ADRC Consortium for Clarity in ADRD Research Through Imaging (CLARiTI)



Collection and Shipment Training



Training Overview: CLARiTI

GUIDs

- Kit Review & Kit Request Module
- Specimen Labeling Instruction
- Sample Collection and Processing
- Shipping and Packaging Sample Shipments
- Creating Airbills and Scheduling UPS Pickup
- Sample Form
- Common Nonconformance Issues
- NCRAD Resources and Contact Information



Globally Unique Identifier (GUID)

The GUID is a participant ID that allows researchers to share data specific to a study participant, without exposing personally identifiable information

A GUID is made up of random alpha-numeric characters and does not include any PHI in the identifier



GUID (Globally Unique Identifier)

- 1. Create an account: <u>https://bricsguid.nia.nih.gov/portal/jsp/login.jsp</u>
- 2. Once you have an account, go to the GUID Tool-Create GUID
- 3. To open the 'Launch GUID Tool' you will need to have Java installed on your device
- 4. When the GUID Tool is open, you will need the following information (CLARiTI MOP Appendix A):
 - Complete legal given (first) name of participant at birth
 - Participant's middle name, if applicable
 - Complete legal family (last) name of participant at birth
 - Day of birth
 - Month of birth
 - Year of birth
 - Name of city/municipality in which participant was born
 - Country of birth



Kit Request Module https://kits.iu.edu/clariti



CLARiTI Kit Request Module

AAA ⊕⊡

- Enter Email
- Choose your site from drop-down list



National Centralized Repository for Alzheimer's Disease and Related Dementias

CLARiTI Kit Request System

Please select your site from the list below. 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.

Our standard shipping time for all orders is 3 weeks.

We can ship this kit request by: 03-28-2024

If you need any supplies in this order prior to 03-28-2024, you must contact the NCRAD coordinator for this study: gosnellm@iu.edu

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

Please enter your email address here to receive a confirmation email after completing the survey: * must provide value	doej@institution.edu	
Study Site * must provide value	8 - Somewhere University 🗸 🗸	
Somewhere University Jennifer Doe Somewhere Alzheimer's Disease Center 1234 Main St, Room 123 Somewhere, IN 46202 Phone: (000) 555-5555 Email: primarycontact@institution.edu		
Is the contact name above correct? * must provide value	⊖ Yes ⊖ No	set
Is the shipping address above correct? * must provide value	○ Yes ○ No	set
Is the e-mail address above correct? * must provide value	⊖Yes ⊖No	set

- The coordinator name and contact information will appear.
- Verify that this information is accurate and correct if necessary.



CLARITI Kit Request Module

Specimen Collection Kits	
CLARITI Blood Collection	
Contains supplies for collecting 30 ml of blood total:	(1)
 30 ml of blood for Plasma and Buffy Coat 	Collects 30 ml blood
* must provide value	
Shipping Kits	
CLARITI Frozen Shipping Supply Kit (Large Shippers)	H
* must provide value	Up to 8 subjects per frozen shipping kit
Supplemental Kits	
CLARITI Supplemental Kit	•
* must provide value	
Extra Supplies	
Do you need extra supplies?	(H) O Yes
bo you need extra supplies.	○ No

- Can place an order for:
 - Blood collection kit
 - Frozen shipping kit
 - Supplement kit (one per year)
 - Individual supplies
- Enter kit order amounts
- Please do not order in bulk. Kit contents expire.
- Click "Submit" to complete your request

*Allow for 3 weeks for kits to arrive when placing order

CLARITI Kit Types

CLARiTI Blood Kit



CLARiTI Supplemental Kit



CLARiTI Frozen Shipping Supply Kit (Large Shippers)





Specimen Labels



Three Label Types





Kit Number Labels

Kit Number 489799

- Ties all biospecimens and kit contents together for each participant at each visit
- Provides quality assurance
- Will be placed on the following locations:
 - 1. Blood Sample and Shipment Notification Forms
 - 2. Cryoboxes that house aliquots during shipping
 - 3. One extra label provided





- Participants will be identified by their Site and PTID and sites will be responsible for handwriting this onto the provided labels
 - Must use fine point permanent marker
- Placed on blood collection EDTA tubes



Collection Tube and Aliquot Labels



CLARITI 0043821076 BUFFYCOAT Kit #: 489799

- Collection Tube/Aliquot labels are specific to the type of biospecimen
- Have 4 components:
 - Study name
 - 10 digit unique specimen barcode
 - Collection Group
 - Kit number
- Place on EDTA tubes and processed cryovials



Blood Collection Tubes

Label 1: Site and PTID label



Label 2: Collection Tube label



All collection tubes will have two labels:

- Handwritten Site and PTID label
- Collection tube label



Labeling Biologic Samples



- Write site ID and participant ID with finepoint marker prior to label placement
- Label all collection and aliquot tubes <u>before</u> cooling, collecting, processing or freezing samples
- Label only <u>one</u> participant's tubes at a time to avoid mix-ups
- 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



Specimen Collection and Processing: Specimen Tube Types

Туре	Tube Photo	Size	Purpose	Amount
EDTA Tube		10 ml	Whole blood collection	3
Conical Tube		50 ml	Pooling plasma from EDTA tubes	1
Cryovial		2 ml 1.5 ml aliquots of plasma from conical tube		Up to 9
Cryovial		2 ml	Aliquot residual plasma <1.5 ml after filling purple top cryovials	1
Cryovial		2 ml	~1.0 ml aliquots of buffy coat from EDTA tubes	3



Plasma/Buffy Coat Collection and Processing: 30 ml



coat aliquots within 2 hours of collection.



Plasma Collection

- Processed plasma creates up to nine 1.5ml aliquots in purple cap cryovials
- Residual plasma is placed in blue cap cryovial



10 mL EDTA tube after centrifuge







Buffy Coat Collection

- Expected to have a reddish color from the RBCs.
- Be sure to only place the buffy coat from one EDTA tube into each cryovial
- Create up to 3 buffy coats









Packaging Sample Shipments



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



Sites provide pelleted dry ice for shipments

~45 lbs. per batch shipment (8 cryoboxes per large shipper)



Frozen Shipment Packaging

- Use the biohazard bag to package the frozen 25slot cryobox
- Confirm the kit number label has been placed on the outside of the cryobox





Frozen Shipment Packaging

- Place 2-3 inches of pelleted dry ice in the bottom of the Styrofoam shipping container, then insert the cryoboxes laying <u>upright</u>
- Fill shipper to the top with pelleted dry ice
- Each Styrofoam shipper must contain about 45 lbs (20 kg) of pelleted dry ice
- Each large frozen shipper holds up to 8 cryoboxes





Frozen Shipping – Dry Ice Requirements

Dry Ice label should not be covered with other stickers and must be completed, or the shipping carrier will reject/return your package!

Net weight of dry ice in **kg**

Dry lceFor Diagnostic or
Medical Purposes OnlyNo Shipping Papers RequiredContains20
kg of Dry Ice



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"





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 <u>must</u> be done 1st

Shipment	Information		
Study Group			~
Weight		IB	~
Dry Ice Weight		IB	~
Description of Return	Biological Specimens	20	•
Pickup Request	Diological Specifiens		

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



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
- Hit "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

Address Book				0000 0	company –	
RETURNS	Company		Select	CLARITI Boston	Boston University Medical Center	Eric Steinber
Group	CLARITI (NCRAD)					
Code						
Company						
Contact						
Address 1						
Address 2						
Address 3						
City						
State/Province						
Postal Code						
Country / Territory		~				
Email Phone or Fax	Account / Tax					



Verify Information

	Ship From	Shipment Info	ormation	
		Study Group	CLARITI (NCRAD)	~
Q	Clear	Weight		LB 🗸
Code	CLARITI Boston	Dry Ice Weight		LB 🗸
Company	Boston University Medical Center	Description of Return	Biological Specimens	
Contact	Eric Steinberg	Dislam Dequest	Lienegical opcontione	
Address 1	72 East Concord Street	Pickup Request		
Address 2	GCRU			
Address 3	Evans Building, 8th Floor			
City	Boston			
State/Province	MA			
Postal Code	02118			
Country / Territory	United States			

Please double check that both the shipping information AND study reference are correct for this shipment



Entering Shipment Information

• Frozen shipments

- 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				~		
Weight			LB	~		
Dry Ice Weight			LB	~		
Description of Return		Biological Specimens				
Dislan Deguest						



Need to request UPS Pickup?

- 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
 - Users must schedule pickup minimum 1 hour before "Earliest Time Ready"
- 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
 - Room number field is free text
 - Floor field is numerical only
- Hit "Save" when done

Study Group	
Weight	LB
Dry Ice Weight	L8
Description of Return	Biological Specimens

Create Pickup Request

. X

Pickup Date	2021-03-15	
Earliest Time Ready	HH MM (24 hours formal)	
Latest Time Ready	HH:MM (24 hours format)	
Contact Name		
Contact Phone		
Payment Method	Pay by shipper account	¥
Room Number		
Floor		





Shipping Packages

 If all fields in "Ship From" and "Shipment Information" fields are completed (and if necessary, pickup request is completed), click Ship in the bottom right corner of the page





Accessing Airbill

- Two documents will be created
- Save the Shipment Receipt and the UPS Waybill
- The "Pickup No:" is the reference number to your specific pickup request in case there are any issues with your package being picked up by UPS
- Check Pickup Status by going to 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

Shipment Receipt



Airbill





Accessing Airbill

- Print out the UPS air waybill
- Fold the UPS air waybill and slide it inside the plastic UPS sleeve (NCRAD will provide these in kit requests)
- Peel the back off the plastic UPS sleeve and stick the sleeve to your package, making sure it is laying as flat as possible along the surface of the package.





Creating Airbills & Scheduling Pick Ups: Reprinting/Voiding Airbills

ShipExec	Shipping - History	[™] Ind of Day ▼	R	eprin	t by clicking	; printe	r icon			
Start Ship Date	2021-03-15									
id Ship Date	2021-03-15									
	Select Site	\checkmark								
		~								
		~		Global		Shipper	Consignee	Ship	Weight	Rated
		~	Action	MSN	Tracking Number ≑	Reference [‡]	Reference	Date [‡]	÷	Weight [‡]
				0506	1707609\\\/9420941076		6693930	2020	2018	2018
				9506	129/080004300419/0		0003030	12-08	20 LB	20 LD
Consinnee										
Collegnee										
				ord by	v clicking th		n			

- 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"



Blood Sample and Shipment Notification Form





Biospecimen Collection, Processing, and Shipment Manual

Appendix C: Blood Sample and Shipment Notification Form Please email the form on or prior to the date of shipment.

	To: Kelley Fa	ber Email: a	alzstudy(@iu.edu P	hone: 1-800-526-2839		
From:			UPS	tracking #:	1Z976R8W84_		
Phone:			Emai	l:			
Study: CLA	RITI Sex: M F	/ear of Birth: _					
Site ID:	PT ID:				KITBA	RCODE	
GUID:		Visit:Ba	aseline	24 month	L		
Blood Coll	ection:			1			
	Date of Draw:	[M	IMDDYY]	Time of D	raw:	[ННММ]	
	Date subject last ate:	[M	MDDYY]	Time subj	ect last ate:	[ННММ]	
Blood Pro	cessing:	Plasma	a & Buffy	/ Coat (EDTA	Tube)		
	EDTA #1 specimen number (Last four digits):			Original blo	ood volume of EDTA #1:	mL	
	EDTA #2 specimen number (Last four digits):		N/A	Original blo	ood volume of EDTA #2:	mL	
	EDTA #3 specimen number (Last four digits):		N/A	Original blo	ood volume of EDTA #3:	mL	N/A
	Time spin started:	(нн	[HHMM]		Duration of centrifuge:	mii	ns
	Temp of centrifuge:	°C			Rate of centrifuge:	× g	
	Time aliquoted:	(нн	MM]	Number of	1.5 mL plasma aliquots created (purple cap):		
Volume (les	e of residual plasma aliquot ss than 1.5 mL in blue cap):	mL	N/A	Specin plasma al	nen number of residual liquot (Last four digits):		□n/a
Buffy	coat #1 specimen number (Last four digits):				Buffy coat #1 volume:	mL	
Buffy	coat #2 specimen number (Last four digits):		N/A		Buffy coat #2 volume:	mL	N/A
Buffy	coat #3 specimen number (Last four digits):	[N/A		Buffy coat #3 volume:	mL	N/A
	Time aliquots frozen:	(нн	мм]	Storage t	temperature of freezer:	°c	
Notes:							

Blood Sample and Shipment Notification Form



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 samples.



Email: alzstudy@iu.edu



Noncomformance 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.

NCRAD Website



NCRAD Website: Helpful Pages

https://ncrad.org/contact/hours/holiday-closures

Holiday Closures

Date	Holiday
January 1	New Year's Day
3 rd Monday in January	Martin Luther King, Jr Day
4 th Monday in May	Memorial Day
June 19	Juneteenth (observed)
July 4	Independence Day (observed)
1 st Monday in September	Labor Day
4 th Thursday in November	Thanksgiving
4 th Friday in November	Friday after Thanksgiving
December 25	Christmas

https://ncrad.org/shipping_address.html

Market Shipping Address

NCRAD Indiana University School of Medicine 351 W. 10th St TK-217 Indianapolis, IN 46202

UPS Shipping Resources

To generate air waybills and schedule UPS pickups for shipments to NCRAD, please visit the UPS ShipExec[™] Thin Client website.

For instructions on how to use the UPS ShipExec[™] Thin Client website, please refer to the NCRAD UPS ShipExec[™] Thin Client Guide.

Navigating UPS ShipExec™







Contact Information



