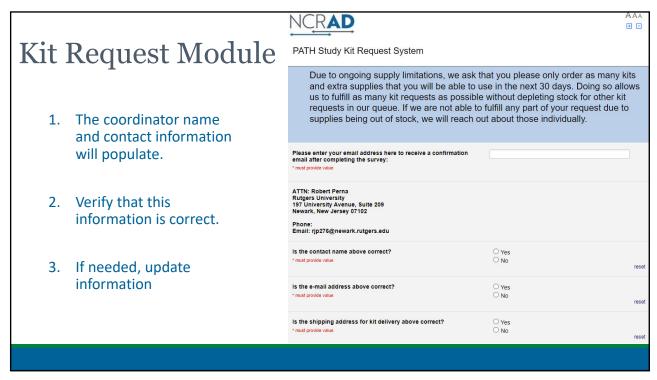
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## Kit Request Module

https://redcap.uits.iu.edu/surveys/?s=AJYP4X7MMKRNWTD3

- Kits and individual supplies available to order:
  - Blood Collection Kit
  - Blood Supplemental Kit
  - Frozen Shipping Kit
  - Individual Supplies





ATTN: Robert Perna Rutgers University 197 University Avenue, Suite 209 Newark, New Jersey 07102 Kit Request Module Phone: Email: rjp276@newark.rutgers.edu Is the contact name above correct? 1. The coordinator name **New Contact Name** and contact information Is the e-mail address above correct? will populate. New E-mail Address 2. Verify that this information is correct. Is the shipping address for kit delivery above correct? New Shipping Address 3. If needed, update information NCRAD

## Kit Request Module

- 1. Verify the address from where samples will be shipped out.
- 2. If needed, update information

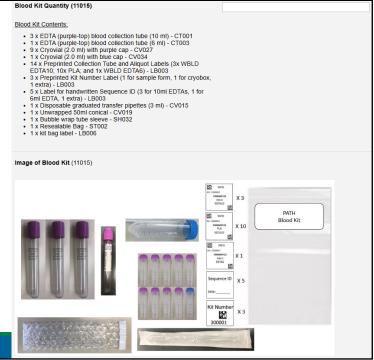
Samples delivered to NCRAD will be shipped from the address below. Is this correct?	○ Yes ○ No	rese
197 University Avenue, Suite 209 Newark, New Jersey 07102 * must provide value		



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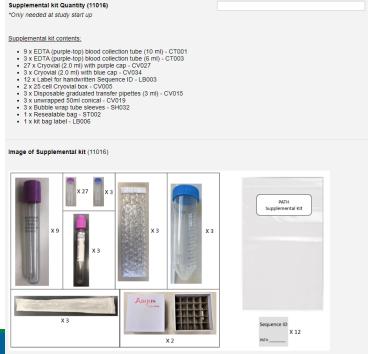
## Kit Request Module

- Indicate the quantity of Blood Kits needed.
- Kit components are listed for your convenience.



#### Kit Request Module Supplemental kit contents: 9 x EDTA (purple-top)

- Supplemental kits should primarily be ordered at study start up, and rarely throughout the course of the study.
- Kit components are listed for your convenience.



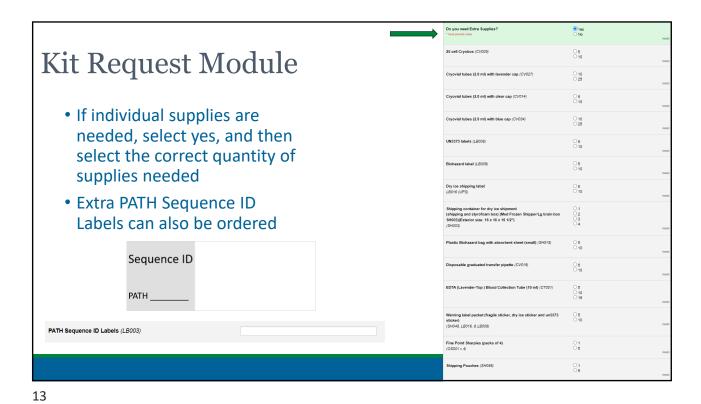
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## Kit Request Module

- Frozen shipping kits can be ordered for samples shipping back to NCRAD
- Kit components are listed for your convenience.

# \*\*Will fit samples from 16 subjects (8 x 25-cell cryoboxes with samples from 2 subject visits per box) Frozen Blood Shipping Supply Kit Contents: - 8 x Plastic Biohazard bag with absorbent sheet (small) - SH015 - 8 x 25 cell Cryovial box (put samples from 3 participants per cryobox) - CV005 - 1 x Shipping pouch - SH058 - 1 x Shipping box/Syrofoam container - SH003 - 1 x Kraglie Label - LB006 - 1 x Kraglie Label - SH048 - 1 x Dry Ice Label - LB016 - 1 x Resealable bag - ST016 Image of Frozen Blood Shipping Supply Kit Quantity (10719)

Frozen Blood Shipping Supply Kit Quantity (10719)



Kit Request Module

- Please allow 3 weeks for your order to be processed.
- Add any relevant comments
- Click "Submit" to turn in your request.
- The IU staff will notify you that your request has been received and address any issues.

Our standard shipping time for all orders is 3 week	s.
We can ship this kit request by: 02-15-2024	
If you need any supplies in this order prior to 02-15 coordinator for this study: agericks@iu.edu.	-2024, you must contact the NCRAD
Comments	Expand
Submit	

NCRAD

## Kit Request Module

- You are responsible for ordering kits and maintaining supplies on site for scheduled participants.
- To order kits, sites will use the Indiana University online kit ordering module: <a href="https://redcap.uits.iu.edu/surveys/?s=AJYP4X7MMKRNWTD3">https://redcap.uits.iu.edu/surveys/?s=AJYP4X7MMKRNWTD3</a>
- Allow around 3 weeks for your order to be processed and shipped.



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# Specimen Labels

#### Specimen Labels

- Label type summary:
  - Kit Number Labels
  - Sequence ID Labels
  - Collection and Aliquot Tube Labels
    - Differ by specimen type
- All labels are provided in the kits



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## Specimen Labels: Kit Number Labels

- Used to track patient samples and provide quality assurance
- Will be placed on:
  - Biological Sample and Shipment Notification Form
  - Outside of cryobox(es) that houses aliquot tubes during storage and shipment





#### Specimen Labels: Sequence ID Labels

- Participants will be identified by their Sequence ID
- Sites will be responsible for handwriting the IDs on the provided labels
  - Fill in labels prior to adhering to tubes
  - Must use fine-point marker
- Placed on the blood collection tubes:
  - 3 x EDTA (Purple-Top) 10 ml Blood Collection Tubes
  - 1 x EDTA (Purple-Top) 6 ml Blood Collection Tube

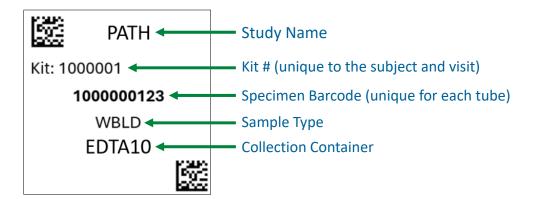
Sequence ID

PATH

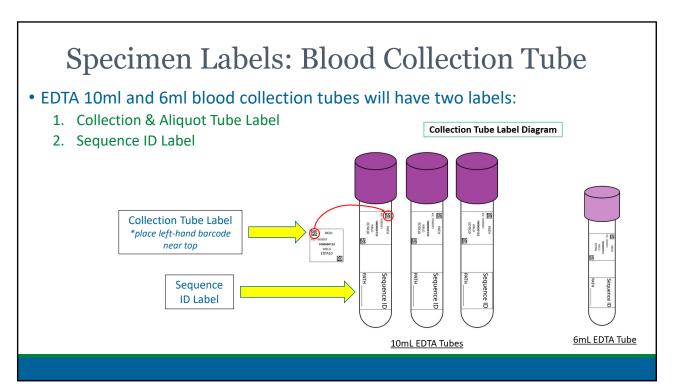


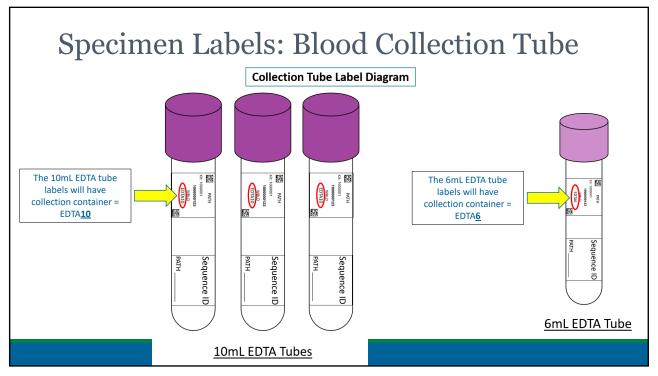
19

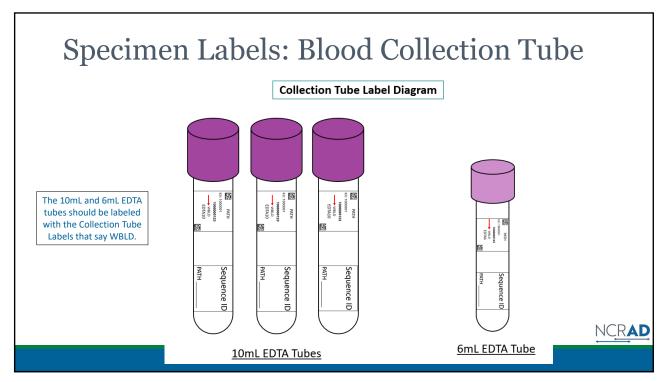
# Specimen Labels: Collection & Aliquot Tube Labels





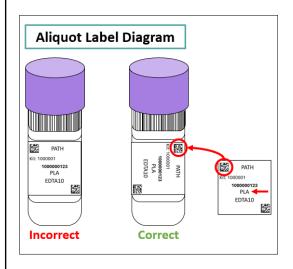






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## Specimen Labels: Plasma Aliquot Tubes



- Each 2ml cryovial will have one label: Collection & Aliquot Tube Label
- Purple & blue cap cryovials should have a collection & aliquot tube label with <u>PLA</u> on it.
- Place the left-hand barcode near the cap



## Specimen Labels – Provided in Blood Kit



#### 3 x Kit Number Labels

- Place one on the Sample Form.
- Place the other on the outside of the cryobox holding the samples
- There will also be one extra label



#### 5 x Sequence ID Label

- Place on the 3 x 10mL EDTA purple-top blood collection tubes and the 1 x 6mL EDTA purple-top blood collection tube
- There will also be one extra label



#### 3 x Collection and Aliquot Tube Label – WBLD EDTA10

 Place the 3 labels with specimen type WBLD and Collection Container EDTA10 on the 10mL EDTA purple-top blood collection tubes



#### 10 x Collection and Aliquot Tube Label - PLA EDTA10

 Place these labels on the 9 on the purple-top cryovials and one blue-top cryovial



#### 1 x Collection and Aliquot Tube Label – WBLD EDTA6

 Place the label with specimen type WBLD and Collection Container EDTA6 on the 6mL EDTA purple-top blood collection tube



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# Specimen Labels: Labeling Biologic Samples

- Label all collection and aliquot tubes <u>before</u> collecting, processing or freezing samples.
- Label only <u>1</u> participant's tubes at a time to avoid mixups.
- Wrap the label around the tube <u>horizontally</u>. Label position is important for <u>all</u> tube types.
- Make sure the label is completely adhered by rolling between your fingers.



# Handling/ Processing Study Specimens

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#### Site Required Equipment

- Blood Collection/Safety Equipment:
- 1. Personal Protective Equipment (PPE)
  - Lab Coat, Safety Glasses
- 2. Tourniquet
- 3. Alcohol Prep Pad
- 4. Gauze Pad
- 5. Butterfly Needles
- 6. Bandage
- 7. Sharps Bin and Lid

- Processing/Storage Equipment:
- 1. Centrifuge capable of ≥2000 xg
- 2. -80°C Freezer
- Shipping Equipment:
- 1. Dry ice pellets



# Blood Collection & Processing: Sample Collection Tube

3 x 10ml EDTA (Lavender-Top) Tube



1 x 6ml EDTA (Lavender-Top) Tube





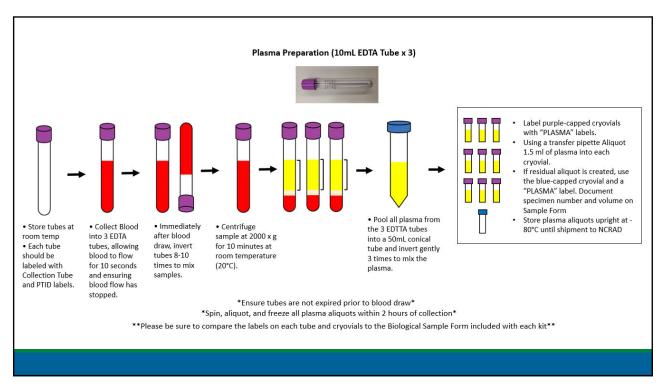
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#### Blood Collection & Processing: Aliquot Cryovials & Cap Colors

Cap Color	Sample Type
Lavender Cap	Plasma
Blue Cap	Residual plasma



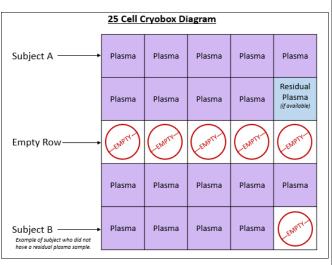




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#### Sample Packaging

- Place the labeled, filled cryovials in a 25 cell cryobox.
- Label the cryobox lid with a Kit Number Label.
- Place samples from 2 participant visits per 25 cell cryobox.
- Ensure all labeled and frozen plasma aliquots from a single participant visit are grouped within two consecutive rows in a cryovial box.
- An empty row should separate one participant's samples from another participant's samples.
- Place on pelleted dry ice and Transfer to -80°C Freezer when possible.
- Store all samples at -80°C until shipped to NCRAD on pelleted dry ice.







Cryoboxes should contain samples from 2 participant visits.

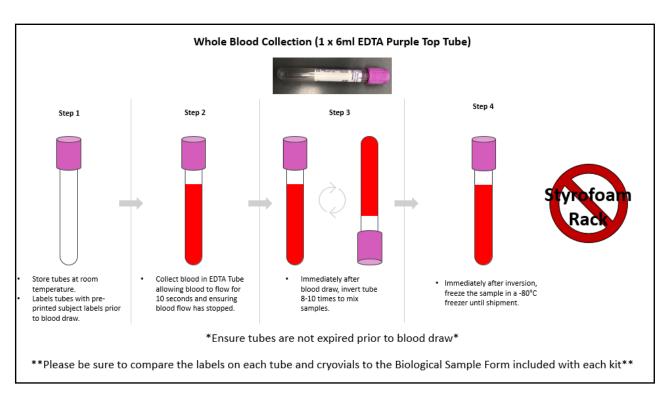
- a. Each participant visit will have up to 10 x Plasma Aliquots.
- This means there should be no more than 20 samples per cryobox.







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# Biological Sample and Shipment Notification Form



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#### Biological Sample and Shipment Notification Form

- Blood Collection for:
  - Plasma
  - Whole Blood for DNA
- Please make sure this form is filled out completely by the person collecting the samples AND the person processing.

To: Kelley Faber	Email: alzstudy@iu.edu	Phone: 1-800-526-2839
eneral Information:	Kit Barcode:	
ordinator Name:		
e Contact Phone:		}
e Contact Email:		
ite:		
udy: □AA □AAL □C	ov	
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bject Sex: □ M □ F		
bject Year of Birth:	<u></u>	
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	ck):[HHMM]	
3. Last time subject ate (MM/I		
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ood Processing:	Plasma (3 x 10mL EDTA Lavender Top Tubes)	
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#### Biological Sample and Shipment Notification Form

- Participant Sequence ID will be in one of the three following formats: A###, L###, or C###
  - Participant Sequence ID format A### corresponds to study AA

General Information:	Email: alzstudy@iu.edu	Phone: 1-800-526-2839	1
	Kit Barcode:		1
Coordinator Name:			
Site Contact Phone:			
Site Contact Email:			I
Date:			
Study: XAA □AAL □COV			I
/isit (circle one): 1 2 3 4	5 6 7 E		I
Subject Sex: 🗆 M 🗆 F			
Subject Year of Birth:	_		I
Fracking #:			
Blood Collection:			1
1. Date Drawn (MM/DD/YYYY):			
2. Time of Drawn (24 hour clock			
3. Last time subject ate (MM/DE			
	clock):[HHMM]		I
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Original volume drawn (3x10 ml Time spin started (24 hour clock		TA #2:mL EDTA #3:mL [HHMM]	
Duration of centrifuge:	1-	minutes	
Temp of centrifuge:		°C	
Temp of centrifuge: Rate of centrifuge:		°C	
Rate of centrifuge: Time aliquoted:			
Rate of centrifuge: Time aliquoted: Number of 1.5 mL plasma (purpl		xg [HHMM]	
Rate of centrifuge: Time aliquoted: Number of 1.5 mL plasma (purp If applicable, volume of residual	plasma aliquot (less than 1.5 mL-Blue ca	xg (HHMM) nL or $\Box$ N/A	
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#### Biological Sample and Shipment Notification Form

- Participant Sequence ID will be in one of the three following formats: A###, L###, or C###
  - Participant Sequence ID format L### corresponds to study AAL

To: Kelley Faber	Email: alzstudy@iu.edu	Phone: 1-800-526-2839	
General Information:	Kit Barcode:		
Coordinator Name:			
Site Contact Phone:			
Site Contact Email:		: <b> </b>	
Date:			
Study: DAA XAAL DO			
/isit (circle one): 1 2 3	4 5 6 7 E		
Subject Sex:   M  F			
Subject Year of Birth:			
Fracking #:	<del></del>		
Blood Collection:			
1. Date Drawn (MM/DD/YYY)			
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<ol><li>Last time subject ate (MM)</li></ol>			
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#### Biological Sample and Shipment Notification Form

- Participant Sequence ID will be in one of the three following formats: A###, L###, or C###
  - Participant Sequence ID format C### corresponds to study COV

To: Kelley Faber	Email: alzstudy@iu.edu	Phone: 1-800-526-2839	ר ו ר
General Information:	Kit Barcode:		<b>1</b> ∣
Coordinator Name:			
Site Contact Phone:	i		
ite Contact Email:			
Date:			
tudy:   AA   AAL   C			
/isit (circle one): 1 2 3	1 5 6 7 E		
ubject Sex:   M  F			
Subject Year of Birth:	_		
Fracking #:			
Blood Collection:			<b>기</b> │
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#### Biological Sample and Shipment Notification Form

- Participant Sequence ID will be in one of the three following formats: A###, L###, or C###
  - Participant Sequence ID format A### corresponds to study AA
  - Participant Sequence ID format L### corresponds to study AAL
  - Participant Sequence ID format C### corresponds to study COV
- No other combination of Participant Sequence ID and Study should be used.
- If a form is received where the Participant Sequence ID is in the format A###, but the study chosen is <u>NOT</u> AA, our team will flag this as an error and follow up with you.

To: Kelley Faber	Email: alzstudy@iu.edu	Phone: 1-800-526-2839
eneral Information:	Kit Barcode:	
oordinator Name:		
te Contact Phone:	i	
te Contact Email:		
ate:		<u> </u>
udy: DAA BAAL DE		
sit (circle one): 1 2 3	4 5 6 7 E	
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1. Date Drawn (MM/DD/YYYY		
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Rate of centrifuge:		xg
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	al plasma aliquot (less than 1.5 mL-Blue	
	er of residual plasma aliquot (Last four di	
Time aliquots placed in freeze		[HHMM]
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Original volume drawn (1x6 m		mL
Time tube placed in freezer (2	4 hour clock):	[HHMM]
Storage temperature of freezo	er:	°c

#### Biological Sample and Shipment Notification Forms

- A scanned copy of the sample form must be emailed to NCRAD prior to the date of sample arrival: alzstudy@iu.edu
- Please include a hard copy of sample forms in all shipments of frozen samples.



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# Sample Shipping

#### Frozen Shipping: Guidelines

#### Ship Monday-Wednesday Only

- Hold packaged samples in a -80°C freezer until pickup.
- Batch Samples together
  - Up to 8 Cryoboxes
  - Batch shipping should be performed every month or as a full shipment of specimens accumulates, whichever is sooner.



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#### Sample Shipping Summary

Collection Tube	Drawn At	Specimen Type	Aliquot Volume	Total Number of Aliquots	Shipping Temperature
3 EDTA (Purple-Top) Blood Collection Tubes (10 ml)	All Visits	Plasma	1.5 ml plasma aliquots	Up to 10	Frozen
1 EDTA (Purple-Top) Blood Collection Tube (6 ml)	All Visits	Whole Blood	N/A	N/A	Frozen



#### Frozen Shipping

1. Place the frozen, filled, and labeled 6mL EDTA tube into the bubble wrap tube sleeve.



1. Place cryovial box and the 2 x bubbled-wrapped 6mL EDTA tubes from the corresponding visits in a clear biohazard bag. Place a filled cryobox in a biohazard bag.



2. Seal biohazard bag according to the instructions on the bag. **IMPORTANT**: Place only ONE cryobox and TWO 6ml EDTA tubes per Biohazard bag.



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#### Shipping Dry Ice Requirements

- Each Styrofoam shipper can hold 8 cryoboxes.
- Place approximately 2-3 inches of pelleted dry ice in the bottom of the Styrofoam shipping container.
- Place the biohazard bags into the Styrofoam-lined shipping container on top of the pelleted dry ice.
- Please ensure that cryovial boxes are placed so the cryovials are upright.
- Completely fill the inner Styrofoam with pelleted dry ice pellets to ensure the frozen state of the specimens during transit.
- Each Styrofoam shipper should contain about 45 lbs (20 kg) of pelleted dry ice.





#### Shipping: Dry Ice Requirements

- Package must be labeled with a UPS Dry Ice Label
- Class 9 Dry Ice label should not be covered with other stickers and must be completed, or the shipping carrier will reject/return your package!
- Fill out the amount of dry ice in the package



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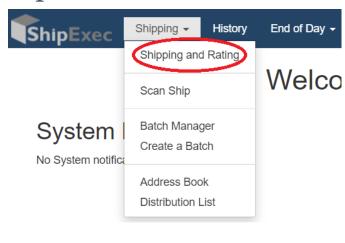
#### Shipping Frozen Samples

• Scan the Biological Sample and Shipment Notification Form and email it to alzstudy@iu.edu ahead of the shipment.



#### Shipping Frozen Samples

- Log in to ShipExec™ Thin Client: https://kits.iu.edu/ups
- Click on the "Shipping" dropdown and click on "Shipping and Rating"



NCRAD

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#### Shipping Frozen Samples

- Select your study from the "Study Group" drop down on the right side of the main screen (PATH). Choosing your study will automatically filter the address book to only addresses within this study.
- Click on the magnifying glass icon in the "Ship From" section to search for your shipping address.



#### Shipping Frozen Samples

- Enter Package Information
  - Enter the total weight of your package
  - Enter the pelleted dry ice weight
- Click **Ship** in the bottom right of the page when complete.
- Click the blue **Pickup Request** button to schedule a UPS pickup. Enter the earliest pickup time and latest pickup time in 24-hr format.
- · Click Save.



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#### Shipping Frozen Samples

- Print the airbill that is automatically downloaded.
- Fold airbill, and place inside plastic UPS sleeve. Peel the back off of the UPS sleeve and stick the sleeve to the top of the package. Do NOT overlap other labels or package seams.



#### Shipping Regulations and Training

#### **PLEASE NOTE:**

- All study personnel responsible for shipping should be certified in biospecimen shipping.
- It is the responsibility of each site to ensure that the appropriate training has been provided and conducted in regards to IATA shipping.

Please see following slides for resources.



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#### **Federal Regulations/Training**

- Sites are responsible for ensuring proper training is obtained.
- Current federal and international regulations require anyone directly involved with the shipment of potentially infectious materials and other regulated biological materials (including biological specimens and cultures) <u>be properly trained on pertinent shipping</u> requirements.
  - 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



#### UN3373 Biological Substance, Category B Training

- Biological Substance, Category B are specimens being transported for "investigational purposes"
- Recommend: investigator sites document training of category B/dangerous goods
- We recommend establishing a record of your staff's training and date of instruction
- The training records must be made available upon request by the appropriate national authority
  - Additional information from the Department of Transportation (DOT) can be found on their website http://hazmat.dot.gov

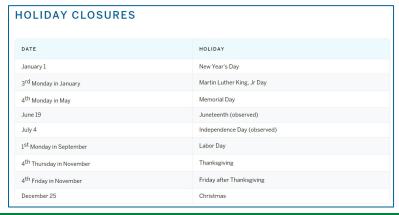


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#### NCRAD Website

#### Helpful Pages:

https://ncrad.org/holiday\_closures.html





# NCRAD Website: PATH Active Study Page

#### THE PATHWAYS ACTIVE STUDY PAGE

Welcome PATH Study staff, coordinators, and PI's.

This section encompasses study specific tools and videos for your reference. If you have any questions, comments, or new ideas please contact NCRAD by **email** or phone **1-800-526-2839** or directly at **317-278-8413**.



Training videos, manual of procedures, and sample form are available for reference on the PATH Active Study Page.



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#### **Contact Information**

Questions?

Please contact NCRAD Coordinators at:

• Phone: 1-800-526-2839 or 317-278-1133

• E-mail: alzstudy@iu.edu or agericks@iu.edu

• Website: www.ncrad.org

