ARTFL-LEFFTDS Manual Update Training: V 5.2016

NCRAD

Training Overview:

- Study Update Overview
- Kit/Kit Request Module Update
- Specimen Label Update
- Sample Handling/Processing Update
- Sample Shipping Update
- Sample Form Updates
- Questions?

Study Update Overview – Top 3 Changes

1. Addition of new biospecimens to both ARTFL and LEFFTDS participants
   - Additional EDTA Tubes and Serum Tube
2. New blood draw order
   - PAXgene™ Tube now drawn LAST
3. Shipping supplies have been updated for the increase in specimens collected
   - Introduction of 81-slot cryobox

Updated ARTFL and LEFFTDS Study Specimens

	ARTFL	LEFFTDS (Visit 1)	LEFFTDS (Visit 2)	LEFFTDS (Visit 3)
DNA (Buffy Coat)	X	X	X	X
Plasma	X	X	X	X
PBMC	X	X	X	X
Serum	X	X	X	X
RNA	X	X	X	X
CSF	X*	X	X	X

*Select participant population Only

New Blood Draw Order

Tube Type	Number of Tubes Drawn	Tube Image
1. EDTA (Lavender-Top) Tube (10 ml)	x3	
2. Sodium Heparin (Green-Top) Tube (10 ml)	x1	
3. Serum Determination (Red-Top) Tube (10 ml)	x1	
4. PAXgene™ Tube (2.5 ml)	x3	

Kit Request Module Update

http://kits.iu.edu/artfl-lefftds/

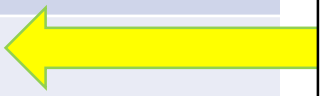
Available Kits:

1. ARTFL-LEFFTDS Universal Blood Kit (V 10.2015)
2. ARTFL-LEFFTDS Universal Blood Kit (V 5.2016)
3. Optional NCRAD Kit - CSF
4. Green Top-Sodium Heparin Tube Redraw/Take Home Kit
5. Lavender Top-EDTA Tube Redraw/Take Home Kit
6. Frozen Shipping Supply Kit (V 10.2015)
7. Frozen Shipping Supply Kit (V 5.2016)
8. ARTFL/LEFFTDS Supplemental Kit
9. Individual Supplies

Please note: ARTFL Base and LEFFTDS Cycle 1, Visit 1 kits will no longer be available.

ARTFL-LEFFTDS Universal Blood Kit

Quantity	ARTFL-LEFFTDS Universal Blood Kit Components
3	EDTA (Lavender-Top) Blood Collection Tube (10 ml)
1	Sodium Heparin (Green-Top) Blood Collection Tube (10 ml)
1	Serum Determination (Red-Top) Blood Collection Tube (10 ml)
3	PAXgene™ Blood Collection Tube (2.5 ml)
30	Cryovial tube (2 ml) with lavender cap
10	Cryovial tube (2 ml) with red cap
3	Cryovial tube (2 ml) with clear cap
2	Cryovial tube (2 ml) with blue cap
4	Disposable graduated transfer pipette
51	Pre-printed labels for blood collection and aliquot tubes
5	Pre-printed labels with kit number
9	Labels for handwritten Site and RAVE ID
1	Cryovial tube box (holds up to 81 cryovials)
1	Shipping Supplies for ambient shipment of PBMC: Small canister (95kPa Certified) Small IATA shipping box Absorbent tube sleeve Sheet of bubble wrap List of contents Fed Ex Clinic Pak FedEx return airbill

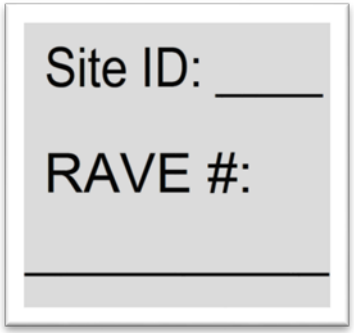


Automatically includes all shipping supplies to safely ship PBMC sample to NCRAD

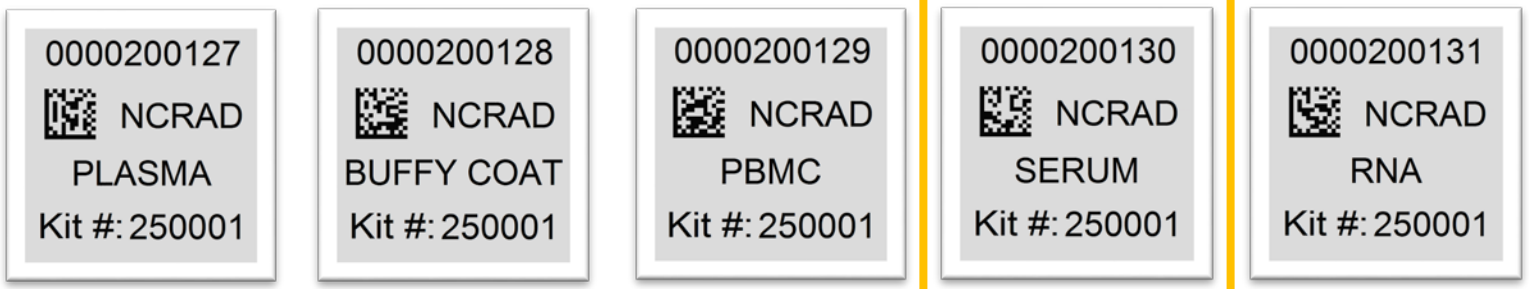
Specimen Label Update

Three Label Types

Kit Number



Site and RAVE ID



Collection and Aliquot Tube

Collection Tubes - BLOOD

EDTA
Tube

Sodium Heparin
Tube

Serum Determination
Tube

PAXgene™
Tube

Handling/Processing Study Specimens

- Updated Plasma and Buffy Coat Processing Schematic
- NEW Serum Processing Schematic

New Blood Draw Order

Tube Type	Number of Tubes Drawn	Tube Image
1. EDTA (Lavender-Top) Tube (10 ml)	x3	
2. Sodium Heparin (Green-Top) Tube (10 ml)	x1	
3. Serum Determination (Red-Top) Tube (10 ml)	x1	
4. PAXgene™ Tube (2.5 ml)	x3	

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

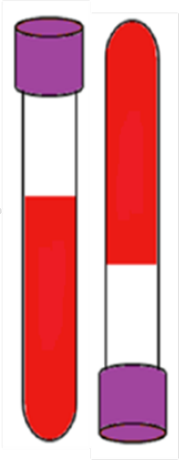
Step One

- Store tubes at room temperature.
- Label tubes with pre-printed subject labels prior to blood draw.

Step Two

- Collect blood in EDTA Tube allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three

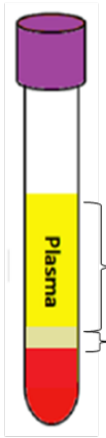


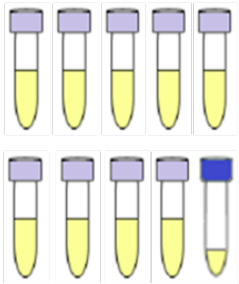
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

Step Four

- Centrifuge samples at 1500 x g for 15 minutes at 4°C.
- EDTA Tubes need to be spun, aliquoted, and in the freezer within 2 hours from the time of collection.

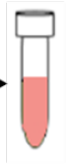
Step Five





- Label cryovial tubes with preprinted labels.
- Aliquot 0. 5 ml into each cryovial tube.
- If residual aliquot is created, use blue cap to indicate volume difference and document Specimen Number on Biological Sample and Shipment Notification Form.
- Store plasma aliquots at -80°C until shipment.

Step Six



- Label cryovial tube with preprinted label.
- Using a clean transfer pipette, collect the buffy coat (may have residual plasma and some RBCs included).
- Transfer the buffy coat into the cryovial tube.
- Store buffy coat aliquot at -80°C until shipment.

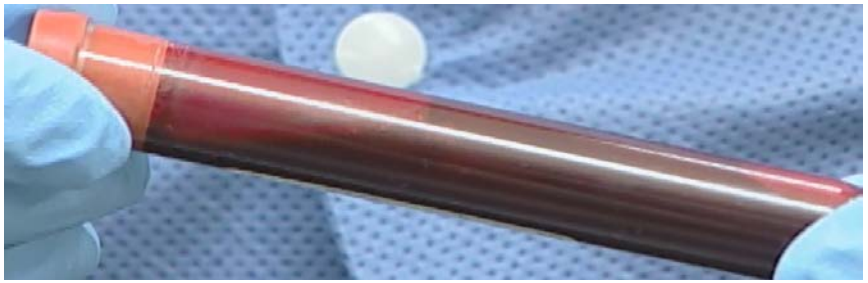
- **Three EDTA (Lavender-Top) Blood Collection Tubes will yield approximately:**
  - **24 to 30 Plasma aliquots with 0.5 ml per aliquot**
  - **3 Buffy Coat aliquots with 1.0 ml per aliquot**

New Blood Collection Tube: Serum Determination Tube

Serum Determination Tube (unfilled)

Serum Determination Tube
(Immediately after blood draw – pictured below)

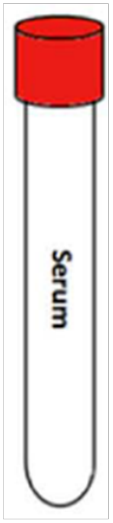
** Please note: After standing at room temperature for 30 minutes, blood will be clotted and immobile**



Serum Determination Tube (after centrifuged)

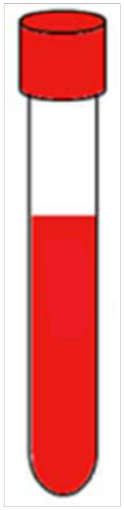
Serum Preparation (10 ml Red-Top Tube)

Step One



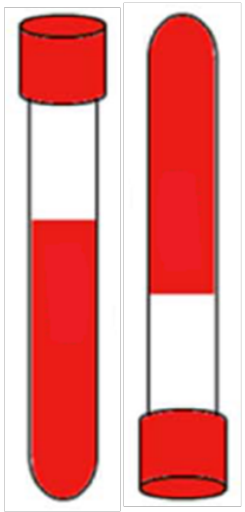
- Store tubes at room temperature.
- Label tubes with pre-printed subject labels prior to blood draw.

Step Two



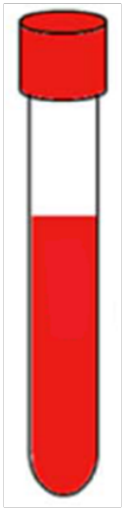
- Collect blood in Serum Tube allowing blood to flow for 10 seconds and ensuring blood flow has stopped.

Step Three



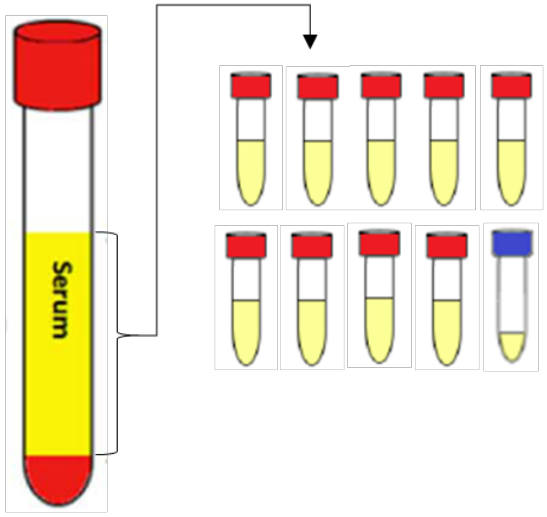
- Immediately after blood draw, invert tubes 8-10 times to mix samples.

Step Four



- Allow blood to clot for 30 minutes.
- Centrifuge samples at 1500 x g for 15 minutes at 4°C.
- Serum samples need to be spun, aliquoted, and in the freezer within 2 hours from the time of collection.

Step Five



- Label cryovial tubes with preprinted labels.
- Aliquot 0. 5 ml into each cryovial tube.
- If residual aliquot is created, use blue cap to indicate volume difference and document Specimen Number on Biological Sample and Shipment Notification Form.
- Store serum aliquots at -80°C until shipment.

Sample Shipments/ Shipping Supplies

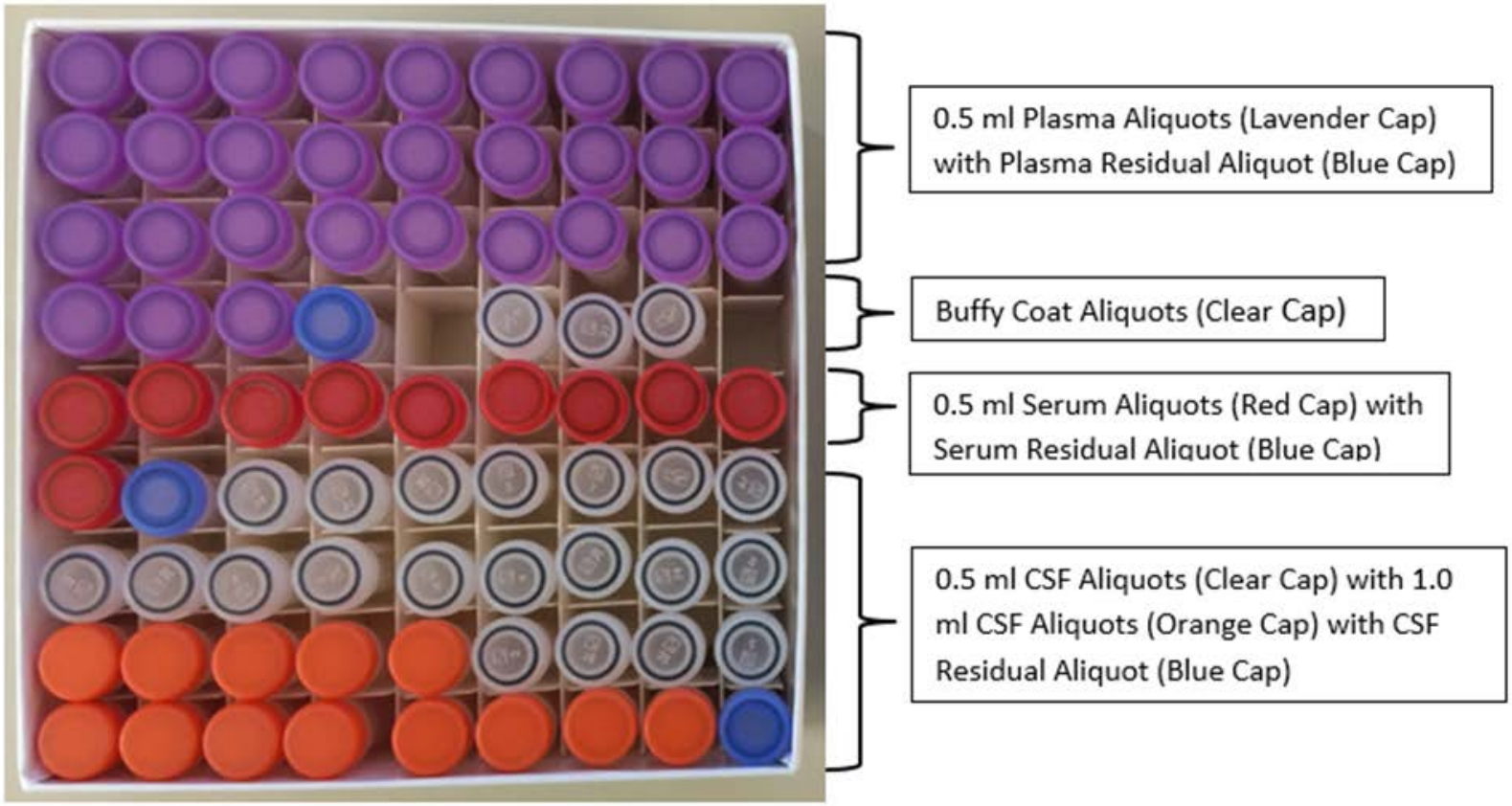
Additional Kit Supplies

- Cryovial Cap Colors:

Cap Color	Sample Type	Cap Image
Lavender	Plasma	
Clear	Buffy Coat	
Red	Serum	
Clear	CSF Aliquot (0.5 ml)	
Orange	CSF Aliquot (1.0 ml) and CSF Aliquot to local lab	
Blue	Residual Aliquot (Plasma, Serum, or CSF)	

Additional Kit Supplies Cont.

- 81-Slot Cryobox and Large Biohazard Bag



Additional Kit Supplies Cont.

- Large biohazard bag to accommodate 81-Slot Cryobox
- Frozen shipments should now only include biospecimens for 4 participants

Sample Shipment Summary

Sample Type	ARTFL	LEFFTDS	Processing/ Aliquoting	Tubes to NCRAD	Ship
Whole blood (Lavender-Top EDTA) for isolation of plasma & buffy coat (for DNA extraction)	Yes (V1)	Yes (V1, V2, V3)	0.5 ml plasma aliquots per 2 ml cryovials	24-31	Frozen
	Yes (V1)	Yes (V1, V2, V3)	1 ml buffy coat aliquot per 2 ml cryovial	3	Frozen
Whole blood (Green-Top Sodium Heparin) for isolation of PBMCs	Yes (V1)	Yes (V1, V2, V3)	N/A	1	Ambient
Whole blood (Red-Top Serum) for isolation of serum	Yes (V1)	Yes (V1, V2, V3)	0.5 ml serum aliquots per 2 ml cryovials	8-11	Frozen
Whole blood (PAXgene™) for RNA extraction	Yes (V1)	Yes (V1, V2, V3)	N/A	3	Frozen
CSF	Some	Yes (V1, V2, V3)	0.5 ml and 1 ml CSF aliquots per 2 ml cryovials	Up to 33	Frozen

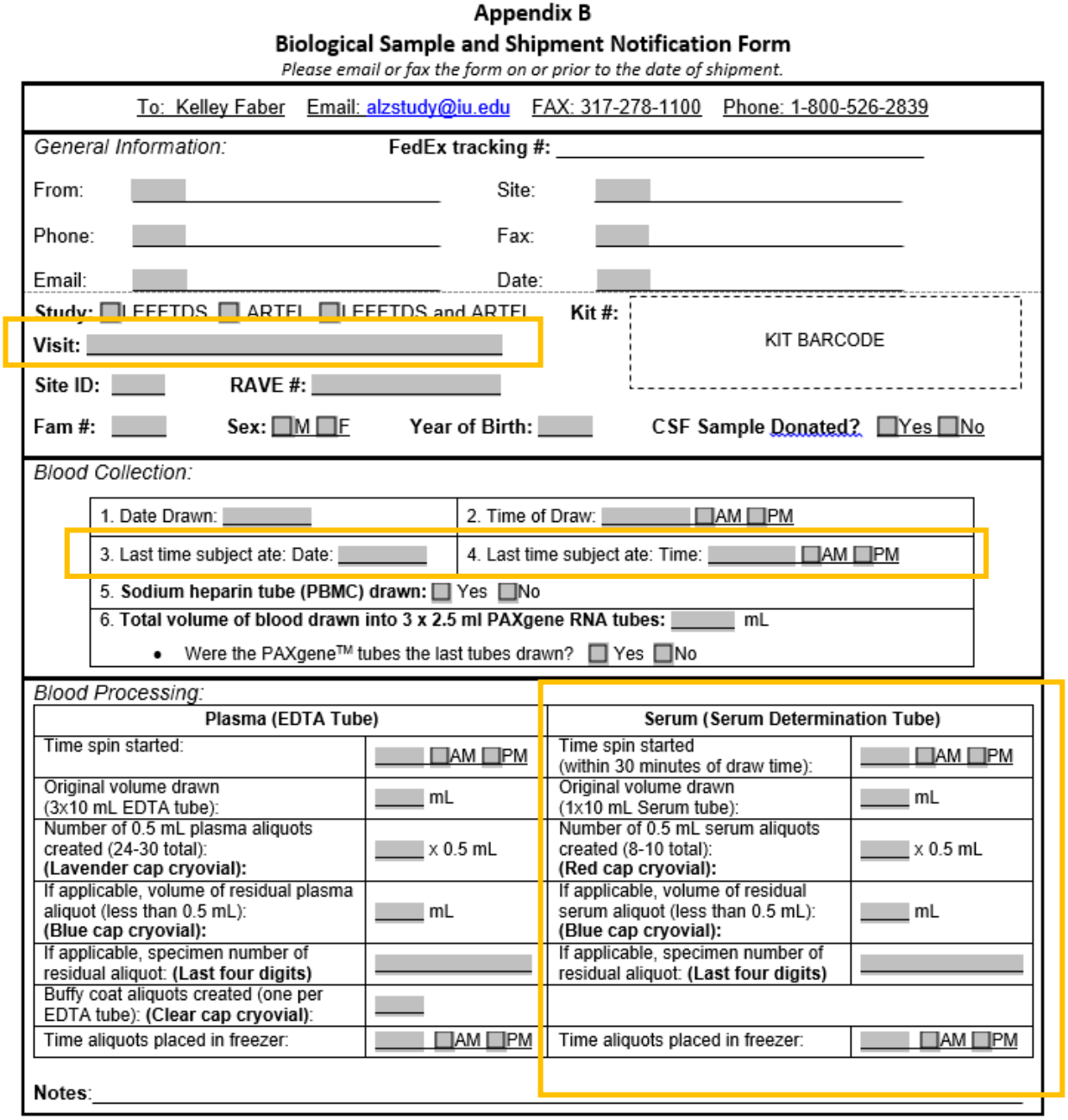
Ambient Sample Shipment

- Ship the sample(s) to IU on the day of collection.
- ***Sample(s) must be received at IU a day after collection.***
- ***Only ship Monday through Thursday***
  - ***No Saturday Shipments***

Frozen Sample Shipment

- All other samples
  - Plasma, Buffy Coat, Serum, PAXgene™, and CSF
  - **Ship Monday-Wednesday Only**
- Hold packaged samples in a -80°C freezer until pickup.
- Batch Samples together
  - 4 participant samples (Plasma, Buffy, Serum, CSF, RNA)
  - **Batch shipping should be performed quarterly or as a full shipment of specimens accumulates, whichever is sooner.**

Biological Sample and Shipment Notification Form Update



Appendix B

Biological 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 FAX: 317-278-1100 Phone: 1-800-526-2839

General Information: **FedEx tracking #:** _____

From: _____ Site: _____

Phone: _____ Fax: _____

Email: _____ Date: _____

Study: ☐ LEFFTDS ☐ ARTFL ☐ LEFFTDS and ARTFL **Kit #:** KIT BARCODE

Visit: _____

Site ID: _____ **RAVE #:** _____

Fam #: _____ **Sex:** ☐M ☐F **Year of Birth:** _____ **CSF Sample Donated?** ☐Yes ☐No

Blood Collection:

1. Date Drawn: _____	2. Time of Draw: _____ ☐AM ☐PM
3. Last time subject ate: Date: _____	4. Last time subject ate: Time: _____ ☐AM ☐PM
5. **Sodium heparin tube (PBMC) drawn:** ☐ Yes ☐No	
6. **Total volume of blood drawn into 3 x 2.5 ml PAXgene RNA tubes:** _____ mL • Were the PAXgene™ tubes the last tubes drawn? ☐ Yes ☐No	

Blood Processing:

Plasma (EDTA Tube)		**Serum (Serum Determination Tube)**	
Time spin started:	_____ ☐AM ☐PM	Time spin started (within 30 minutes of draw time):	_____ ☐AM ☐PM
Original volume drawn (3x10 mL EDTA tube):	_____ mL	Original volume drawn (1x10 mL Serum tube):	_____ mL
Number of 0.5 mL plasma aliquots created (24-30 total): **(Lavender cap cryovial):**	_____ x 0.5 mL	Number of 0.5 mL serum aliquots created (8-10 total): **(Red cap cryovial):**	_____ x 0.5 mL
If applicable, volume of residual plasma aliquot (less than 0.5 mL): **(Blue cap cryovial):**	_____ mL	If applicable, volume of residual serum aliquot (less than 0.5 mL): **(Blue cap cryovial):**	_____ mL
If applicable, specimen number of residual aliquot: **(Last four digits)**	_____	If applicable, specimen number of residual aliquot: **(Last four digits)**	_____
Buffy coat aliquots created (one per EDTA tube): **(Clear cap cryovial):**	_____		
Time aliquots placed in freezer:	_____ ☐AM ☐PM	Time aliquots placed in freezer:	_____ ☐AM ☐PM

Notes: _____

- **Now includes expanded blood processing section for both plasma and serum, new field for Visit Number, and expanded date/time of last time subject ate.**
- **Both ARTFL and LEFFTDS participants should have all aspects of form completed prior to submission**

CSF Sample and Shipment Notification Form Update

Appendix C

CSF 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 FAX: 317-278-1100 Phone: 1-800-526-2839

General Information: **FedEx tracking #:** _____

From: _____ Site: _____

Phone: _____ Fax: _____

Email: _____ Date: _____

Study: ☐LEFFTDS ☐ ARTFL ☐LEFFTDS and ARTFL **Kit #:** KIT BARCODE

Site ID: _____ **RAVE #:** _____

Fam #: _____ **Sex:** ☐M ☐F **Year of Birth:** _____ **Visit:** _____

CSF Collection:

1. Date of Collection: _____	2. Time of collection: _____ ☐AM ☐PM
3. Last time subject ate: Date: _____	4. Last time subject ate: Time: _____ ☐AM ☐PM
5. Collection process: ☐ Gravitational OR ☐ Pull	

CSF Processing:

1. Total number of CSF **aliquot** tubes: _____	4. Total number of CSF **0.5 mL aliquots transferred** to NCRAD: **(Clear cap cryovial)**: _____
2. Total amount of CSF **collected** (mL): _____	5. Total number of CSF **1.0 mL aliquots transferred** to NCRAD: **(Orange cap cryovial)**: _____
3. Time frozen: _____ ☐AM ☐PM	6. If applicable, volume of CSF residual aliquot (less than 0.5 mL): **(Blue cap cryovial)**: _____
7. If applicable, specimen number of residual aliquot tube: **(Last four digits)**: _____	

Notes: _____

- **Now includes Visit Number**
- **Please note that fasting information is obtained through "Last Time Subject Ate"**
- **Both ARTFL and LEFFTDS participants should have all aspects of form completed prior to submission**

Questions?

- Please utilize the “Chat” window at the bottom of the Adobe Connect Screen.

Or

- Contact Ashley Vetor at:
  - Phone: 317-278-9546
  - Email: abozell@iu.edu