

Neurodegeneration in Aging Down Syndrome: A Longitudinal Study of Cognition and Biomarkers of Alzheimer's Disease

in collaboration with

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

**Blood-Based Biospecimen Training Slides** 

## **Contact Information**

• Questions?

Please contact NCRAD Coordinators at:

- Phone: 1-800-526-2839
- E-mail: <u>alzstudy@iu.edu</u>
- Website: <u>www.ncrad.org</u>



### Training Overview:

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

### NiAD Blood Based Collection Schedule for DS Participants:

	Baseline	16-Month	32-Month	48-Month
Serum	Х	Х	Х	**
DNA	Х	X*	Х	* *
Plasma	Х	Х	Х	**
Karyotyping	Х			

- \* DNA from the 16-Month Visit (University of Pittsburgh ONLY) will not be shipped to NCRAD, but maintained at the site.
- \*\* No Blood based biomarkers are collected at the 48-month visit

### NiAD Blood Based Collection Schedule for Sibling Controls:

	Baseline	16-Month	32-Month	48-Month
DNA	Х			
Plasma	Х			

\* Blood is only collected at the baseline visit for sibling controls.

# Kit Request Module

#### http://kits.iu.edu/adds-niad



## Kit Request Module

- An initial stock of kits will be delivered prior to the designated site specific start date.
- Kits and individual supplies are available to order:
  - NiAD DS Participant Blood Kit
  - NiAD Sibling Control Blood Kit
  - NiAD Frozen Shipping Supply Kit
  - Blood Supplemental Kit
  - CSF Supplemental Supply Kit
  - Lumbar Puncture Trays
  - CSF Shipping Supply Kit

## NCRAD Kit Request Module



- 1. Choose your site from the drop down list
- 2. The coordinator name and contact information will appear
- 3. Verify that this information is accurate, correct if necessary

ADDS	S-NiAD Kit Request System		
	NiAD and/or ADDS Site * must provide value	024 University of Pittsburgh	
	024 - USA: University of Pittsburgh ATTN: Cathy Wolfe Franklin Building Mezzanine 1011 Bingham Street Pittsburgh, PA 15203 Phone: 412-235-5445 Email: wolfec@upmc.edu		
-	Is the contact name above correct? * must provide value	○ Yes ○ No	reset
	Is the shipping address above correct? * must provide value	○ Yes ○ No	reset
-	Is the e-mail address above correct? * must provide value	○ Yes ○ No	reset

Resize font:

## ADDS and NiAD Kits Available

NiAD Sibling Control Blood Kit Qty		
NIAD DS Participant Blood Kit Qty		
ADDS Blood Kit Qty		
NIAD Frozen Blood Shipping Kit Qty		
ADDS Frozen Blood Shipping Kit Qty		
Blood Supplemental Supply Kit Qty		
CSF Supplemental Supply Kit Qty		
Lumbar Puncture Tray Kit Qty		
Frozen CSF Shipping Supply Kit Qty		
	<ul><li>○ Yes</li><li>○ No</li></ul>	eset
Comments		
	Exp	and
Submit		

# Study Visit Kits

NiAD Sibling Control Blood Kit Qty		4
NIAD DS Participant Blood Kit Qty	1	
ADDS Blood Kit Qty		
NiAD Frozen Blood Shipping Kit Qty		
ADDS Frozen Blood Shipping Kit Qty		
Blood Supplemental Supply Kit Qty		
CSF Supplemental Supply Kit Qty		
Lumbar Puncture Tray Kit Qty		
Frozen CSF Shipping Supply Kit Qty		
Do you need Extra Supplies? * must provide value	⊖Yes ● No reset	
Comments	Expand	
Each NiAD DS Participant Blood Kit Contains: 1: EDTA (Lavender-Top) Blood Collection Tube (10 ml) 2: Serum Separator (Gold-Top) Blood Collection Tube (5 ml) 21: Siliconized cryovial tube (0.5 ml) with lavender sticker 21: Siliconized cryovial tube (0.5 ml) with red sticker 1: 15 ml conical 1: Cryovial tube (2.0) with blue cap 1: Disposable graduated transfer pipette 46: Pre-printed Collection and Aliquot Tube Label 3: Pre-printed Kit Number Label 4: Labels for handwritten Site and NIAD ID 2: Microcentrifuge tube box (holds up to 25 microcryovials)		/

- Indicate the quantity needed of each kit
- Once selected, kit
   components of the chosen
   kit will appear at the
   bottom of the screen
   (Pictured)
- Click "Submit" to turn in your request.
- The IU staff will notify you that your request has been received and address any issues.
- \*\*Note: You can order more than one type of kit in a single kit request\*\*

## NCRAD Kit Request Module: When It Must be Used

- Each site will be responsible for ordering kits (labels included) and maintaining supplies on site for scheduled participants
- To order, sites will use the Indiana University online kit ordering module: <u>http://kits.iu.edu/adds-niad</u>
- Allow a minimum of **2 weeks** for your order to be processed and delivered.

# **Specimen Labels**



# Label Type Summary

- 1. Kit Number Labels
- 2. Site and NIAD ID Labels
- 3. Collection and Aliquot Tube Labels
  - Differ by specimen type

# Kit Number Labels



#### Provided by NCRAD in the kits

- Used to track patient samples and provide quality assurance
- Will be placed on the following locations:
  - 1. Biological Sample and Shipment Notification Form
  - 2. Outside cryobox that houses aliquot tubes during storage and shipment

# Site and NIAD ID Label



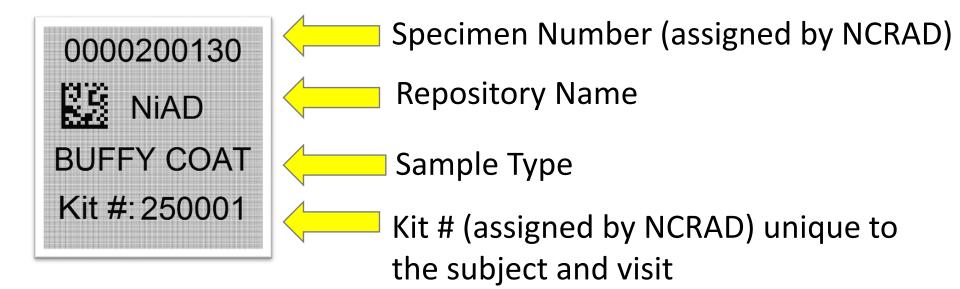
- Subjects will be identified by their site ID and NIAD ID
- The NIAD ID may only be available shortly before the visit
- Sites will be responsible for handwriting this onto the provided labels
  - Must use fine point permanent marker
  - Each site will receive 4 markers in initial kit supply

# Site and NIAD ID Label Cont.



- Write information on label prior to adhering to tube
- Label will be placed on all collection tubes
  - (2) Serum Separator (Gold-Top) Blood Collection Tube (5 ml)
  - EDTA (Lavender-Top) Blood Collection Tube (10 ml)
- Kits will include one extra label

## **Collection and Aliquot Tube Labels**



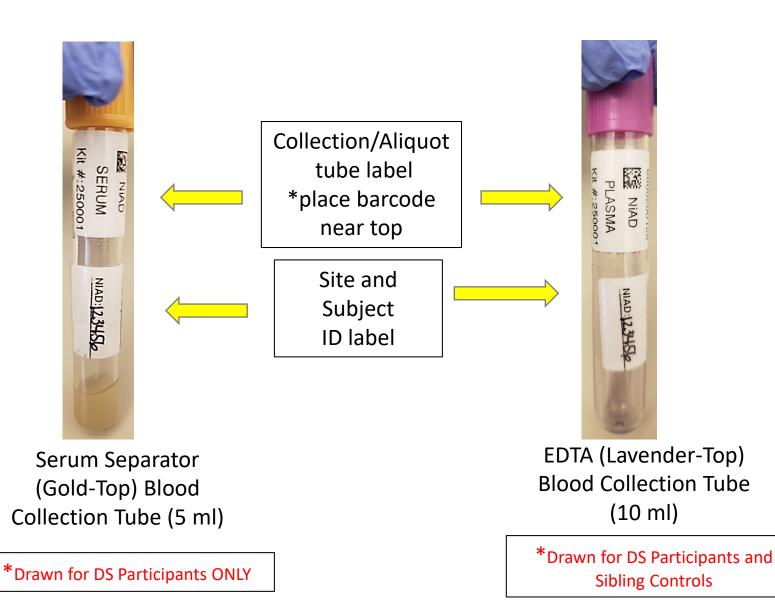
## **Collection and Aliquot Tube Labels- Blood**

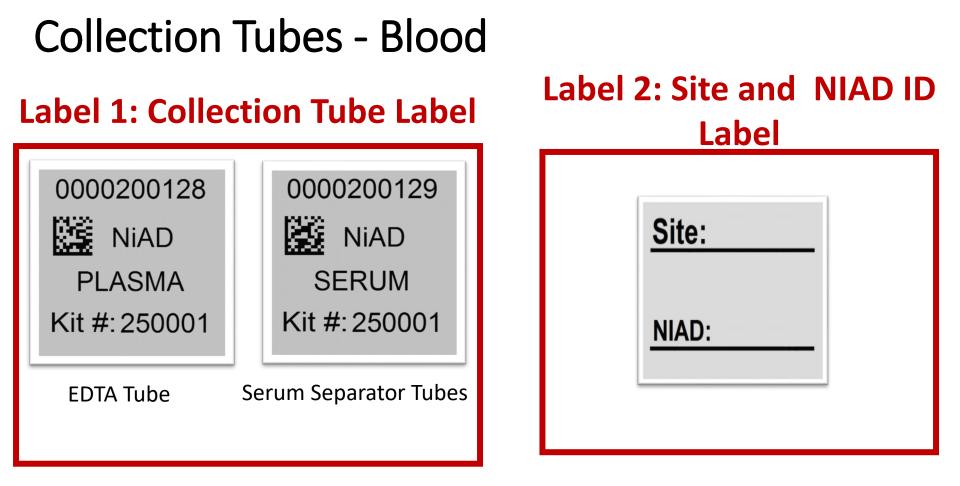




- Labels to be placed on ALL collection and aliquot tubes
  - Serum Separator (Gold-Top) Blood Collection Tube (x2)
    - Serum aliquots
  - 2. EDTA (Lavender-Top) Blood Collection Tube (x1)
    - Plasma aliquots
    - Buffy coat aliquot

#### **Collection Tubes – Blood**





- All collection tubes will have two labels
  - The Collection Tube Labels
  - The handwritten Site and NIAD ID Label

## Aliquot Tube Labels – Serum, Plasma and Buffy Coat



- Collection and Aliquot tube label only
- Please place barcode near cap

# Handling/Processing Study Specimens



# Site Required Equipment

#### Blood Collection/Safety Equipment

- 1. 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  $\geq$ 2000 rcf with refrigeration to 4°C
- 2. -80°C Freezer
- 3. Wet Ice Bucket

### Draw Order

#### \*\*\*Important Note\*\*\*

In order to ensure the highest quality samples are collected, processed, and stored, it is essential to follow the specific collection, processing, and shipment procedures detailed in the following pages. Please read the following instructions first before collecting any specimens. Have all your supplies and equipment out and prepared prior to drawing blood. Draw blood in the following order:

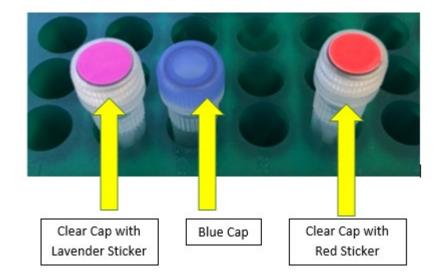
- 1. Serum Separator (Gold-Top) Blood Collection Tube (5 ml) for Serum x 2 (DS Participants ONLY)
- 2. EDTA (Lavender-Top) Blood Collection Tube (10 ml) for DNA and Plasma (DS Participants AND Sibling Controls)
- 3. Sodium Heparin (Green-Top) Blood Collection Tube (10 ml) for Karyotyping (Baseline ONLY for DS Participants ONLY)

## Sample Collection - Blood

	Tube Type	Number of Tubes Drawn	Tube Image
1.	Serum Separator (Gold-Top) Blood Collection Tube (5 ml) DS Participants ONLY	x2	
2.	EDTA (Lavender-Top) Tube (10 ml) DS Participants and Sibling Controls	x1	EPSONE ( SING) 105/1
3.	Sodium Heparin (Green-Top) Tube (10 ml) BASELINE ONLY DS Participants ONLY	x1	

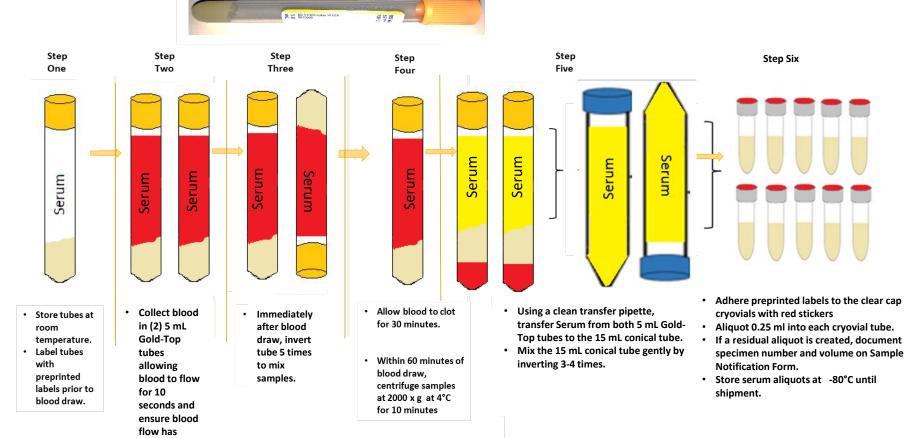
## **Aliquot Cap Colors**

Cap Color	Sample Type
Clear Cap with Lavender Sticker	Plasma and Plasma Residual (<0.25 ml) (Document Specimen Number and Volume of Residual Aliquot on Sample Form)
Clear Cap with Red Sticker	Serum and Serum Residual (<0.25 ml) (Document Specimen Number and Volume of Residual Aliquot on Sample Form)
Blue	Buffy Coat

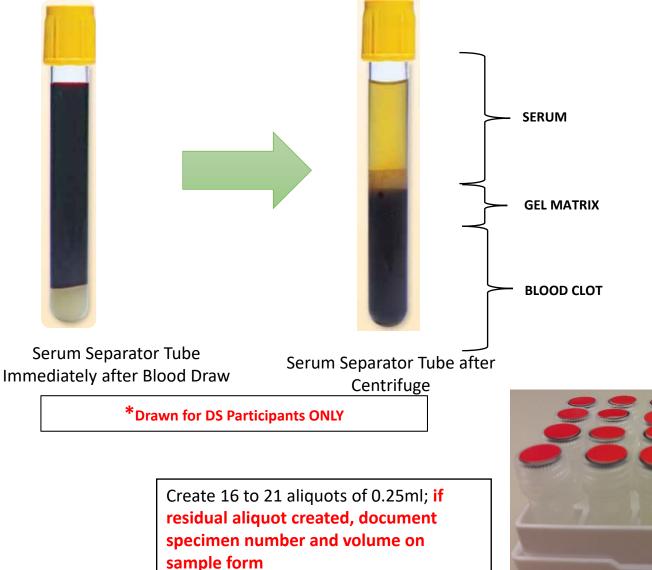


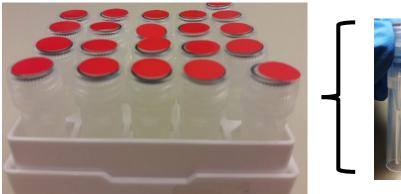
#### Serum Preparation (5 ml Gold-Top Tube)

stopped.

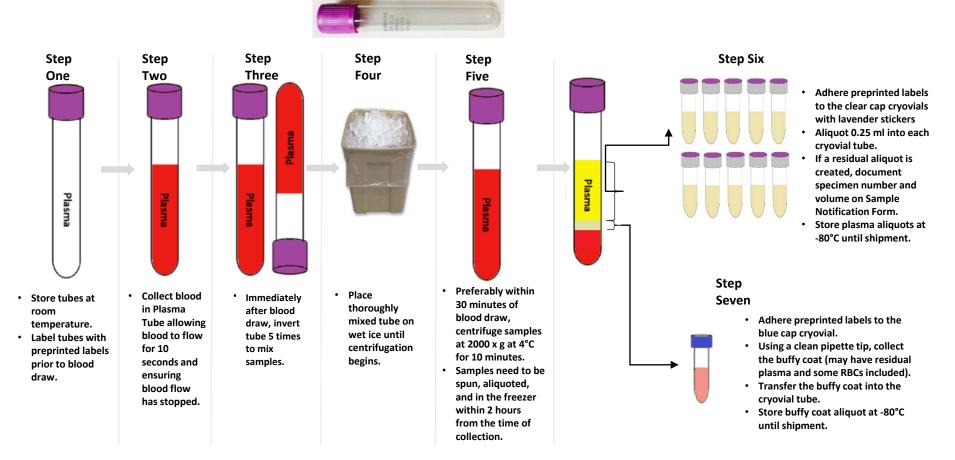


### Serum Separator Tube (Serum Collection)

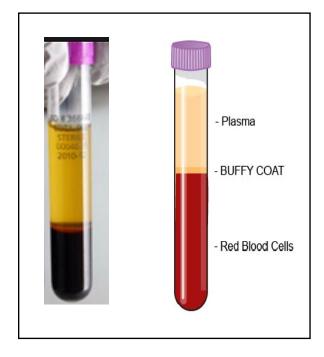


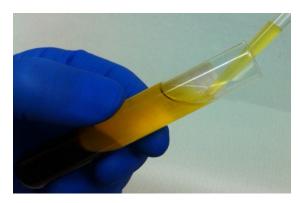


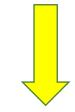
#### Plasma and Buffy Coat Preparation (10ml Lavender-Top Tube)



# EDTA Tube (Plasma Collection)

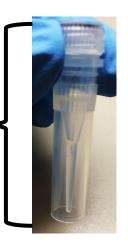




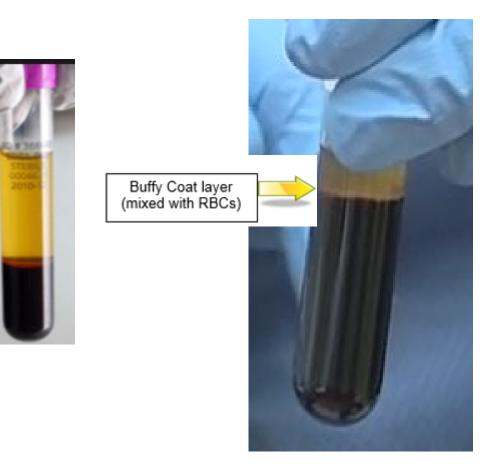


Create 16 to 21 aliquots of 0.25ml; if residual aliquot created, document specimen number and volume on sample form





# EDTA Tube (Buffy Coat Collection)





 Important Note:
 Buffy Coat aliquots will be distinguished from the plasma aliquots through a blue cap.

#### \*Drawn for DS Participants and Sibling Controls

# Sodium Heparin Tube (Karyotype)

- Drawn at baseline ONLY
- Tube does NOT get sent to NCRAD
- Used to obtain karyotype for full or partial trisomy 21 by the local clinical lab.
- Check with local lab for the amount of blood needed, storage, and transport conditions



\*Drawn for DS Participants ONLY at Baseline ONLY

# Sample Shipping



### **Blood Sample Shipment Summary**

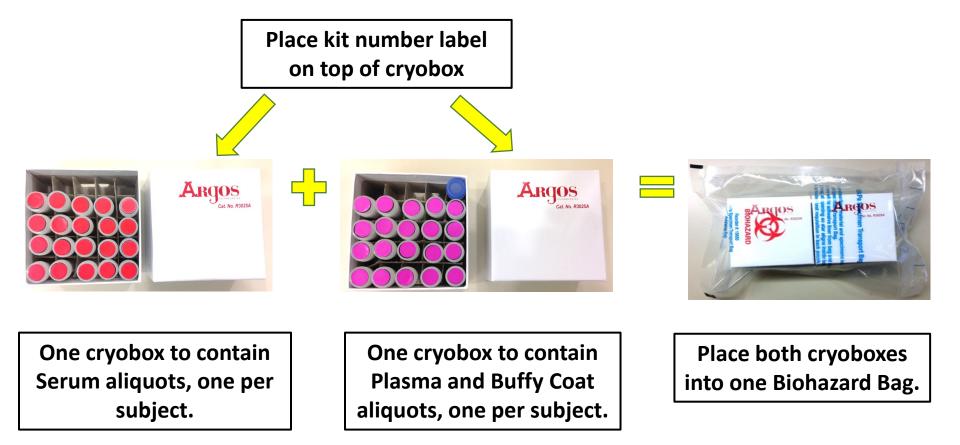
Sample Type	NiAD	Processing/ Aliquoting	Tubes to NCRAD	Ship
Whole blood (Gold- Top SST) for isolation of serum Drawn for DS Participants ONLY	Yes	0.25 ml serum aliquots per 0.5 ml siliconized cryovial (clear caps with RED stickers)	16-21	Frozen
Whole blood (Lavender-Top EDTA) for isolation of plasma & buffy coat (for DNA extraction) Drawn for DS	Yes	0.25 ml plasma aliquots per 0.5 ml siliconized cryovial (clear caps with LAVENDER stickers)	16-21	Frozen
Participants and Sibling Controls	Yes	1 ml buffy coat aliquot per 2.0 ml cryovial (BLUE cap)	1	Frozen

## Frozen Sample Shipping

### Ship Monday-Wednesday Only

- Serum, Plasma and Buffy Coat
- Hold packaged samples in a -80°C freezer until pickup.
- Batch Samples together
  - 10 cryoboxes
  - Batch shipping should be performed quarterly or as a full shipment of specimens accumulates, whichever is sooner.

#### Frozen Shipping - Cryoboxes



# Shipping Frozen Samples

- Schedule FedEx or UPS (US and UK)
  - Please note: international shipments require completed International Commercial Invoice, Declaration of Goods Document, and International Fed Ex Airbills
- Send Biological Sample and Shipment Notification Form to IU (US) <u>ahead of shipment</u>
  - Email: alzstudy@iu.edu or
  - Fax: 317-321-2003

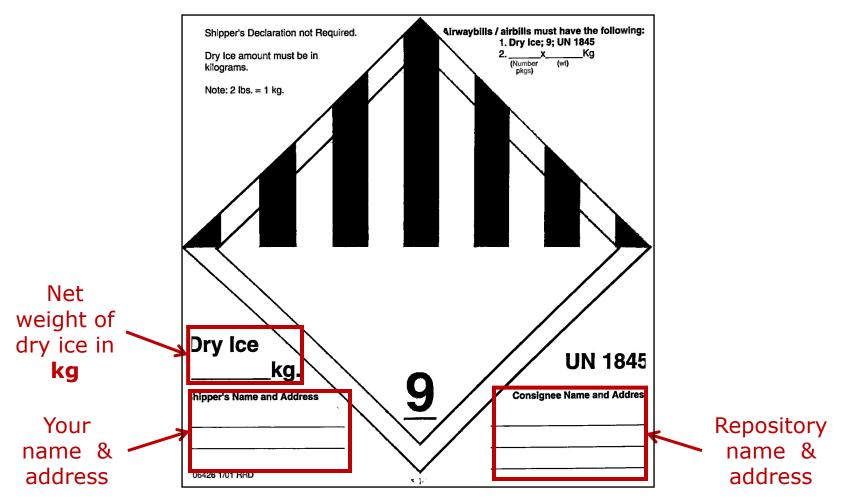
#### **Frozen Shipping – Dry Ice Requirements**



- Fully cover the cryoboxes with about 2 inches of dry ice in the provided shipper.
- Each Styrofoam shipper must contain about 45 lbs (20 kg) of dry ice.

#### **Frozen Shipping – Dry Ice Requirements**

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!



#### **Frozen Shipping - Fedex Airbill**

Airbill must be completed or the shipping carrier will reject/return your package!

+	Free       Package         Express       Dackage         1       From Please print and press hard.         Date       Sender's FedEx	Form     D2DD       4     Express Package Service       Next Business Day	s &
1B	Senc r's Nam Phone ( )	FedEx First Oversignil     Erriest next busine morning delivery to select     locations. Frid morphenetts will be delivered on     Mondy users Standard Delivery is selected.     Saturday Delivery NOT available.	Appendix
<b>0</b> 0	Com, my	Next buiness mening "Friday shipments will be delivered on Monday unless Saturday Delivery is selected.	
ο 1.800.463.3339	Addr ssDeput/Peor/Subs/Peor	FedEx Standard Overnight Net business afterrorist Saturdy Delwry NOT available.	Dangerous
	City State ZIP	5         Packaging         * Declared values limit \$500.           FedEx Envelope*         FedEx Pak*         FedEx Box         FedEx Tube	goods info (for dry ice
Om 1.800.GoFedEx	2 For a decise will appear on protection of the part of of the	By the second	shipments only)
fedex.com	Company     Direction     Address     351     West     10 <sup>th</sup> Strell     10 <sup>th</sup> Strell     10 <sup>th</sup> <th>obtaining a signature for delivery.     may sign for delivery.</th> <th>Net weight of</th>	obtaining a signature for delivery.     may sign for delivery.	Net weight of
	Use this line for the HOLD location address or for continuation of your shipping address. City INDIANAPOIS State JN ZIP 46202	7 Payment Bill to: Sender Sender Sector Basedon Recipient Third Party Credit Card Sector Na Sector Na S	] CastvCh ck
	Ship it. Track it. Pay for it. All online. Go to fedex.com.	bs. 500 10 tability is limited to USS100 unless you declare th byber value. See back for details ply using this sithill you agree to the service conditions on the back of this sind and and in the current fields. Service builds, including terms that limit our liability. Rev. Date 2/15 - Plart FIE7002 - 0.0012-2015 Fields + PRINTED IN U.S.A. RRDA 9000	FedEx Account Number

#### Frozen Shipping - Fedex Airbill – International

Your name.

address & phone	Express Expanded Service International Air War For teles envices and options are available to all deets	aybill Instans	The service order has changed in Section 4. Signature options have been added to Section 6.		
Conversional mode	Date         Standar Frederik           Date         ABL/DD/VV         Account Number           Skolder         Penna           Name         Penna           Company         Address           Address         Address           Country         Possel           Country         Possel           Example         Address           Address         Address           Address         Address           Address         Address           Address         Address           Address         Address           Address         Address	de	Fed: Stratty Numer     B.J.D.9     4.3.7.4     P.B.J.2     runn 0.1k.     L.4.2.5       Fed: Express Reakage Service     Reakager up to 7.8 Me. / 48 kg       HD: E: Service order has changed. Phase solect carolity.       Fed: Runt. First     Fed: Runt. Priority       Fed: Runt. Priority     Fed: Runt. Economy       4b     Express Freight Service       Fed: Runt. Priority     Fed: Runt. Economy Freight       Fed: Runt. Priority     Fed: Runt. Economy Freight       Pressent minute that the up to memory     Fed: Runt. Economy Freight       Fed: Runt. Priority Freight     Fed: Runt. Economy Freight		Dangerous goods info (for dry ice shipments only)
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## Biological Sample and Shipment Notification Forms

- A copy of the sample form *must* be emailed or faxed to NCRAD prior to the date of sample arrival.
- Please include sample forms in all shipments of frozen and ambient samples.
- Email: <u>alzstudy@iu.edu</u>
- Fax: 317-321-2003



#### **Biological Sample Notification Form- Blood**

		Biosp	ecimen Collection, Process	-
NCRAD Shipment Manual				
	Арре	ndix B		
			Site ID:	
	<u> </u>		Visit Mo:	_
5		ipment Notific		
	il: alzstudy@iu.edu	FAX: 317-321-2003	Phone: 1-800-526-2839	
General Information:				
From:		Date:		
Phone:		Email:		
Study: NiAD DS Participant Sibling Contr	rol - [Plasma/Buffy Coat	Kit #:		
Sex: M F Year of Birth:	only]		KIT BARCODE	
FedEx tracking #:				
Blood Collection:		2 (D /24)		
1. Date Drawn: [YYYYMMDD]		nour clock): [HH]		
3. Last time subject ate (Date): [YY	YYMMDD]	<ol> <li>Last time subject a</li> </ol>	te (24 hour clock):	[HHMM]
5. Was the EDTA tube placed on ice immediately after i	nverting tube 5 times u	intil centrifugation began	? Yes No	
Blood Processing:				
Plasma (EDTA/Lavender Top Tube)		Serum	(Serum Separator/Gold Top Tube	)
Time spin started (24 hour clock):	[HHMM]	. Time spin started ( draw time):	24 hour clock) (30 minutes after	[HHMN
Duration of centrifuge:	[minutes]		uge:	[minute
Temp of centrifuge:°C      Rate of centrifu	ge: x g	Temp of centrifuge	e:°C • Rate of centrife	uge: x (
Original volume drawn (1x10 mL EDTA tube):	mL	Original volume drawn	(2x5 mL Serum tube):	m
Time aliquoted:	[HHMM]	Time aliquoted:		[HHMM
Number of 0.25 mL plasma aliquots created (16-20 total) (Siliconized cryovial):	x 0.25 mL	Number of 0.25 mL seru (Siliconized cryovial):	um aliquots created (16-20 total)	x 0.25 m
If applicable, volume of residual plasma aliquot (less than 0.25 mL) (Siliconized cryovial):	mL	If applicable, volur than 0.25 mL) (Sili	ne of residual serum aliquot (less conized cryovial):	ml
If applicable, specimen number of residual aliquot (Last four digits):		If applicable, specimen (Last four digits):	number of residual aliquot	
	[uubaba]	Time aliquots place	ed in freezer (24 hour clock):	[HHMN
Time aliquots placed in freezer (24 hour clock):	[HHMM]			
Time aliquots placed in freezer (24 hour clock):     Storage temperature of freezer: Buffy coat aliquot created (one per EDTA tube) (Blue cap	°C	Storage temperate	ure of freezer:	

#### Blood collected for:

- Plasma
- Buffy Coat
- Serum

Version 03.2020

#### Send by E-mail or Fax prior to shipment, and include a copy in each shipment

#### NCRAD Website Helpful Pages



- <u>https://ncrad.org/holiday\_closures.html</u>
- <u>https://ncrad.org/friday\_blood\_draws.html</u>

#### **Mat to do for Friday Blood Draws**

NCRAD is not open for business on Saturday or Sunday; therefore, we ask that no samples be shipped on a Friday. We cannot guarantee the conditions in which the samples will be held by the shipping courier over the weekend. It is important to have plans in place for each type of sample to be held over the weekend prior to shipping. Please refer to the table below for how to handle samples drawn on a Friday.

When possible, please only ship frozen samples on Monday-Wednesday. There is always the potential for an unexpected shipping courier delay and by shipping Monday through Wednesday there should be enough time to receive the samples before the weekend.

Sample Type	Tube Type	Product	Shipment Method	Friday Draw Instructions
Whole Blood	Sodium Heparin	PBMC	Ambient	DO NOT DRAW ON FRIDAY. Must be drawn on Monday – Thursday.
Whole Blood	EDTA Tube	DNA Only	Ambient	Do NOT refrigerate. Please keep sample at room temperature until the specimen can be shipped via next day delivery methods the following Monday.

#### **hh** Holiday Closures

Date	Holiday
January 1	New Year's Day
3 <sup>rd</sup> Monday in January	Martin Luther King, Jr Day
4 <sup>th</sup> Monday in May	Memorial Day
July 4	Independence Day (observed)
1 <sup>st</sup> Monday in September	Labor Day
4 <sup>th</sup> Thursday in November	Thanksgiving
4 <sup>th</sup> Friday in November	Friday after Thanksgiving
December 25	Christmas

https://www.ncrad.org/resource\_adds\_niad.html

#### ADDS/NiAD Active Study Page

₹ itti tida	NCRAD			\$ Do	nate E	Contact	Q Search
Home	About NCRAD	Information For Families	Biospecimens & Data	Banking NCRA		Tools for Stud	
ADDS/Ni	AD Active Stud	y Page			XXX		THE NCRAD
AD	v	Welcome ADDS/NiAD Stu	udy staff, coordinators, ar es study specific tools and		<b>m</b> łı	SAMP	We Bank
Alzheimer 's disease i	r		i have any questions, con it NCRAD by email or pho 39.		-	ad Docun	
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#### ADDS Blood-Based Biomarker Collection Schedule for NCRAD:

*^	Baseline	3-Month	16-Month	19-Month	32-Month	35- Month
DNA		~		~		~
Plasma		~		~		~
Serum		~		~		~

#### NiAD Blood-Based Biomarker Collection Schedule:

	Baseline	16-Month	32-Month	48-Month
DNA	~	<b>*</b> *	~	**
Plasma	~	~	~	**
Serum	~	~	~	**

but maintained at the site.

\*\*No Blood Based Biomarkers are collected at the 48-month visit.

#### NiAD Blood-Based Biomarker Collection Schedule for Sibling Controls:

	Baseline	16-Month	32-Month	48-Month
DNA	~			
Plasma	~			

#### Study Resources

Kit Request Module	
Study Specific Sample Notification Forms	
ADDS/NIAD Manual of Procedures	
Study Related Video Tutorials	
ADDS/NIAD Training Slides	

#### Additional Resources

ADDS/NiAD Kit Request System Friday Blood Draws Shipping Address Holiday Closures

#### **Ouestions/Comments**

Email: alzstudy@iu.edu Phone: 800-526-2839

## **Contact Information**

• Questions?

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- E-mail: <u>alzstudy@iu.edu</u>
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