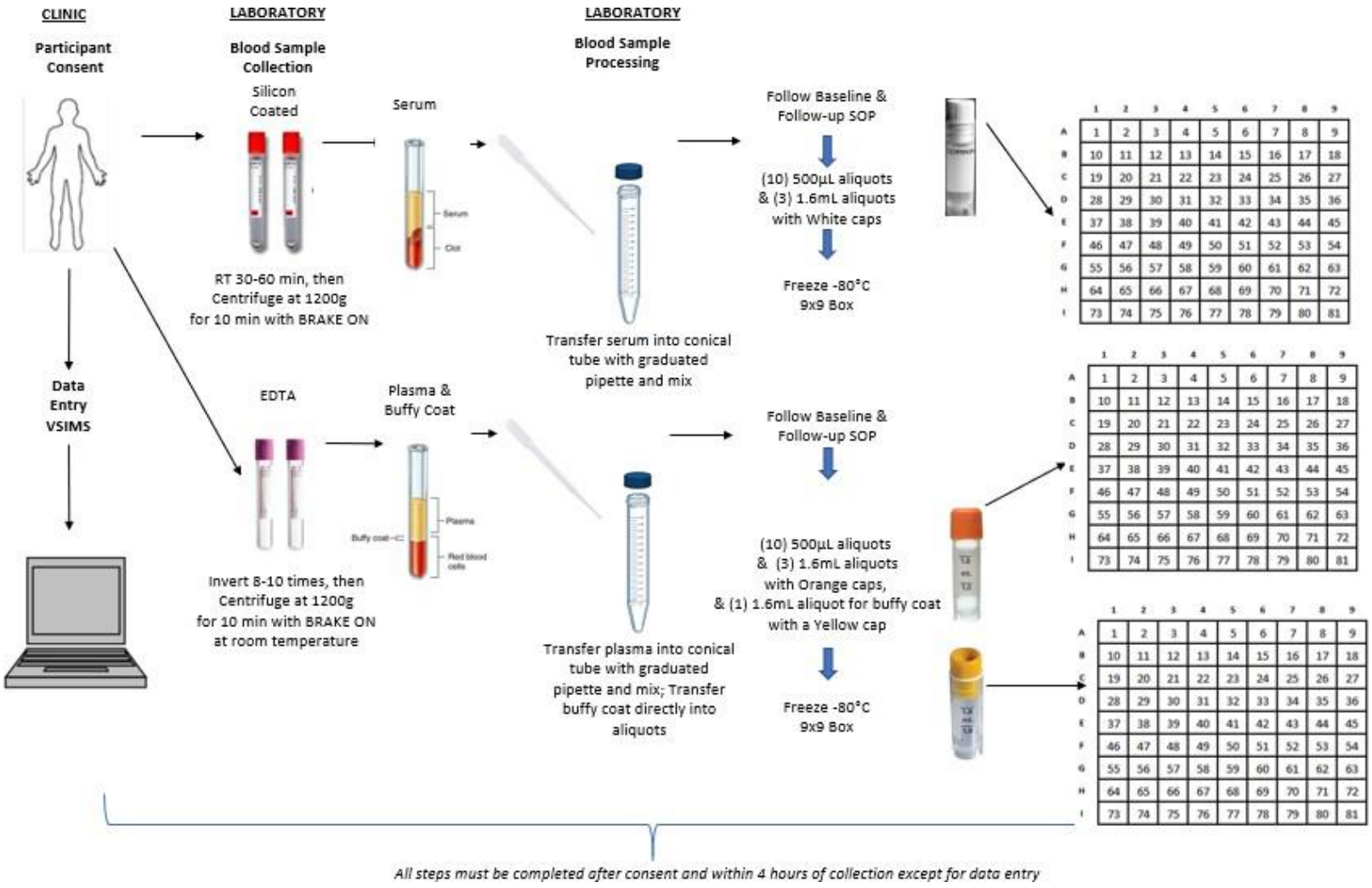
MOP, Section 11.9 Appendix 9:

New Onset Diabetes Study
Biospecimen Standard Operating Procedures

Contents

Blood Products



Purpose:

The purpose of this procedure is to outline the process for collecting, processing, and storing of blood specimens and derivatives.

Materials Needed to Collect, Process, and Store NOD Specimen:

1. –80ºC (or lower) Freezers with emergency backup generators (site provided)
2. Crushed ice or 4^0C refrigerator for EDTA tubes if a delay in processing is anticipated (site provided)
3. Centrifuge **(Refrigerated is NOT needed) (site provided)**
4. Appropriate racks to hold tubes in upright position (site provided)
5. Participant ID labels, Biospecimen ID labels, Biospecimen worksheets **(Provided by DMCC)**
6. Biospecimen Kit **(Provided by Frederick National Laboratory for Cancer Research (FNLCR))**
7. Shipment Kit (Provided by FNLCR)

Biospecimen Kit includes:	
a)	2 – 10mL EDTA tubes for plasma & buffy coats **[BD Diagnostics, 366643]*, in a bubble wrap sleeve** No more than a total of 20mL should be collected, and if less than a total of 20mL is collected in the 2 – 10mL ETDA tubes, an additional tube can be used from a different Kit and a replacement can be requested from FNLCR.
b)	2 – 10mL Red top tubes, no SST (serum separator tubes), for serum **[BD Diagnostics, 367820]*, in a bubble wrap sleeve** No more than a total of 20mL should be collected, and if less than a total of 20mL is collected in the 2 – 10mL Red top tubes, an additional tube can be used from a different Kit and a replacement can be requested from FNLCR.
c)	2 – 15mL Conical tubes **[Corning, 352097or similar]**
d)	4 – Graduated pipettes **[Cardinal Health, CH5214-12 or similar]** to accommodate serum transfer and aliquoting, plasma transfer and aliquoting, and buffy coat aliquoting Sites who have access to a micropipette and 1mL pipette tips may choose to use this device to aliquot the specimens in place of the disposable pipettes provided in the Kit.
e)	13 – 2mL orange cap aliquot cryovials with screw top gasket closure for frozen plasma samples (10 x 0.5 mL and 3 x 1.6 mL) **[Corning, 430659]***
f)	13 – 2mL white cap aliquot cryovials with screw top gasket closure for frozen serum samples (10 x 0.5 mL and 3 x 1.6 mL) **[Corning, 431421]***

g)	1 – 2mL yellow cap aliquot cryovials for frozen buffy coat (1 x 1.6 mL) **[Corning, 431417]***

***The exact vendor and catalog number listed must be used for the materials that have an asterisk.**

Shipment Kit:	
a)	Outer Cardboard Box
b)	UN3373, Biological Substance, Category B label and Class 9, Dry Ice Label
c)	Insulated shipping box with inner styrofoam box and outer cardboard box provided by FNLCR. **[Inmark SKU #20497 (07 Series Solution F, 44L, Std Wall, Cat B Shipper)]**
d)	Cardboard insert
e)	Biohazard bag and sleeve for the freezer storage boxes
f)	Absorbent Sheets
g)	Cardboard freezer storage boxes provided by FNLCR and received inside the shipping box mentioned above in item "c". **[VWR #89214-752 2" Cryogenic box, with drain slots, with grids, 81 cell divider or similar –but must be 81 cell], with an absorbent sheet secured with a rubber band**
h)	Rubber bands
i)	Return label

1. Collection

1.1 Do not collect blood specimens unless consent has been obtained.

1.2 Blood collection should be performed by a licensed phlebotomist, nurse, anesthesiologist, medical doctor, or a clinical research coordinator trained in phlebotomy.

1.3 Collection should be performed in an adequate setting, e.g. in the phlebotomy room, or on the ward. Blood collection in the operating theater should be avoided, if possible.

1.4 A total of 40 mL of blood will be collected. Order of blood draw collection should be:

- 2 – 10mL Red Top Serum Tubes
  Avoid collecting more than 20mL of blood. If less than a total of 20mL is collected in the 2 – 10mL Serum tubes, an additional Serum tube can be used from a different Kit and a replacement can be requested from FNLCR
- 2 – 10mL EDTA Purple Top Tubes—Note: These must be filled to line on label for proper EDTA

blood ratios, invert gently 8-10 times to mix (careful not to shake too hard or buffy coat cells could lyse)
Avoid collecting more than 20mL of blood. If less than a total of 20mL is collected in the 2 – 10mL ETDA tubes, an additional ETDA tube can be used from a different Kit and a replacement can be requested from FNLCR

Step 1. Assemble the supplies to be used in obtaining the specimen. Do not label the vacutainer tubes until specimen is obtained. **Note: When affixing the labels to the vacutainer tubes, always wrap the label from the left around to the right of the tube while holding it in the upright position.**

Step 2. Put on disposable gloves.

Step 3. The patient should be comfortably seated in a venipuncture chair. The arm should be positioned on a slanting armrest in a straight line from the shoulder to the wrist. The arm should not be bent at the elbow.

Step 4. Apply a tourniquet 2 inches above the antecubital fossa or above area to be drawn with enough pressure to provide adequate vein visibility. Have the patient form a fist. Select the site for venipuncture.

Step 5. Clean the forearm of the patient with antiseptic wipe in a circular motion beginning at the insertion site. Allow the antiseptic to dry.

Step 6. Anchor the vein by placing the thumb 2 inches below the site and pulling the skin taut to prevent the vein from moving. The holding finger is placed below the site, not above, to prevent accidentally sticking the finger with the needle.

Step 7. Using the dominant hand, insert either the butterfly needle or straight needle. Push the evacuated tube onto Luer adapter.

Step 8. Release the tourniquet once blood flow is established.

Step 9. Carefully remove the tubes when full without dislodging the needle. The tube will automatically stop filling when the vacuum is gone leaving the tube approximately three-fourths full.

Step 10. Lightly place a sterile gauze pad over the venipuncture site. Gently remove the needle.

Step 11. Apply pressure to the site with sterile gauze. Apply bandage. Instruct the patient to leave the bandage on for at least 15 minutes.

Step 12. Dispose of the needle in a sharps container.

Step 13. Remove gloves and wash hands.

Note: A repeat blood draw may be performed if the appropriate tubes were not able to be collected at one time.

1.5 After the blood collection, place the appropriate Kit ID Serum Tube Label and Kit ID Plasma Tube Label on each of the collection tubes.

1.6 On the Red Top Tubes (Serum) and EDTA Tubes (Plasma/Buffy Coat) Worksheets:

- Make sure the pre-printed Kit ID number on the worksheet matches the Kit ID number on both Serum Tube Label and Plasma Tube Label affixed to the collection tubes.
- Affix the correct Participant ID Label. This is critical for associating the Kit ID to the correct

participant.

- Complete the Date collected and Time collected of the draw on the Biospecimen Worksheets
- Complete the fasting status on the Biospecimen Worksheet
- Use comments field to explain why the desired volume not obtained if applicable

2. Processing

2.1 Appropriate precaution should be taken for all patient blood samples as the infectious status of specimens cannot always be determined.
2.2 All centrifuge spins should be performed using lids that prevent aerosol release from blood samples.

Notes:

- This SOP applies to the collection of serum, plasma, and buffy coat.
- This SOP does not cover safety procedures for the collection and processing of these samples and personnel must follow institutional biosafety guidelines.
- This SOP does not cover informed consent procedures.
- Definition: g force (G) = relative centrifugal force (RCF)
    - Note: RCF does not equal revolutions per minute (RPM) and centrifuge RPM settings must be calculated based on the rotor inside the centrifuge. Refer to the equipment manual.

Serum (Silicon Coated)

Step 1. Collect approximately 10mL in each of the two (2) red top blood collection tubes ("vacutainers").

Step 2. Set the red top blood collection tubes upright after the blood is drawn at room temperature for a minimum of 30 to a maximum of 60 minutes to allow the clot to form. If the blood is not centrifuged immediately after the clotting time (30 to 60 minutes at room temperature), the tubes should be refrigerated or on wet ice (4°C) for no longer than 4 hours.

Step 3. Centrifuge at 1200g for 10 minutes with the BRAKE ON at room temperature.

Step 4. Pool serum (the supernatant or upper layer) in one 15mL conical tube and mix using a graduated pipet. If one of the tubes are hemolyzed, do not pool. Process each tube separately. Note: Use all serum except the last 1/4 inch to avoid red blood cell contamination. If a gel-like mass is present, pierce gently with a graduated pipette tip and re-centrifuge at 1200g for 5 minutes, then aliquot into desired amount.

Step 5. Aliquot the serum into the white cryovials with the appropriate labels using a graduated pipet. After collecting ten (10) 500µl aliquots, aliquot 1600µl into three (3) white cryovials. If you do not have enough volume to fill all three (3) x 1600µl aliquots it is acceptable to divide the remaining volume equally between the final three (3) aliquots and note the actual volume in VSIMS during key-entry. **Note: 0.5mL = 500µl and 1.6mL = 1600µl. Every possible attempt should be made to collect all expected aliquots, but collecting less than the expected aliquots will not prevent you from confirming the patient into the NOD study.**

Sites who have access to a micropipette and 1mL pipette tips may choose to use this device to aliquot the specimens in place of the disposable pipettes provided in the Kit.

Step 6. Close the caps on the cryovials tightly. This process should be completed within 1 hour of centrifugation.

Step 7. Check that all aliquot vial caps are secure and that all vials are labeled. **Note: When affixing the specimen ID labels to the vials, always wrap the specimen ID label from the left around to the right of the vial while holding it in the upright position.**

Step 8. Freeze serum specimens at –80°C no more than 4 hours after the blood draw. Serum aliquots can be temporarily refrigerated or stored on wet ice (4ºC, <4 hours) until able to freeze at -

80°C. **Note: The sample should not be thawed prior to shipping.**

Step 9. The samples should be stored locally at the site until FNLCR has initiated the Material Transfer Agreement and provided shipping information. The DMCC will let you know when your institution has an MTA in place with FNLCR.

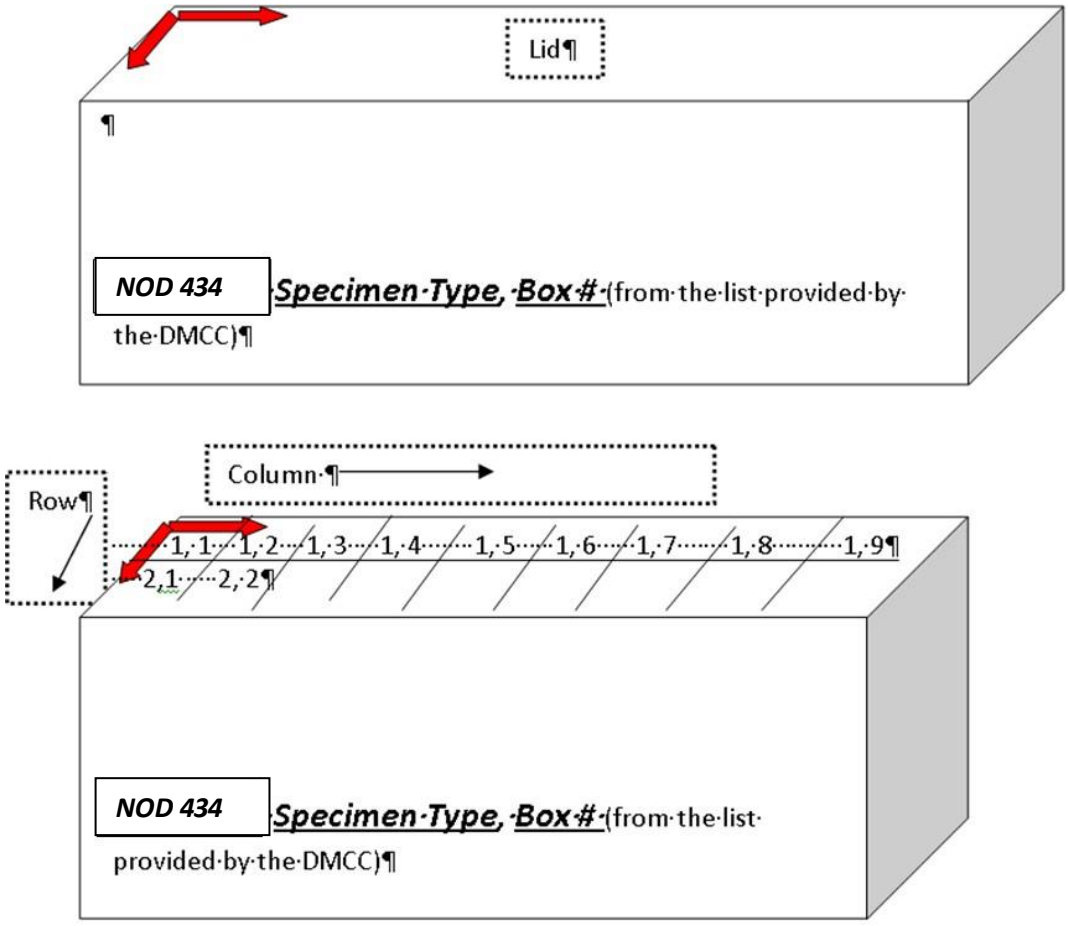
Step 10. Complete the worksheet documenting the processing questions and storage location.

Step 11. The DMCC will generate each sites' first set of Box ID#. The sites will be responsible for generating additional Box ID# in VSIMS prior to specimen entry. Write the specimen type and Box ID# on the front face of the lid and on the front face of the box. Please refer to the figure below to determine where to write the Box ID#. The inside of the box can be labeled A to I for the rows and 1 to 9 for the columns.

Step 12. Place the serum in a 9x9 Box with the corresponding specimen type and Box ID#. **Note: Do not mix specimen types in a box.**

Step 13. Fill each box so there are no empty spaces. **Note: A participant's sample may be separated into different boxes in order to fill the box completely.**

- **Warning**: Excessive centrifuge speed (over 2000g) may cause tube breakage and exposure to blood and possible injury. If needed, RCF for a centrifuge can be calculated. For an on-line calculator tool, please refer to: http://www.changbioscience.com/cell/rcf.html or http://insilico.ehu.es/mini_tools/rcf_rpm.php



Besides including the Box ID#, NOD Protocol ID# and Specimen Type on the outside of the box and lid, place a label on the outside of the box lid to denote the FRONT of the box and another on the same side of the lower portion of the box so the two line up. This will help determining the orientation of the inner cells and help with mapping.

Plasma (EDTA tube)

Step 1. Collect approximately 10mL of blood in each of the two (2) EDTA blood collection tubes

Step 2. Mix blood thoroughly after draw by inverting the tube 8 to 10 times.

Step 3. Store vacutainer tubes upright at 4°C (refrigerated or on wet ice) until centrifugation. **Note: Blood samples should be centrifuged, processed, and in -80°C freezer within 4 hours of blood collection.**

Step 4. Centrifuge at 1200g for 10 minutes at room temperature with the **BRAKE ON**. After centrifugation, the sample should separate into 3 layers: top layer is the plasma, middle layer is the white (buffy coat) and the bottom red blood cells.

Step 5. Carefully collect the plasma layer with an appropriate graduated pipette without disturbing the buffy coat from all two (2) EDTA tubes and transfer into one 15mL conical tube. Mix.

Care should be taken to prevent disturbing the buffy coat layer, which could result in contamination. **Note: If one of the tubes are hemolyzed, do not pool. Process each tube separately. Ensure sample homogeneity.**

Step 6. Aliquot plasma using a graduated pipet into 500µL aliquots (orange cryovials). After collecting ten (10) 500µl aliquots, aliquot 1600µl into three (3) orange cryovials. If you do not have enough volume to fill all three (3) x 1600µl aliquots it is acceptable to divide the remaining volume equally between the final three (3) aliquots and note the actual volume in VSIMS during key-entry. **Note: 0.5mL = 500µl and 1.6mL = 1600µl. Every possible attempt should be made to collect all expected aliquots, but collecting less than the expected aliquots will not prevent you from confirming the patient into the NOD study.**

Sites who have access to a micropipette and 1mL pipette tips may choose to use this device to aliquot the specimens in place of the disposable pipettes provided in the Kit.

Step 7. Check that all aliquot vial caps are secure and that all vials are labeled. **Note: When affixing the specimen ID labels to the vials, always wrap the specimen ID label from the left around to the right of the vial while holding it in the upright position. Freeze vials in upright position.**

Step 8. Freeze plasma specimens at –80°C no more than 4 hours after the blood draw. Plasma aliquots can be temporarily (< 4 hours) refrigerated or stored on wet ice (4°C) until able to freeze at –80°C. **Note: The sample should not be thawed prior to shipping**

Step 9. The samples should be stored locally at the site until FNLCR has initiated the Material Transfer Agreement and provided shipping information.

Step 10. Complete the worksheet documenting the processing questions and storage location.

Step 11. The DMCC will generate each sites' first set of Box ID#. The sites will be responsible for generating additional Box ID# in VSIMS prior to specimen entry. Write the specimen type and Box ID# on the front face of the lid and on the front face of the box. Please refer to the figure below to determine where to write the Box ID#. The inside of the box can be labeled A to I for the rows and1 to 9 for the columns.

Step 12. Place the plasma in a 9x9 Box with the corresponding specimen type and Box ID#. **Note: Do not mix specimen types in a box.**

Step 13. Fill each box so there are no empty spaces. **Note: Samples may be separated into different boxes in order to fill the box completely.**

- **Warning**: Excessive centrifuge speed (over 2000g) may cause tube breakage and exposure to blood and possible injury. If needed, RCF for a centrifuge can be calculated. For an on-line calculator tool, please refer to: http://www.changbioscience.com/cell/rcf.html or http://insilico.ehu.es/mini_tools/rcf_rpm.php

Buffy coat from the above EDTA tubes

Step 1. After the plasma has been aspirated off, use a graduated pipette to carefully collect the buffy coat layer (middle white layer) from the two (2) EDTA tubes and transfer all of the buffy coat (up to 1.6mL) into one (1) yellow cryovial. Care should be taken when collecting the plasma to prevent

disturbing the bottom layer which could result in contamination. **Note: 1.6mL = 1600µl.**

Sites who have access to a micropipette and 1mL pipette tips may choose to use this device to aliquot the specimens in place of the disposable pipettes provided in the Kit.

Step 2. Check that aliquot vial cap is secure and that the vial is labeled. **Note: When affixing the specimen ID labels to the vials, always wrap the specimen ID label from the left around to the right of the vial while holding it in the upright position. Freeze vials in upright position.**

Step 3. Freeze buffy coat specimens at –80°C no more than 4 hours after the blood draw. **Note: The sample should not be thawed prior to shipping**

Step 4. The samples should be stored locally at the site until NCI-Frederick has initiated the Material Transfer Agreement and provided shipping information. The DMCC will let you know when your institution has an MTA in place with FNLCR.

Step 5. Complete the worksheet documenting the processing questions and storage location.

Step 6. The DMCC will generate each sites' first set of Box ID#. The sites will be responsible for generating additional Box ID# in VSIMS prior to specimen entry. Write the specimen type and Box ID# on the front face of the lid and on the front face of the box. Please refer to the figure below to determine where to write the Box ID#. The inside of the box can be labeled A to I for the rows and1 to 9 for the columns.

Step 7. Place the buffy coat in a 9x9 Box with the corresponding specimen type and Box ID#. **Note: Do not mix specimen types in a box.**

Step 8. Fill each box so there are no empty spaces. **Note: Samples may be separated into different boxes in order to fill the box completely.**

Shipping and Receiving

Frozen Shipment Instructions

1) Ship only Monday – Wednesday

2) Consider staggered shipping of boxes to minimize the loss of large volumes of samples and based on institutional shipping experience with major shipping carriers.

3) Consider the local weather forecasts in anticipation of delays in shipping

4) Retrieve all samples stored from boxes. In VSIMS use the reporting menu to confirm all processing questions are complete for these boxes. Also check the box space reports to ensure the boxes are documented as being full in VSIMS prior to shipping. This eliminates undocumented samples from being shipped.

5) When creating the shipping manifest, you must have the box numbers being shipped and the FedEx tracking number to be used. FedEx tracking labels are included in each of the shipping boxes received from FNLCR.

6) Once samples are ready to be physically shipped from a site to FNLCR, they must be "electronically shipped" in the VSIMS. This will send an automated e-mail notification to the repository to notify them of an incoming shipment. The receiver will be provided with a shipping list and courier tracking number to track the physical location of the samples. Each site should print/save a copy of the shipment manifest before closing out VSIMS.

   VSIMS is accessed through http://www.compass.fhcrc.org/vsims

   NCIFCONNECTspt@mail.nih.gov (this address is monitored by multiple staff members).

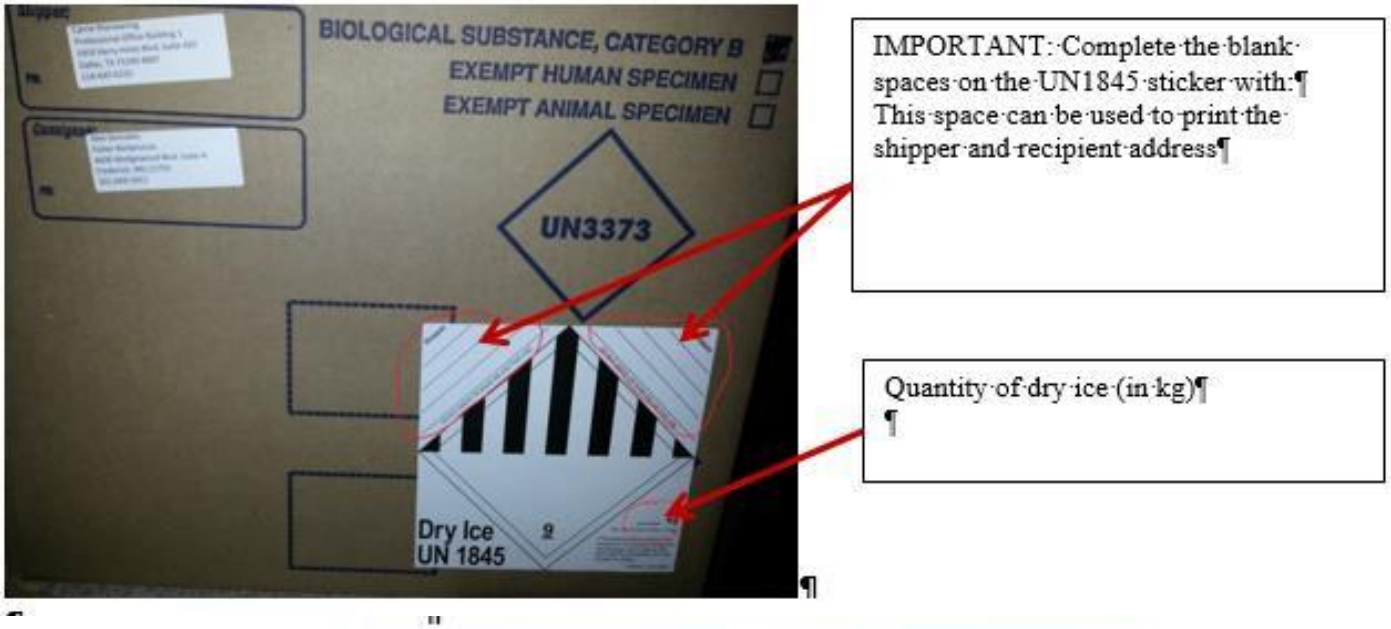
7) Use insulated shipping boxes provided by FNLCR, with the inner foam box and outer cardboard box.

8) Pack the samples according to Standard UN 3373 (IATA Shipping Instructions 650) for "Biological Substance, Category B", i.e. triple packaging with two water tight and pressure safe layers with absorbent material in between. Triple packaging consists of the following:

   a. A leak proof primary receptacle (Eg. Cryovial)
   b. A leak proof secondary packaging (Eg. biohazard bag + 95kPa sleeve; or 95kPa Biohazard bag)
   c. An outer rigid packaging of adequate strength for its capacity, mass and intended use (Eg. cardboard shipping box with inner foam box)

9) If site is not using the FNLCR provided shipper then the site must ensure that the package passes the IATA drop test from a height of not less than 1.2 m. For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging.

10) Marking Requirements: Packages containing UN3373 materials must be clearly marked with the proper shipping name of "Biological substance, Category B" with the characters being at least 6 mm high. Packages must also have the mark illustrated in Packing Instruction 650 clearly and legibly displayed on the external surface of the outer packaging adjacent to the proper shipping name. The UN3373 mark must be in a square on point configuration (diamond shaped) with each side being a minimum of 50 mm (or 2 inches) in length with the UN3373 characters being at least 6 mm in height. In addition, UN1845 stickers will be use in accordance with IATA regulations for shipping dry ice



11) Include sufficient dry ice for the planned shipping time and include enough dry ice to protect the samples in the event of a one-day delay of transit. **Note: Please do not try to save shipping costs by putting less dry ice in the package. Thawed samples cannot be used for this research.**

12) If site is not using the FNLCR provided shipper then the site must ensure that the container is large enough to hold sufficient dry ice to ensure samples arrive frozen.

Best Practices to consider for **Dry Ice Shipments:**

a. **Dry Ice:** Use as much dry ice as possible depending on the number of boxes that will be included in the shipment. Use more for larger shipping boxes, proportional to their size.

b. **Box to Dry Ice Ratio is critical**

- **Optimal situation:** maximum of 8 sample boxes (9x9 boxes) and 45-55 lbs (20-25 kg) of dry ice.
- The following calculator could be used as an example https://calculator.academy/dry-ice-calculator According to the calculator the 24-quart shipping box with outer dimension of 14 x 14 x 14.63 inches can generally ship more than two 81-slot boxes at a time with approximately 15 lbs (7 kg) of dry ice minimum.

13) Multiple boxes of the specimen samples can be shipped in one insulated shipping box at a time.

- Selecting box number(s) in VSIMS will display the sample IDs of the samples that are supposed to be in the box that is about to be shipped.
- Always take a moment to perform the following steps to ensure the samples in the box matches the samples on the shipping list.
- Have dry ice nearby to place the boxes on while out of the freezer (required). Do not let samples sit for more than 1-2 minutes at room temperature. Freeze-thaw cycles are not allowed for the samples.

14) Check that the number of samples in the box is the same as the number of samples listed on the shipping list:

a. If the number of samples in the box and the number of samples on the shipping list does not match, do a quick but careful inventory. Make sure not to let the samples get warm and thaw.

b. If there are extra samples in the box that are not on the list, pull them out for later evaluation. **DO NOT SHIP SAMPLES THAT ARE NOT ON THE SHIPPING LIST**.

15) Spot-check a few of the samples. Pull a couple of samples from the box and check to see if they are on the shipping list.

a. If they are not on the shipping, the wrong box may have been pulled from the freezer.

b. Carefully inventory the box (See Item 11a).

c. Verify box contents with the use of a "box map" (in addition to the shipping list).

	1	2	3	4	5	6	7	8	9
A	1	2	3	4	5	6	7	8	9
B	10	11	12	13	14	15	16	17	18
C	19	20	21	22	23	24	25	26	27
D	28	29	30	31	32	33	34	35	36
E	37	38	39	40	41	42	43	44	45
F	46	47	48	49	50	51	52	53	54
G	55	56	57	58	59	60	61	62	63
H	64	65	66	67	68	69	70	71	72
I	73	74	75	76	77	78	79	80	81

16) Do not ship the samples until the number of samples on the shipping list matches the number of samples in the box. Enter the shipping date and tracking number for courier in VSIMS.

17) Print copies of the shipping list for the contents in all boxes and file in the site's research records.

18) Include a shipping list of the shipment contents inside all boxes shipped. FNLCR will receive an auto-email notification and electronic manifest.

Specimen Shipping Address & contact information

All specimens must be shipped via Priority Overnight for delivery the next day. DO NOT ship on days that would cause the specimens to arrive on a weekend or holiday.

Contact FNLCR at NCI-FrederickCSPBPTLStaff@mail.nih.gov for any questions related to anticipated delivery dates (for example, the observed holidays at FNLCR).

Ship specimens to:

Shipments should be addressed to:
NCI at Frederick Central Repository
4600 Wedgewood Blvd
Suite H Loading Dock
Frederick, MD 21703
Tel: 301-732-8200
Email: NCIatFrederickCentralRepositoryOperations@mail.nih.gov

**** Please only ship specimens on Monday, Tuesday or Wednesday of a given week.****
Priority Overnight Carrier Examples:

a. UPS
b. FedEx (Prepaid/address shipping labels are included in the specimen shipper boxes provided by FNLCR)
c. World Courier
d. DHL

Specimen Receiving

Shipped specimen samples will be received by FNLCR. The repository will follow the steps below to acknowledge the specimen receipt and track the location of the specimens within FNLCR:

1) Receive the shipment and verify the condition of the packaging. Verify the box count matches the manifest.
2) Scan the contents of each box into the BSI Tracking System located at FNLCR.
3) Notify both the sending site and the DMCC by e-mailing the receipt and any discrepancies.

NOD PURPLE TOP TUBES (PLASMA & BUFFY COAT)

Version 4.0 Revised 09-25-2020

Kit #102	Date collected: __ - __ - ____ Time collected: __ : __ ☐ AM ☐ PM	Participant ID (affix label):

Staff ID: ____ Fasting? (at least 8 hours of no food or drink except water) ☐ Yes ☐ No ☐ Unknown

** If No or Unknown, reschedule the draw*

What is the date you last ate or drank anything except plain water? __ - __ - ____

What is the time you last ate or drank anything except plain water? __ : __ ☐ AM ☐ PM

Tubes inverted 8-10 times? ☐ Yes ☐ No

Tubes stored upright at 4°C (refrigerated or on wet ice) until centrifugation? ☐ Yes ☐ No ☐ N/A

Centrifuged at 1200g for 10 min at RT w/ brake on? ☐ Yes ☐ No

Time specimen placed in freezer: __ : __ ☐ AM ☐ PM Are specimens frozen at -80°C or colder? ☐ Yes ☐ No

Was there an equipment failure / deviation from protocol not described above? ☐ Yes ☐ No ☐ Unknown

Was specimen thawed as part of current action? ☐ Yes ☐ No

☒ *if collected*		Volume	Freezer #	9x9 Box #	Row	Column	Hemolyzed/Lipemic/Icteric? (circle all that apply)	SOP followed?
☐ PL01	4341420091	500 µL					H, L, I	Y / N / Unk
☐ PL02	4349623231	500 µL					H, L, I	Y / N / Unk
☐ PL03	4348357306	500 µL					H, L, I	Y / N / Unk
☐ PL04	4346373426	500 µL					H, L, I	Y / N / Unk
☐ PL05	4343460659	500 µL					H, L, I	Y / N / Unk
☐ PL06	4349470556	500 µL					H, L, I	Y / N / Unk
☐ PL07	4347443279	500 µL					H, L, I	Y / N / Unk
☐ PL08	4346760908	500 µL					H, L, I	Y / N / Unk
☐ PL09	4349539886	500 µL					H, L, I	Y / N / Unk
☐ PL10	4349291508	500 µL					H, L, I	Y / N / Unk
☐ PI11	4347530013						H, L, I	Y / N / Unk
☐ PL12	4343258325						H, L, I	Y / N / Unk
☐ PL13	4349790693						H, L, I	Y / N / Unk

Are specimens frozen at -80°C or colder? ☐ Yes ☐ No Was specimen thawed as part of current action? ☐ Yes ☐ No

Was there an equipment failure / deviation from protocol not described above? ☐ Yes ☐ No ☐ Unknown

☒ *if collected*		Volume	Freezer #	9x9 Box #	Row	Column	SOP followed?
☐ BC1	4347953681						Y / N / Unk

Comments: _____

NOD RED TOP TUBES (SERUM)

Version 4.0 Revised 09-25-2020

Kit #102	Date collected: __ - __ - ____ Time collected: __ : __ ☐ AM ☐ PM	Participant ID (affix label):

Staff ID: ____ Fasting? (at least 8 hours of no food or drink except water) ☐ Yes ☐ No ☐ Unknown
** If No or Unknown, reschedule the draw*

What is the date you last ate or drank anything except plain water? __ - __ - ____

What is the time you last ate or drank anything except plain water? __ : __ ☐ AM ☐ PM

Time at RT to clot 30-60? min: ☐ Yes ☐ No

Centrifuged at 1200g for 10 min at RT w/ brake on? ☐ Yes ☐ No

Was a second centrifugation performed 1200g for 5 minutes? ☐ Yes ☐ No

Time specimen placed in freezer: __ : __ ☐ AM ☐ PM Are specimens frozen at -80°C or colder? ☐ Yes ☐ No

Was there an equipment failure / deviation from protocol not described above? ☐ Yes ☐ No ☐ Unknown

Was specimen thawed as part of current action? ☐ Yes ☐ No

☒ *if collected*	Volume	Freezer #	9x9 Box #	Row	Column	Hemolyzed/Lipemic/Icteric? (circle all that apply)	SOP followed?
☐ SR01 4347893559	500 µL					H, L, I	Y / N / Unk
☐ SR02 4347636141	500 µL					H, L, I	Y / N / Unk
☐ SR03 4345009803	500 µL					H, L, I	Y / N / Unk
☐ SR04 4346673110	500 µL					H, L, I	Y / N / Unk
☐ SR05 4348906794	500 µL					H, L, I	Y / N / Unk
☐ SR06 4343421559	500 µL					H, L, I	Y / N / Unk
☐ SR07 4346821594	500 µL					H, L, I	Y / N / Unk
☐ SR08 4348505824	500 µL					H, L, I	Y / N / Unk
☐ SR09 4341344272	500 µL					H, L, I	Y / N / Unk
☐ SR10 4343010235	500 µL					H, L, I	Y / N / Unk
☐ SR11 4348821331						H, L, I	Y / N / Unk
☐ SR12 4344859647						H, L, I	Y / N / Unk
☐ SR13 4346616352						H, L, I	Y / N / Unk

Comments: _____