Appendix 2:

TRACK-TBI Precision Medicine Option 1 Phase II

Biospecimens Manual of Procedures (MOP)

06 April 2021

v1.5

- **You are receiving this MOP because your site has agreed to participate in this TRACK-TBI Precision Medicine study. The 5 participating sites in this study include:**

  03 UCSF

  07 Pittsburgh

  12 Pennsylvania

  14 MCW

  15 Utah

- **DO NOT BEGIN USING THIS PROTOCOL UNTIL YOUR INSTITUTION HAS RECEIVED THE NECESSARY IRB APPROVAL**
- **A waiver of consent may be used to collect and process blood draws during the first 24 hours of the study once a subject is enrolled (waiver language will vary by site).**
- **DO NOT SHIP SPECIMENS COLLECTED UNDER WAIVER UNLESS CONSENT IS SIGNED WITHIN WAIVER PERIOD.**
- **Buffy coat samples may be collected under waiver, but only ship buffy coat specimens for subjects who have consented to possible future genetic testing.**
- **Biospecimen Sample Collection Schedule**

Schedule of blood sample Collection (from time of traumatic brain injury)	***<6 hr***	***12 hr***	***24 hr***	***Day 2***	***Day 3***	***Day 5***	***Day 14***	***Day 42***	***Day 90***
Blood collection	✓	✓	✓	✓	✓	✓	✓	✓	✓

- **The National TBI Biospecimens Repository (NTBI-BR) will be serving as the biorepository for TRACK-TBI projects, including the Precision Medicine study.**

Precision Medicine Biospecimen Collection Summary (Baseline and Follow-up Visits)

Sample Type	Tube Type	Number of Blood Tubes and Cryovials Supplied in Kit	Processing/ Aliquoting	Cryovials to NTBI-BR
Whole Blood for Isolation of Plasma and Buffy Coat (for DNA extraction)	**6 ml Purple Top EDTA Tube**	1	**N/A**	**N/A**
	Plasma: 1.5 ml cryovials with purple caps	6 cryovials + 6 purple screw tops	0.5 ml plasma aliquots per 1.5 ml cryovial	6
	Buffy Coat: 1.5 ml cryovial with clear cap	1 cryovial + 1 clear cap	0.5 ml buffy coat aliquot per 1.5 ml cryovial	1* (baseline visit only)
Whole blood for isolation of serum	**6 ml Red Top SCA Tube**	1	**N/A**	**N/A**
	SERUM: 1.5 ml cryovials with red caps	6 cryovials + 6 red screw tops	0.5 ml serum aliquots per 1.5 ml cryovial	6
Blood TOTAL	12 ml	13 cryovials with color-coded caps 1 lavender top- 6 ml 1 red top- 6 ml		13 cryovials from baseline visit; 12 cryovials from follow-up visits

Tube Type	Sample Type	# of Cryovials/Caps Supplied in Kit	Processing/ Aliquoting	Specimens to NTBI-BR
15 mL polypropylene conical tube	Whole CSF	5 cryovials + 5 clear screw tops	0.5 ml CSF aliquots per 1.5 ml cryovial	5

Table of Contents

1. Abbreviations

EDTA	Ethylene Diamine Tetra-acetic Acid
IATA	International Air Transport Association
NTBI-BR	National TBI Biospecimens Repository
PPE	Personal Protective Equipment
RCF	Relative Centrifugal Force
RPM	Revolutions Per Minute
TBI	Traumatic Brain Injury

2. Purpose

The purpose of this Manual is to provide all study personnel (Principal Investigators, study coordinators, phlebotomists, nursing and laboratory staff) at the enrolling sites with instructions for the collection of whole blood, fractionation of blood from vacutainer tubes, aliquoting, labeling, freezer storage and shipping frozen samples to the National TBI Biospecimens Repository (NTBI-BR) located in Pittsburgh. The following samples will be collected:

- Serum
- Plasma
- Buffy Coat (for DNA extraction)

3. Biorepository Information

3.1 National TBI Biospecimens Repository Contacts

NTBI-BR Director: Ava Puccio, RN, PhD
Neurotrauma Clinical Trials Center
University of Pittsburgh
Department of Neurological Surgery
200 Lothrop Street, Suite B-400
Pittsburgh, PA 15213
Office: 412-648-9246
Mobile Phone: 412-298-7033
Email: puccioam@upmc.edu

NTBI-BR Manager: Miri Rabinowitz, PhD
Office: 412-648-2031
Mobile Phone: 412-491-6199
Email: rabinowitzmk@upmc.edu

NTBI-BR Supervisor: Mike Mancinelli
Office: 412-648-2389
Mobile Phone: 484-885-8211
Email: mancinellimd@upmc.edu

3.2 Hours of Operation

The NTBI-BR operates from 9 AM to 4 PM EST, Monday through Friday.

Frozen samples must be shipped Monday – Wednesday only.

Frequency of shipments will depend on enrollment rate at each study site. Shipping volume may vary by site enrollment. Shipments should contain no less than four (4) cryoboxes, and no more than sixteen (16) cryoboxes. For common scenarios with packing and shipment, refer to Section 8 of this MOP.

Frozen samples should be shipped at least quarterly, or as determined by the Site PI in collaboration with the Biorepository Manager or Supervisor. Please ensure adequate storage at -80°C prior to shipment. Contact the NTBI-BR Manager prior to arranging any shipments.

Check weather reports to make sure impending weather events (blizzards, hurricanes, etc.) will not impact the shipping or delivery of the samples.

3.3 Holiday Schedules

Please be sure to verify with your courier's schedule prior to shipping close to a holiday.

Holiday Observations* – United States

Date	Holiday
New Year's Day	January 1
Martin Luther King Day	3rd Monday in January
President's Day	3rd Monday in February
Memorial Day	4th Monday in May
Independence Day	July 4
Labor Day	First Monday in September
Columbus Day	2nd Monday in October
Veteran's Day	2nd Monday in November
Thanksgiving	4th Thursday of November
Day after Thanksgiving	4th Friday of November
Christmas Day	December 25

***Additionally, each year the University of Pittsburgh is officially closed from December 24 through January 2. Do not schedule any shipments during this time**.

4. Supplies and Equipment

4.1 Supplies and Equipment Provided by the Enrolling Sites:

The following are necessary for the collection of whole blood and are to be **supplied by the local institution**:

- Personal Protective Equipment: lab coat, nitrile/latex gloves, safety glasses
- Tourniquet
- Alcohol prep pad
- Gauze pad
- Bandage
- Butterfly needle
- Microcentrifuge tube rack
- Cryogenic gloves
- Sharps bin and lid
- Biohazard disposal

Each site must have access to the following equipment:

- Centrifuge capable of ≥ 1500 rcf (1500 x g)
- -80°C Freezer

4.2 Specimen Collection Kit Contents

The NTBI-BR will provide research specimen collection kits. The kits will include the Vacutainer tubes needed for whole blood collection, and cryovials and color-coded caps for plasma/serum/buffy coat aliquots. Labels pre-printed with study information specific to the type of sample being drawn will also be provided, as will 81-slot cryoboxes for freezer storage.

Collection kits contain the following supplies to collect samples from a given subject-timepoint. **Do not replace or supplement any of the kit components with your own supplies unless you have received approval from Biorepository Laboratory Manager to do so.**

Kit Supplies

Blood Draw Kit Components

Quantity	Baseline Kit Components
13	Polypropylene cryovial tubes
6	Purple caps (for plasma)
6	Red caps (for serum)
1	Clear cap (for buffy coat/DNA) *
1	6 ml EDTA (purple top) blood collection tube
1	6 ml Serum determination tube (red top)
3	Disposable graduated transfer pipettes

Quantity	Baseline Kit Components
5	1.5 mL Polypropylene cryovial tubes
5	Clear caps
1	15 mL conical polypropylene tube
1	Disposable graduated transfer pipettes

* The baseline visit includes aliquoting the buffy coat in cryovials using the clear caps; the buffy coat is NOT collected in visits after the baseline visit unless the sample was compromised, and a replacement can be obtained from the next obtained plasma sample.

4.3 Initial Supply of Study Materials to Study Sites

Each site will initially be supplied with 30 blood draw kits, 6 cryoboxes, and 15 sheets of pre-printed labels.

4.4 Resupply to Study Sites

Each site will be responsible for maintaining and requesting adequate inventory after the initial supply has been sent. Regularly check your supplies (including Vacutainer expiration dates*) and order additional kits and sheets of pre-printed labels before you run out so you are prepared for both scheduled and unanticipated visits.

Email the Biorepository Manager to request a resupply of kits. Allow **14 days** for kit orders to be processed and delivered.

*Take note that Vacutainer expiration dates on the tubes are in the format: **YYYY-MM-DD**

5. Blood Collection and Processing Procedures

*****Important Note*****

In order to ensure the highest quality samples are collected, processed and stored, it is essential to follow the procedures detailed in the following pages. Please read the following instructions before collecting any specimens. Have all study supplies, forms and equipment out and prepared prior to drawing blood. Draw blood in the order of the most essential* for this research study, i.e. first collect the purple top tube for plasma, then the red top tube for serum.

***This blood draw order differs from standard clinical practice.**

5.1 Sample Collection and Quality

Care must be taken during collection of study samples to prevent hemolysis and/or contamination.

The following techniques shall be used to prevent possible backflow and hemolysis:

- Place donor's arm in a downward position.
- Avoid drawing blood from a hematoma
- If drawing from an existing IV using a syringe, avoid drawing the plunger back too forcefully.
- Avoid using very small needles.
- Make sure the venipuncture site is dry.
- Avoid a probing, traumatic venipuncture.
- Hold tube in a vertical position, below the donor's arm during blood collection.
- Avoid prolonged tourniquet application or fist clenching.
- Release tourniquet when final tube is nearly filled.
- Make sure tube additives do not touch stopper or the end of the needle during venipuncture.
- **Ensure that the blood has stopped flowing into the tube before removing the tube from the holder.**
- Vacutainer tubes are designed to draw the correct volume of blood into the tube to mix with any additive.

When obtaining blood through venipuncture, **no more than two attempts** may be performed.

5.2 Labeling Samples

- Each kit is supplied with preprinted labels for the cryovials (13 for the baseline blood draw and 12 for all subsequent blood draws. Buffy Coat is collected only once for each subject).

- Each cryovial will be labeled with a unique alphanumeric string. For example: **PM-07-3001-D-06P** Is the 6th plasma aliquot (06P), from the Day 2 blood draw (D) on subject 3001 from the Pittsburgh site (07).
    - The naming convention is as follows:

Study	Site	Subject ID	Blood Draw (from time of injury)	Specimen Type and Vial
PM	03 (UCSF) 07 (Pitt) 12 (Penn) 14 (MCW) 15 (Utah)	3001 to 3076	A thru I **A:** <6 hr (baseline) **B:** 12 hr **C:** 24 hr **D:** Day 2 **E:** Day 3 **F:** Day 5 **G:** Day 14 **H:** Day 42 **I:** Day 90	Plasma: 01P to 06P Serum: 07S to 12S Buffy Coat: 13D* CSF: 01C to 05C

*D for DNA. Since DNA will only be collected at the baseline blood draw, only samples with an "A" designation will have labels 13D.

Note: There are 6 aliquot cryovials for plasma, 6 aliquot cryovials for serum, and 1 aliquot cryovial for buffy coat. The provided cryovial caps are color-coded. Use the **Purple caps** for plasma; **Red caps** for serum; and **Clear caps** for buffy coat.

In order to ensure the pre-printed label adheres properly to the cryovial, follow these instructions:

- Place labels on **ALL** aliquot cryovials **BEFORE** sample processing/freezing. This should help to ensure the label properly adheres to the cryovials before exposure to moisture or different temperatures.

- Place each label **vertically** on the cryovials.

- Take a moment to ensure the label is **completely adhered** to each cryovial. It may help to roll the cryovial between your fingers after applying the label.

- Be sure to place only **plasma** in cryovials labeled with the suffix **01P to 06P**
  - Depending on the amount of blood drawn you may fill less than 6 cryovials:
    - Use the lowest numbered labels, i.e. 01P, 02P and 03P rather than 03P, 04P and 05P if only 3 cryovials are used.
  - Do not fill more than 6 cryovials; all specimens must have a pre-printed label.
  - Cap with the **PURPLE** caps.

- Be sure to place only **buffy coat** in cryovial labeled with the suffix **13D**
  - Collect the entire white buffy coat layer and as little pellet as possible.
  - Cap with the **CLEAR** caps.

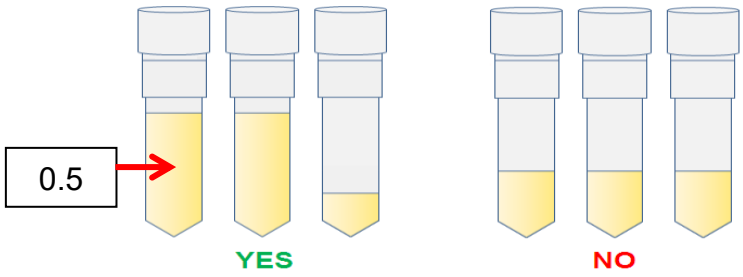
- Be sure to place only **serum** in cryovials labeled with the suffix **07S to 12S**
  - As before, you may fill less than 6 cryovials with serum - use the lowest numbered labels first.
  - Do not fill more than 6 cryovials; all specimens must have a pre-printed label.
  - Cap with the **RED** caps.

- In summary, only place **plasma** in "**P**" labeled cryovials, **buffy coat** in "**D**" labeled cryovials and **serum** in "**S**" labeled cryovials

5.3 Filling Aliquot Tubes (Plasma, Serum, and CSF)

Each kit is provided with 3 disposable transfer pipettes – one each for plasma, buffy coat, and serum - to be used to transfer the fractionated sample to its appropriately labeled cryovial. Cryovials should be filled with 0.5 milliliter of the respective biologic material. Over-filled cryovials may burst once placed in the freezer, resulting in a loss of that sample. You do not have to fill all cryovials provided; you should attempt to fill as many cryovials as possible with 0.5 ml of sample.

Example: if 2.7 ml of sample is obtained, you should fill 5 cryovials each with 0.5 ml, and the 6th cryovial with the remaining 0.2 ml of sample.



*****Important Note*****

Plasma, serum and buffy coat specimens must be placed in the -80° C freezer within 2 hours of whole blood collection.

5.4 Plasma and Buffy Coat Collections

Whole Blood Collection for Isolation of Plasma and Buffy Coat: 6 ml EDTA Purple Top Vacutainer Tube (for processing of plasma and buffy coat aliquots).

1. **Store EDTA Purple Top Tubes at room temperature 64°F - 77°F (18°C to 25°C) before use.**

2. Using a blood collection set and a holder, collect blood into the **6 ml EDTA-Purple tube** using your institution's recommended procedure for collecting whole blood by venipuncture or an indwelling catheter.

   The following techniques shall be used to prevent possible backflow:
   a. Place donor's arm in a downward position.
   b. Hold the tube in a vertical position, below the donor's arm during blood collection.
   c. Release the tourniquet when the final tube is nearly filled.
   d. Make sure tube additives do not touch the stopper or the end of the needle during venipuncture.

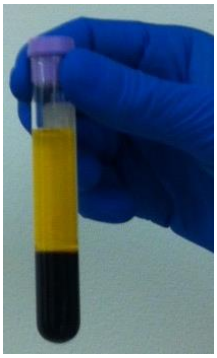
3. Allow at least 10 seconds for a complete blood draw to take place in each tube. **Ensure that the blood has stopped flowing into the tube before removing the tube from the holder.** The tube with its vacuum is designed to draw 6 ml of blood into the tube.

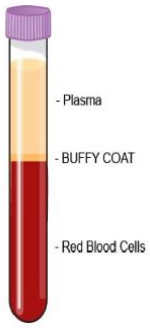
4. **Immediately after blood collection, gently invert/mix (180 degree turns) the EDTA tube 8 – 10 times.**

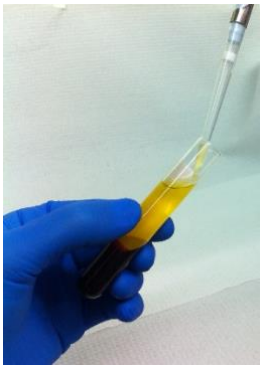
5. Within 60 minutes of whole blood collection centrifuge balanced tubes for 20 minutes at 1500 RCF (x g).
   - **It is critical that the tubes be centrifuged at the appropriate speed to ensure proper plasma separation (see worksheet in Appendix A to calculate RPM in your particular rotor).**
   - Refrigeration prior to or during centrifugation is not recommended.

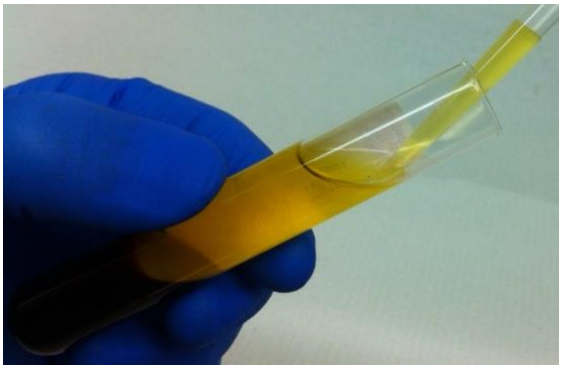
6. Place:
   - Pre-printed "**PLASMA**" labels (01P – 06P) on the 1.5 ml cryovial tubes (6)
   - Pre-printed "**BUFFY COAT**" labels (13D) on 1.5 ml cryovial tubes (1).

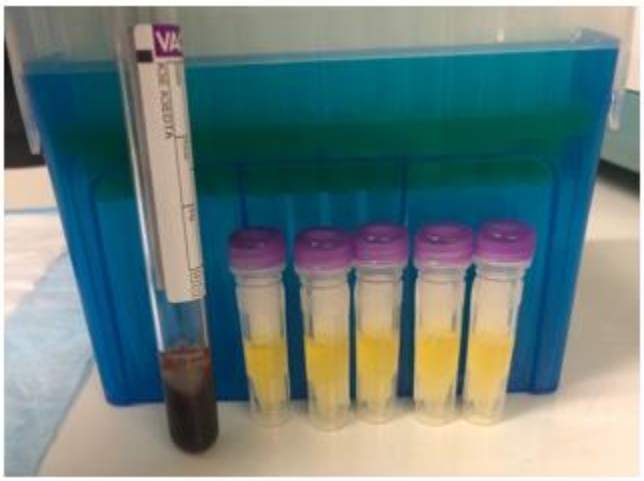
7. Remove the plasma, being careful not to agitate the buffy coat layer or the packed red blood cells at the bottom of the vacutainer tube.
   a. Tilt the tube and place the pipette tip along the lower side of the tube wall without touching the buffy coat layer or the pellet below so that plasma is not contaminated by these materials (see below).
   b. Using a disposable graduated transfer pipette, transfer plasma into the pre-labeled cryovials.
      i. The EDTA vacutainer tube should yield, on average, 4 ml of blood plasma. Aliquot 0.5 ml per cryovial (total vials = 6 with 0.5 ml each).
   c. Be sure to place only **plasma** in cryovials labeled with the suffix **01P to 06P.**
   d. Place a PURPLE cap on each cryovial filled with plasma.









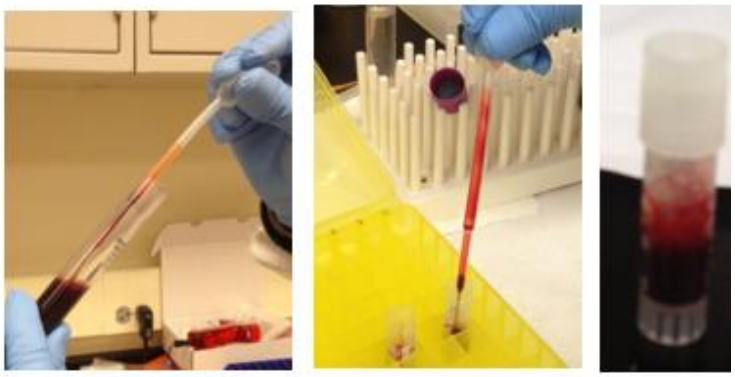


8. Place the labeled cryovials in the 81 grid cryovial box and freeze samples immediately following aliquoting by transferring to **-80°C Freezer**. Store all samples at **-80°C until shipped** to the Biorepository on dry ice.

*****Important Note*****

BUFFY COAT MUST NOT BE COLLECTED IF THE SUBJECT HAS NOT CONSENTED TO POSSIBLE GENETIC TESTING

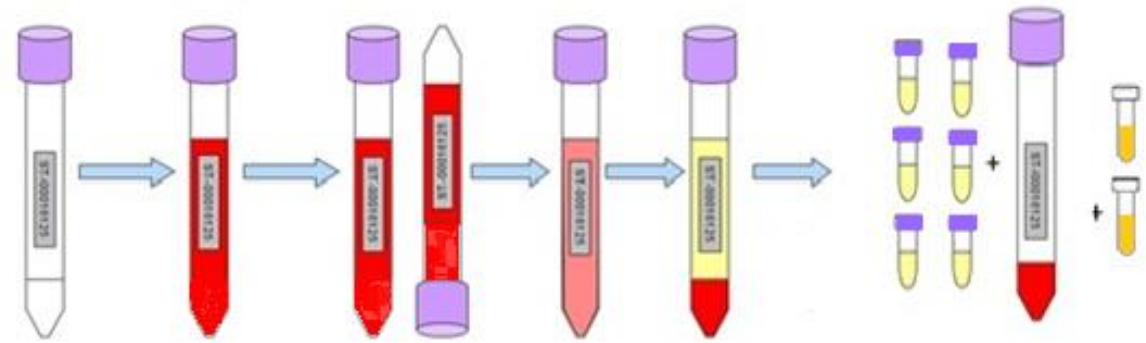
9. <u>In the BASELINE visit ONLY</u>, **after** plasma has been removed from the EDTA, purple top tube, aliquot the buffy coat layer into labeled cryovials with a disposable graduated pipette. Collect all of the white buffy coat layer, with as little incidental collection of pelleted red blood cells as possible.
    a. Each aliquot should be 0.5 ml of buffy coat per cryovial tube in one cryovial tube (as supplied in each specimen kit).
    b. Be sure to place only **buffy coat** in cryovials labeled with the suffix **13D**.
    c. Place a CLEAR cap on each cryovial filled with buffy coat.



10. Place labeled buffy coat cryovials in 81 grid cryovial box and place the box in **-80°C Freezer.**

11. Dispose of the purple EDTA tube (vacutainer) with cell pellet into a biohazard container.

12. Fill in TRACK Precision Medicine Blood Sample Collection Form (Appendix C) during processing with:
    a. Sample Collection Date and Time
    b. Date and Time Plasma Spin Begins
    c. Number of Plasma Aliquots Collected
    d. Number of Buffy Coat Aliquots Collected
    e. Date and Time of Plasma and Buffy Coat in Freezer



1: Store tubes at *room* temperature	2: Collect blood into the purple top tube, allowing blood to flow 10 seconds and ensuring blood has stopped flowing.	3: Immediately after blood draw, invert tube gently 8-10 times to mix sample.	4: Within 60 minutes of whole blood collection Centrifuge sample for 20 min at 1500 x g.	5: Label cryovial tubes with preprinted "plasma" and "buffy coat" labels. Using graduated pipette, aliquot 0.5 ml plasma into each "plasma" cryovial and 0.5 ml buffy coat into "buffy coat" cryovials. Cap plasma cryovials with purple caps; and buffy coat cryovials with clear caps. Store at -80°C until shipment.

5.5 Serum Collection

Whole Blood Collection for Isolation of Serum: 6 ml Red Top Tube (for processing of serum aliquots).

1. **Store 6 ml red top tubes at room temperature 64°F - 77°F (18°C to 25°C) before use.**

2. Using a blood collection set and a holder, collect blood into a 6 **ml red top tube** using your institution's recommended procedure for collecting whole blood by venipuncture or an indwelling catheter.

   The following techniques shall be used to prevent possible backflow:
   a. Place donor's arm in a downward position.
   b. Hold tube in a vertical position, below the donor's arm during blood collection.
   c. Release tourniquet when final tube is nearly filled.
   d. Make sure tube additives do not touch stopper or the end of the needle during venipuncture.

3. Allow at least 10 seconds for a complete blood draw to take place in each tube. **Ensure that the blood has stopped flowing into each tube before removing the tube from the holder.** The tube with its vacuum is designed to draw 6 ml of blood into the tube.

4. **Immediately after blood collection, gently invert/mix (180 degree turns) each tube 5 times.**

5. **Allow blood to clot at room temperature by placing it upright in a vertical position in a tube rack for 30 minutes.**

6. After 30 minutes of clotting and within 60 minutes of whole blood collection, centrifuge the balanced vacutainer tube for 15 minutes at 1500 rcf (x g). **It is critical that the tube be centrifuged at the appropriate speed to ensure proper serum separation. (See worksheet in Appendix A to calculate RPM in your particular rotor)**

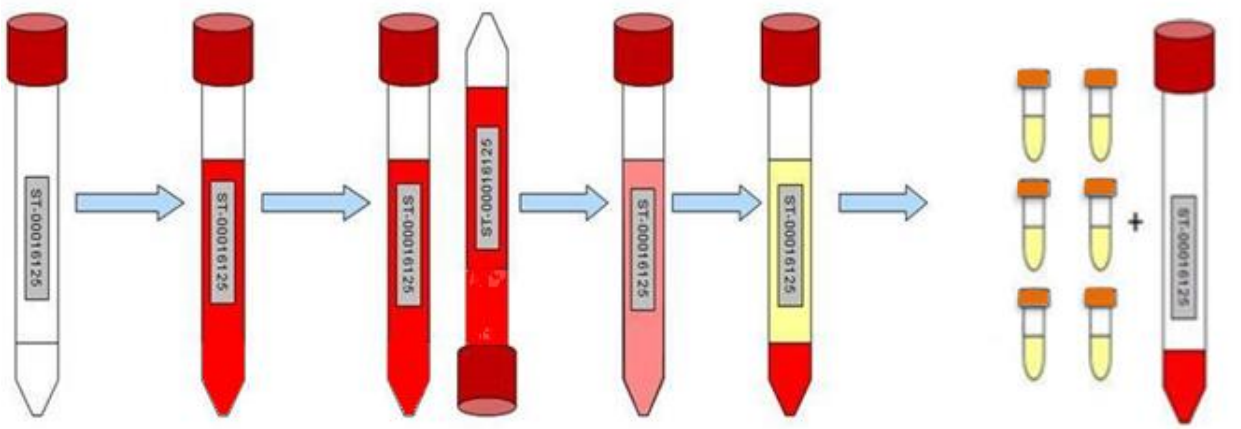
7. Place pre-printed "**SERUM**" (07S-12S) labels on the 1.5 ml cryovial tubes.

8. Remove the serum, being careful not to agitate the clot at the bottom of the vacutainer tube.
   a. Tilt the tube and place the pipette tip along the lower side of the tube wall without touching the pellet.
   b. Using a disposable graduated transfer pipette, aliquot serum into the pre-labeled cryovials.
      i. The red top tube should yield, on average, 4 ml of blood serum. Aliquot 0.5 ml per cryovial (total vials = 6 with 0.5 ml each).
   c. Be sure to place only **serum** in cryovials labeled with the suffix **07S to 12S** (as before, you may fill less than 6 cryovials with serum- use the lowest numbered labels first).
   d. Place an RED cap on each cryovial filled with serum.

9. Place cryovials in 81 grid cryovial box and freeze samples immediately in **-80°C Freezer**.

10. Dispose of the red top serum tube (vacutainer) with the clotted blood in the bottom of the tube into a biohazard container.

11. Fill in the TRACK Precision Medicine Blood Sample Collection form (Appendix C) during processing with.
    a. Date and Time Serum Spin Begins
    b. Number of Serum Aliquots Collected
    c. Date and Time of Serum in Freezer



1: Store tubes at room temp	**2: Collect blood into red top tube, allowing blood to flow for 10 sec and ensuring blood has stopped flowing.**	**3: Immediately after blood draw, invert tube gently 8-10 times to mix sample.**	**4: Allow blood to clot for 30 - 60 mins. Then centrifuge tubes at 1500 x g for 15 minutes.**	**5: Label cryovials with PM "serum" labels. Use graduated pipette to aliquot 0.5 ml of serum into each cryovial. Cap serum cryovials with red caps. Store at -80°C until shipment.**

6. CSF Collection and Processing Procedures

6.1 General Guidelines

The decision to place an External Ventricular Drainage (EVD) is a local clinical decision and is not affected by a patient's participation in TRACK PM. Similarly, indications and procedures for CSF drainage (continuous vs. intermittent drainage) is a local clinical decision and not prescribed in the TRACK PM protocol.

CSF collected for research purposes is fluid that would otherwise be discarded.

- Procedures for inserting the EVD and for collecting fluid from the system are also governed by local Neuro ICU protocols.

- Published guidelines from the American Association of Neuroscience Nurses are available (Am Assc Neurosci Nurses (2011) Care for the patient undergoing intracranial pressure monitoring/external ventricular drainage or lumbar drainage. Glenview (IL) 37 p. [164 Refs]). Link to PDF

- A video demonstrating CSF collection is available here: https://vimeo.com/user120054989/CSFfromEVD
  DISCLOSURE: This tutorial is to assist trained personnel in CSF collection from an EVD.
  - Each site may differ in procedure. Check your local Neuro ICU protocol.
  - Also, this video shows betadine for cleaning the port in a sterile fashion; at some institutions, this may have been changed to chlorhexidine.

- The collection of CSF from the EVD system is performed by trained Neuro ICU nurses or physicians; however, trained research personnel may be granted permission at your institution (check local hospital protocols).

- At most centers, collection of 0.5 – 1 mL of CSF is routinely done daily, to monitor for infection. CSF for research purposes will in most cases be collected at the same time as the daily routine accession of the system.
  - If insufficient CSF is produced, priority will be given for fluid required for patient care.

- An effort should be made to collect the first CSF available at the time of insertion of the EVD. Up to 5 mL should be collected.

6.2 CSF Collection

Steps for Whole CSF Collection and Processing

1. CSF is collected daily from the buretrol. If a bag change occurs in the morning, allow at least 2 hours before collection from buretrol.

2. **Fresh fluid** is collected as follows:
   a. Fluid is collected **using sterile technique** directly from the buretrol.
   b. Up to 5 mL is collected (although in most cases it will be less) and transferred to single polypropylene conical centrifuge tube.
   c. Fluid is allowed to drain into the buretrol by gravity (**never aspirated**).

3. Cell contamination of ventricular CSF is a significant confound. To minimize, CSF is centrifuged.

4. Transport fluid within 30 minutes of collection to the laboratory and centrifuge at 1500 RCF (x g) for 15 minutes. This can be done at the same time as blood processing.

5. Place pre-printed **"CSF"** (01C-05C) labels on the 1.5 ml cryovial tubes.

6. Aliquot supernatant into 1.5 ml polypropylene cryovials using a micropipette with disposable tip.
   a. Up to 5 aliquots are prepared, each containing to 0.5 mL. If more fluid is collected, increase volume of aliquots up to a maximum of 1.0 mL.
   b. Examples:
      i. If 5 mL are collected, distribute into 5x 1 mL aliquots
      ii. If 2.0 mL are collected, distribute into 4 x 0.5 mL aliquots.
      iii. If 1.2 mL are collected, distribute into 2 x 0.6 mL mL aliquots.
   c. Place a CLEAR cap on each cryovial filled with CSF.

7. Place cryovials in 81-grid cryovial box and freeze samples immediately in -80^{o}C freezer.

8. The following are noted on the applicable CRF:
   a. Appearance of fluid (clear, cloudy, bloody)
   b. Date and Time of collection
   c. Time of centrifugation and freezing

9. This CSF collection protocol can run for a maximum of five (5) days:
   a. Collect up to three (3) CSF samples on Day 1 (A, B, and C visits).
   b. Collect one (1) CSF sample on Day 2 (D), Day 3 (E) and Day 5 (F).
   c. If possible, collect the TRACK PM blood sample at the same time as collecting the CSF sample. This will provide a paired blood sample for some of the CSF samples.

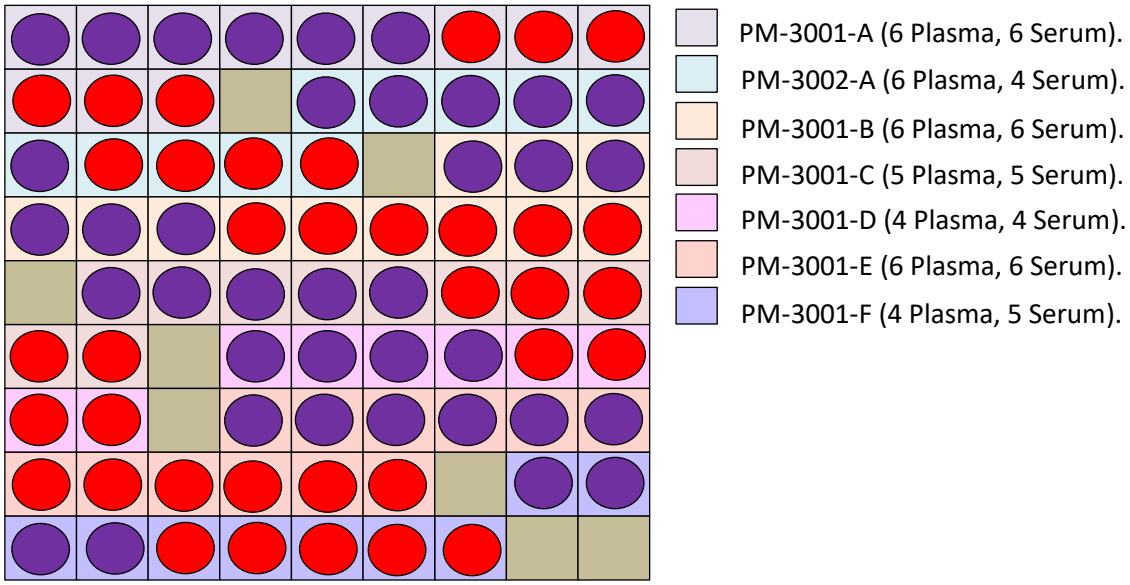
Samples will be shipped to the NTBI-BR at the University of Pittsburgh using same procedures as done for blood samples.

7. Storage of Specimens

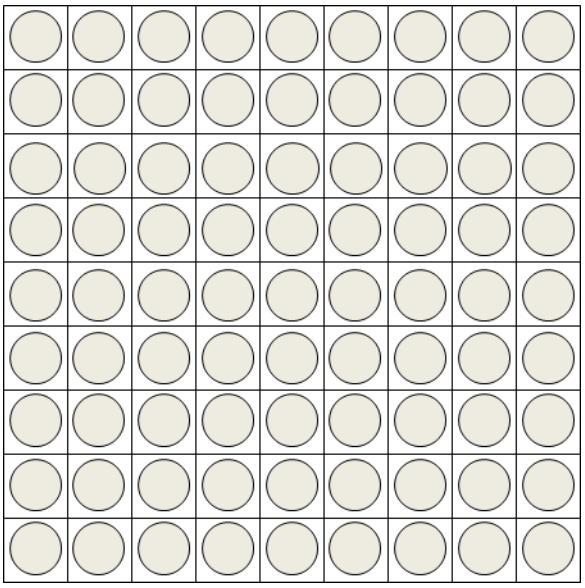
7.1 Storage of Serum, Plasma, Buffy Coat, and CSF Cryovials in Freezer

The supplied cryoboxes should be filled in chronological order of collection to minimize misplacement of samples within the box due to reshuffling of cryovials to keep subject samples next to one another.

- Plasma and serum from all visits may be placed in the box
- All aliquots from a single subject/timepoint are kept together
- Leave an empty space in the box between subject/timepoint

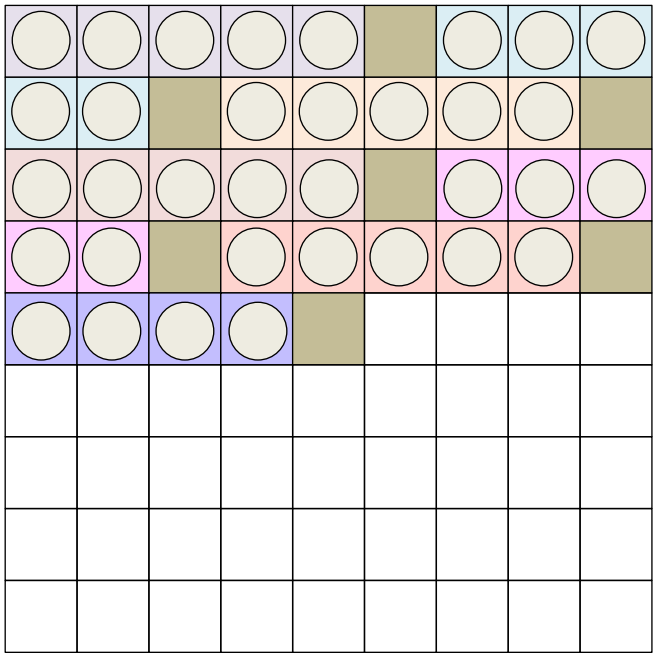


Buffy Coat should be placed in a separate cryobox. It is not necessary to leave spaces between subject/timepoint as done in the plasma/serum box above.



CSF should be placed in a separate cryobox from plasma/serum and buffy coat. CSF should be stored within the cryobox chronologically (as in the plasma/serum cryobox above).

- Plasma and serum from all visits may be placed in the box
- All aliquots from a single subject/timepoint are kept together
- Leave an empty space in the box between subject/timepoint
- Multiple subjects may be placed in the same box. No extra spaces need to be placed between different subjects (i.e., only a single space between subject/timepoint regardless of subject).



PM-07-3001-A (5 CSF)
PM-07-3001-B (5 CSF)
PM-07-3001-C (5 CSF)
PM-07-3001-D (5 CSF)
PM-07-3002-A (5 CSF)
PM-07-3002-B (5 CSF)
PM-07-3001-E (4 CSF)

8. Packaging and Shipping Instructions

8.1 Biospecimens to be sent to the NTBI-BR Laboratory:

The following samples will be collected on each subject:

- Serum
- Plasma
- Buffy Coat (for DNA extraction)
- CSF

Consent forms must specify that any biological samples and de-identified clinical data may be shared with academics or industry through the NTBI-BR. A copy of the consent form for each subject should be kept on file by the investigator.

Do not ship specimens from any subject enrolled under waiver unless consent has been obtained from subject or LAR within waiver period (allowed waiver period may vary by site). Additionally, no buffy coat specimens should be sent to NTBI-BR unless subject or LAR agrees to storage of genetic samples. Specimens that will not be shipped should be destroyed at the enrolling site after consultation with the coordinating site. Internal documentation should be kept recording such sample destructions (see Section 11 Sample Destruction Procedures and Appendix F Sample Destruction Form for more information).

ALL study personnel responsible for shipping should be certified in biospecimen shipping and can obtain training and certification through the CITI training site (Course titled “Shipping and Transport of Regulated Biological Materials” at https://www.citiprogram.org/). Check your local institution’s Environmental Health & Safety if additional training in the Shipment of Hazardous Material is needed.

8.2 Biorepository Shipping Instructions

*****Important Note*****

For frozen shipments, include no more than FIVE Pathopouch A3 envelopes per GDI-80 shipping container in order to have room for enough dry ice to keep samples frozen up to 36 hours.

The labeled, processed, aliquoted and frozen cryovials of plasma, buffy coat, serum will be shipped to the Biorepository as outlined below.

Baseline and Follow-up Shipments to the Biorepository include the following:

- **Frozen 0.5 ml aliquots of plasma (FROZEN SHIPMENT)**
- **Frozen 0.5 ml aliquots of serum (FROZEN SHIPMENT)**
- **Frozen 0.5 ml aliquots of buffy coat (for DNA, BASELINE visit only, FROZEN SHIPMENT)**
- **Frozen 0.5 ml aliquots of CSF (FROZEN SHIPMENT)**

Specimens being shipped to the Biorepository should be considered as Clinical/Diagnostic specimens and as such must be tripled packaged and compliant with IATA Packing Instructions 650. *See the Latest Edition of the IATA Regulations for complete documentation.*

8.3 World Courier Instructions

World Courier will arrange delivery of packaging and dry ice to your site. **Packaging and shipping labels should be ordered three days in advance of shipment.** These will be delivered directly to your site prior to the shipping day. Dry ice will be delivered at the time of pick up. Please note that World Courier drivers cannot assist with packing your shipments.

To arrange for the packaging and pick-up of samples, please contact:

World Courier Tel: (800) 221-6600

Provide the World Courier Representative with the following information:

1. Study Account Number: # XXXXX
2. Time that pick-up is required **(Ship only on Monday-Wednesday!)**
3. Specify the type of samples being sent:
   Blood, serum, plasma. Biological substance category B, Frozen at -80°C.
   on dry ice, to Pittsburgh.
4. State that you will need ALL shipping materials delivered to your site.
5. Specify that dry ice is required at time of shipping

All shipments require the following items:

Shipping materials	Quantity	Description
House WayBill	**1**	Comes pre-printed with Shipper and Consignee information
Box labels		World Courier provides these (both UN 3373 and Dry Ice labels.)
Dry ice (10-kilo bag)	**1-2 (see below)**	World Courier will bring when picking up your shipment. Specify that you need pellets rather than blocks of dry ice.
Intelsius DGP Pathopouch 95 (A3 size)	**Varies (see below)**	The Pathopouch A3 is a large Secondary envelope. One Pathopouch A3 can maximally hold 4 81-grid cryoboxes, stacked 2 high and 2 deep.
Absorbent material vial dividers	**Varies (see below)**	**World Courier provides these. Be sure to ask for them.** Include 1 absorbent material pad in the Secondary envelope with the cryoboxes.

Use the following guide to determine which size of shipping container is necessary:

Shipping Box	Cryoboxes	Description
GDI-80	**Up to 16**	A GDI-80 insulated box can hold 6 Pathopouch A3 packages. This should be large enough for 16 cryoboxes (4 boxes in each of 4 Pathopouches) + dry ice (2 bags).
GDI-45	**Up to 12**	A GDI-45 insulated box can hold 3 Pathopouch A3 packages. This should be large enough for 12 cryoboxes (4 boxes in each of 3 Pathopouches) + dry ice (order 2 bags, may need more than 1 to fill box).
GDI-30	**Up to 4**	A GDI-30 insulated box can hold 2 Pathopouch A3 packages. This should be large enough for 12 cryoboxes (4 boxes in 1 Pathopouch) + dry ice (1 bag).
GDI-15	**1**	A GDI-15 insulated box can hold 1 Pathopouch A3 package. This should be large enough for only a single cryobox + dry ice (1 bag, about half of the bag should fit).

World Courier model GDI-80 insulated shipper

The GDI-80 insulated shipping box is large enough for 5 filled A3 Pathopouches

5 A3 Pathopouches should fit 20 cryoboxes, along with adequate dry ice.

Outer Dimensions: 23 x 21 x 25 inches (57.0 x 52.0 x 63.5 cm)
Inner Dimensions: 17.4 x 15.2 x 19 inches (44.4 x 38.8 x 48.5 cm)

Intelsius DGP Pathopouch 95, Size A3

Each A3 Pathopouch can fit up to four 5 x 5 x 2 inch cryoboxes, stacked 2 x 2.

Each A3 Pathopouch can fit up to four 6-place absorbent vial dividers, stacked 2 x 2.

Outer Dimensions: 16.5 x 11.5 inches (41.9 x 29.2 cm)
Inner Dimensions: 14.1 x 10.3 inches (35.9 x 26.1 cm)

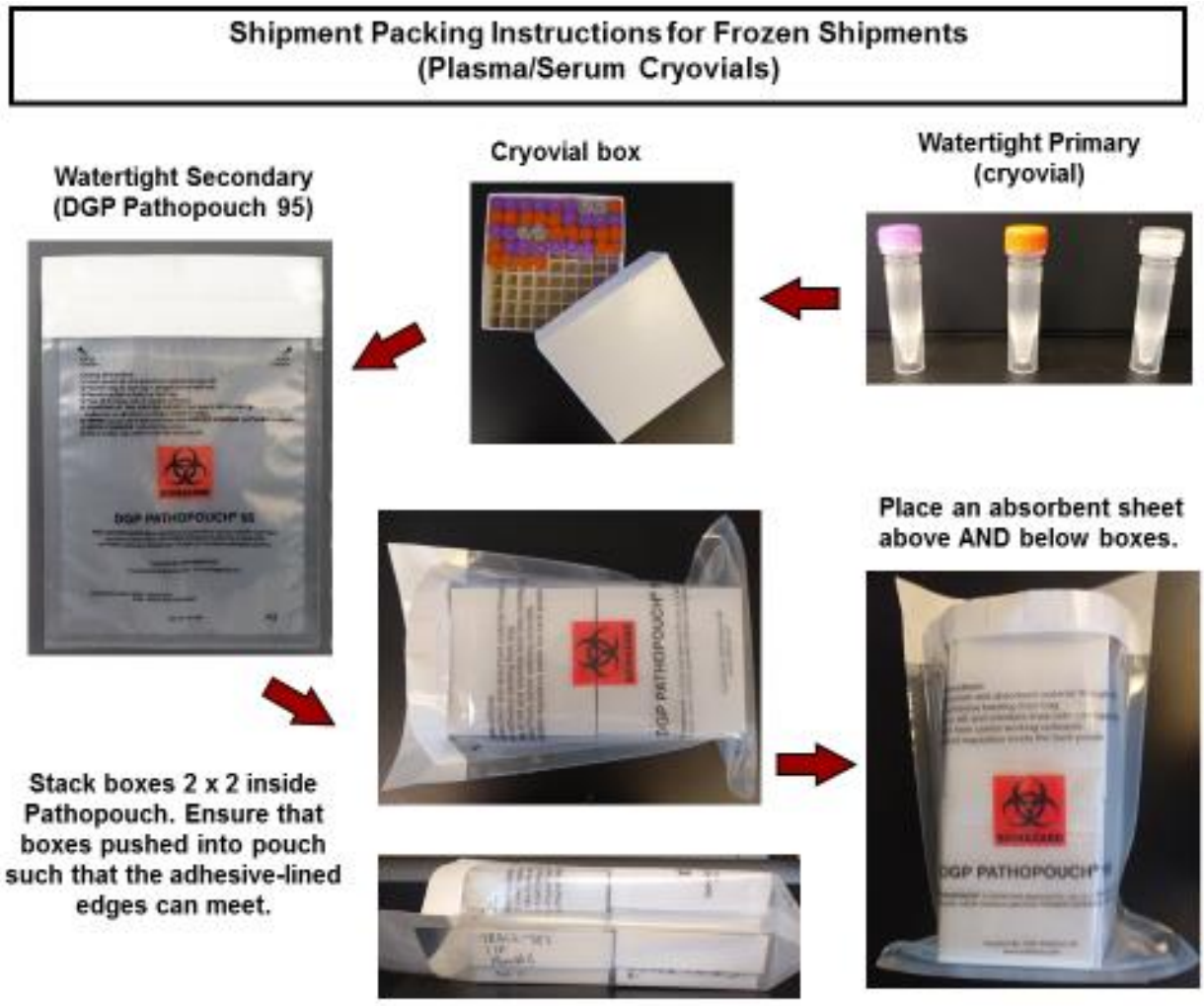
The International Air Transport Association packing instructions for shipping Biological materials, IATA 650, can be found at https://www.iata.org/whatwedo/cargo/dgr/Documents/DGR52_PI650_EN.pdf

IMPORTANT!
FROZEN SAMPLES <u>MUST</u> BE SHIPPED ON MONDAY - WEDNESDAY ONLY!

Triple packaging consists of a primary receptacle, secondary packaging and a rigid outer packaging. The primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packaging must be secured in outer packaging with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

IMPORTANT!

IT IS ESSENTIAL TO KEEP YOUR SAMPLES FROZEN AT ALL TIMES DURING THE PACKING PROCESS



***** Sealing Pathopouches *****

- It is imperative that the Pathopouches are fully sealed. Do not remove the protective tape covering the adhesive until the pouch has been filled.
- Once pouch is filled, remove tape and fold at opening. Line up black lines on both sides of the opening.
- When packing cryoboxes, ensure that corners are adequately sealed.

Shipment Packing Instructions for filling the shipping container with sealed secondary envelopes and dry-ice

Place a layer of dry ice on the bottom of the Styrofoam-lined shipping carton.

Place the sealed Pathopouches **UPRIGHT** in the Styrofoam-lined shipping carton. You should be able to fit 6 within a GDI-80 box (not pictured).

FILL the remaining space in the shipping carton with dry ice, ensuring dry ice surrounds the envelopes and reaches the TOP of the carton

The following video is a guide to filling your GDI-80 shipping box:
https://vimeo.com/211217233
You may ignore the portions pertaining to the cardboard stabilizer (we will be shipping too large a volume to make use of these) and temperature monitor.

IMPORTANT!

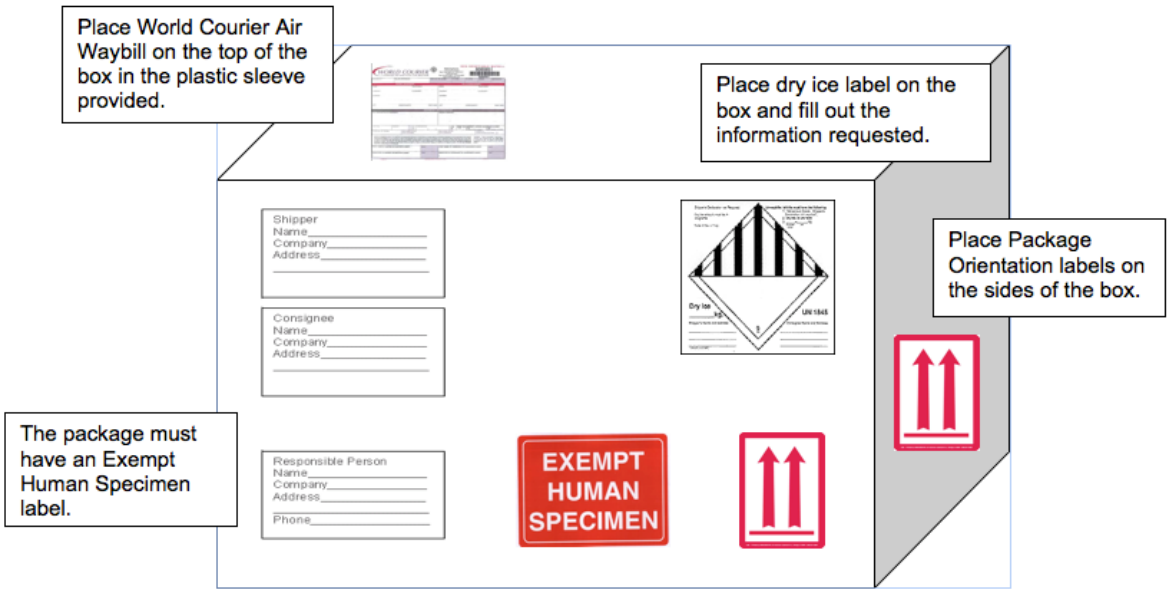
AN ITEMIZED LIST OF CONTENTS MUST BE ENCLOSED BETWEEN THE SECONDARY PACKAGING AND THE OUTER PACKAGING.

*** Packing and Labeling Guidelines ***

IATA 650 guidelines: https://www.iata.org/whatwedo/cargo/dgr/Documents/DGR52_PI650_EN.pdf

- The primary receptacle (frozen cryovials) must be leakproof and must not contain more than 1L total.
- The secondary packaging (DGP Pathopouch 95) must be leakproof and if multiple blood tubes are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent direct contact with adjacent blood tubes.
- Absorbent material must be placed between the primary receptacle (cryovial box containing the frozen cryovials) and the secondary packaging. The absorbent material should be of sufficient quantity in order to absorb the entire contents of the specimens being shipped. Examples of absorbent material are paper towels, absorbent pads, cotton balls or cellulose wadding.
- A shipping manifest of specimens being shipped must be included between the secondary and outer packaging (i.e. between the Styrofoam container and cardboard box).
- The outer shipping container must display the following labels:
  - ✓ Sender's name and address
  - ✓ Recipient's name and address
  - ✓ Responsible Person
  - ✓ The words "Biological Substance, Category B"
  - ✓ UN3373
  - ✓ Class 9 label including UN 1845, and net weight of dry ice contained

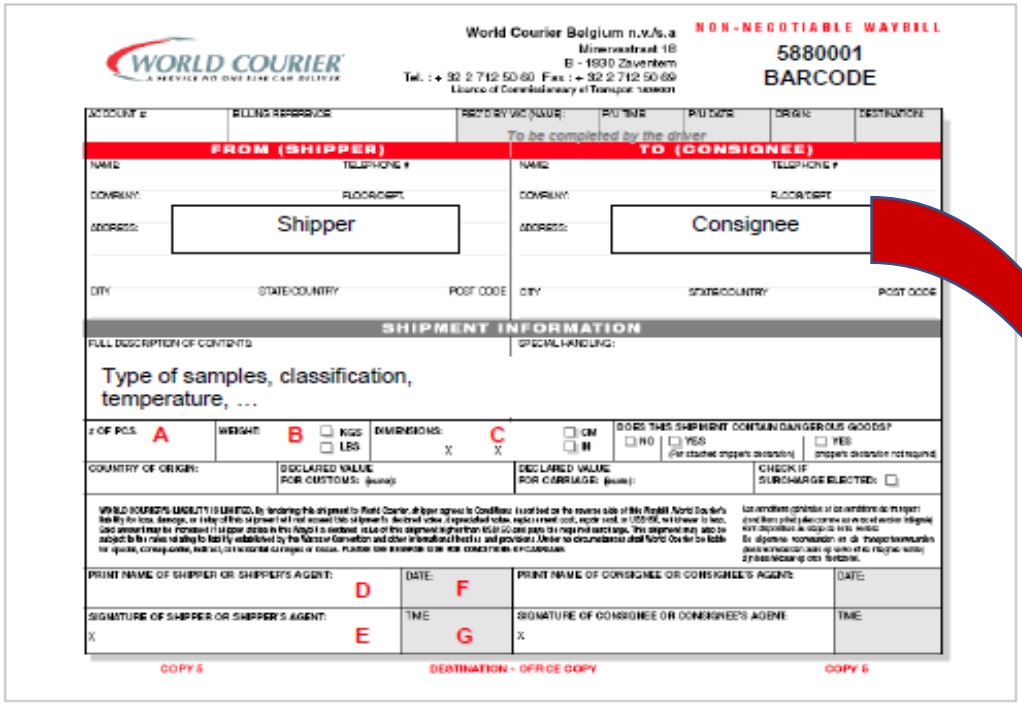
Labeling & Marking Instructions



Required documents

House Waybill (HWB)

- Please affix a waybill (or HWB) to the exterior of each shipment tendered to World Courier.
- World Courier will provide these forms with shipper and consignee information pre-printed for your convenience at the time of pick-up.
- This form is an internal tracking form used to identify your shipment from pick-up to delivery. When inquiring about your shipment, please reference the waybill number in the right hand corner.



Please complete the following information :

- A = number of packages
- B = total weight (kg)
- C = dimensions of the box (thermal box)
- D = full name of the shipper (in capitals)
- E = signature of the shipper
- F = collection date
- G = collection time

Ensure that the Consignee address is:

University of Pittsburgh, Neurotrauma Clinical Trials
ATTN: Michael Mancinelli
3550 Terrace Street
Scaife Hall, Room S-918
PITTSBURGH, PA 15261

1. Contact World Courier to confirm service is available and schedule package supplies to be delivered and schedule the container to be picked up.

2. Notify the Biorepository of your intent to send a shipment by sending an email to the following addresses:

   - rabinowitzmk@upmc.edu
   - mancinellimd@upmc.edu

3. When the shipment is sent send an email to the address above and include the **Excel electronic manifest**

   a. See Appendix G for format of electronic manifest spreadsheet

   b. The Excel electronic manifest is uploaded into the database and should match the specimens being sent. This helps in accessioning the specimens into the database at the Biorepository.

4. If you have any questions or concerns, contact Michael Mancinelli, Biorepository manager.

   a. Email: mancinellimd@upmc.edu
   b. Phone number: (484) 885-8211

SHIP ALL FROZEN SAMPLES MONDAY-WEDNESDAY ONLY!
BE AWARE OF HOLIDAYS!!
BE AWARE OF INCIPIENT INCLEMENT WEATHER THAT MAY DELAY SHIPMENT/DELIVERY OF SAMPLES

9. Sample Quality Checks and Feedback to Projects

In addition to tracking and reconciliation of samples, the condition and number of samples received are tracked by the Biorepository for each sample type. (See Shipment Tracking form – Appendix E) Investigators and clinical coordinators for each project are responsible to ensure the requested amounts of each fluid are collected to the best of their ability and that samples are packed with sufficient amounts of dry ice to avoid thawing in the shipment process.

10. Data Queries and Reconciliation

The Precision Medicine Sample Collection Forms (Appendices C and D) must be completed on the day that samples are collected since they capture information related to the details of the sample collection and processing. These forms include information that will be used to reconcile sample collection and receipt, as well as information essential to future analyses.

QuesGen will be collaborating with the NTBI-BR to reconcile information captured in the QuesGen database compared to samples received and logged at the NTBI-BR. Information that appears incorrect in the QuesGen database will be queried through the standard system.

Data queries or discrepancies with samples shipped versus received at the BR may result from:

- Missing samples at the NTBI-BR
- Incorrect samples collected and shipped to the NTBI-BR
- Damaged or incorrectly prepared samples
- Unlabeled samples, samples labeled with incomplete information, or mislabeled samples
- Discrepant information logged at the BR compared to information entered into the QuesGen database

Protocol compliance and study performance will be monitored by the Clinical Core using the study reports and dashboards provided by QuesGen Systems. Any protocol deviations should be reported and described in full under the research subject's study record in QuesGen, "Subject → Protocol Deviations" tab. Protocol deviations related to biospecimens may include:

- Blood collected for the baseline sample outside of <6 hour window
- Blood processing times deviated from protocol
- Blood collection was missed at any time point until day 5 only if the patient was still hospitalized
- Blood collected outside of the 2-week, 6-week, or 3-month window without prior approval for exception by the Executive Committee approval.
- Blood collection attempt unsuccessful
- Blood draw missed (i.e., follow up completed by phone, examiner error, subject refused)
- Other: (Any deviation not detailed above)

11. Sample Destruction Procedures

Site PIs must notify the coordinating site and NTBI-BR if a subject withdraws consent for specimen storage. The NTBI-BR will be responsible for completing the Sample Destruction Form (see Appendix F) and returning the completed copy to the coordinating site and enrolling site. The NTBI-BR will not destroy specimens unless requested in writing by the coordinating site and enrolling site PI. Records of request, Sample Destruction Form, and other supporting documentation for destruction will be retained at the NTBI-BR and may be requested by coordinating site and/or enrolling site.

12. Appendices

Appendix A: **Rate of Centrifugation Worksheet**

Appendix B: **TRACK-Precision Medicine Specimen Processing Quick Reference**

Appendix C: **Blood Sample Collection Form**

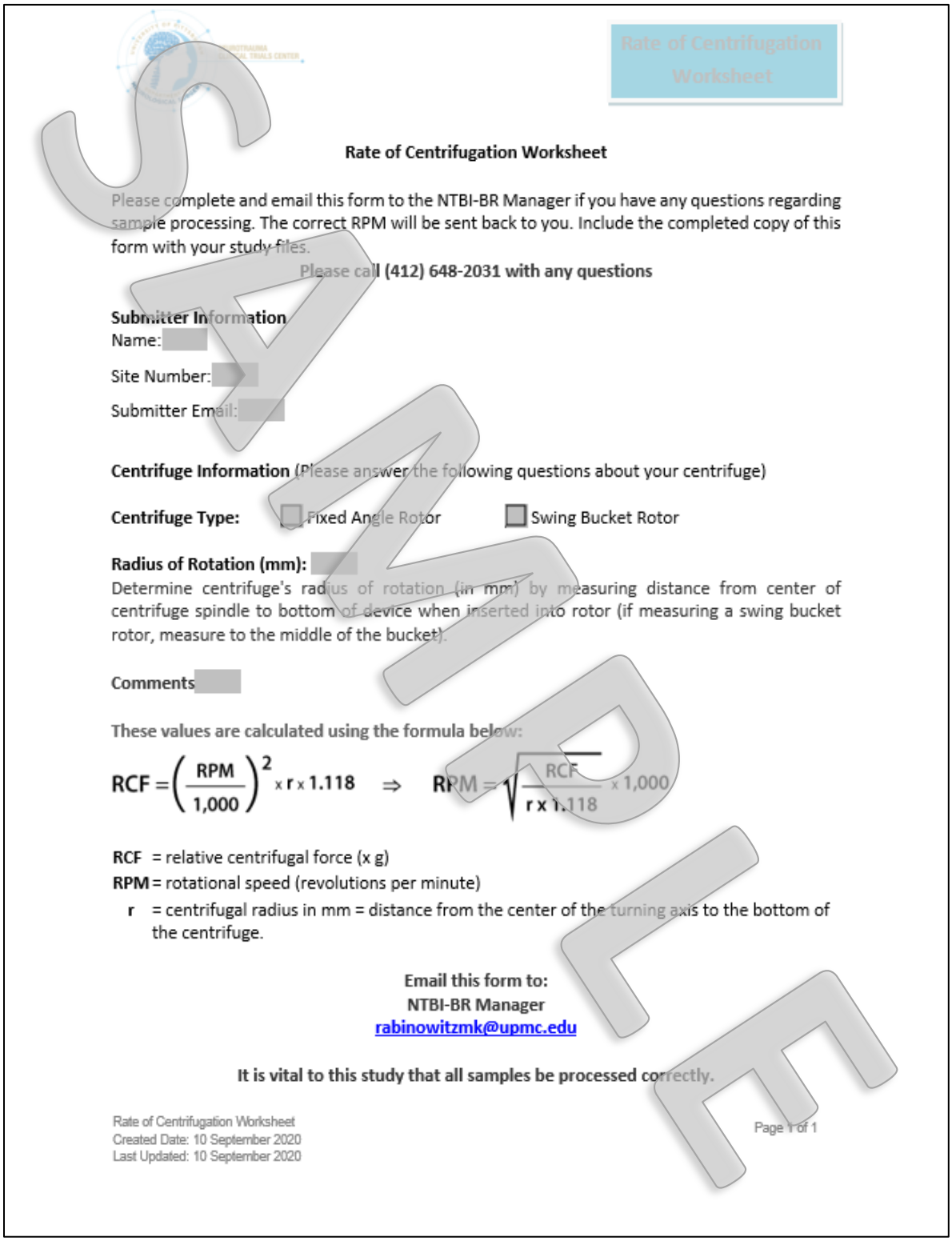
Appendix D: **CSF Sample Collection Form**

Appendix E: **Shipment Tracking Form**

Appendix F: **Sample Destruction Form**

Appendix G: **Biorepository Electronic Manifest Form**

12.1 Appendix A: Rate of Centrifugation Worksheet



Rate of Centrifugation Worksheet

Rate of Centrifugation Worksheet

Please complete and email this form to the NTBI-BR Manager if you have any questions regarding sample processing. The correct RPM will be sent back to you. Include the completed copy of this form with your study files.

Please call (412) 648-2031 with any questions

Submitter Information
Name:

Site Number:

Submitter Email:

Centrifuge Information (Please answer the following questions about your centrifuge)

Centrifuge Type: ☐ Fixed Angle Rotor ☐ Swing Bucket Rotor

Radius of Rotation (mm):
Determine centrifuge's radius of rotation (in mm) by measuring distance from center of centrifuge spindle to bottom of device when inserted into rotor (if measuring a swing bucket rotor, measure to the middle of the bucket).

Comments

These values are calculated using the formula below:

$$RCF = \left(\frac{RPM}{1{,}000}\right)^2 \times r \times 1.118 \quad \Rightarrow \quad RPM = \sqrt{\frac{RCF}{r \times 1.118}} \times 1{,}000$$

RCF = relative centrifugal force (x g)
RPM = rotational speed (revolutions per minute)
r = centrifugal radius in mm = distance from the center of the turning axis to the bottom of the centrifuge.

Email this form to:
NTBI-BR Manager
rabinowitzmk@upmc.edu

It is vital to this study that all samples be processed correctly.

Rate of Centrifugation Worksheet
Created Date: 10 September 2020
Last Updated: 10 September 2020

Page 1 of 1

12.2 Appendix B: TRACK-Precision Medicine Specimen Processing Quick Reference

TRACK-Precision Medicine
Specimen Processing Quick Reference

1 Purple Top K3EDTA Tube

- Spin for 20 Mins. @ 1500 RCF within 1 hour of collection
- Aliquot Plasma into prelabeled 1.5 mL cryovials: 01P-06P with purple caps
- Aliquot in portions of at least 500 uL (0.5 mL)
- DAY 1 ONLY: Aliquot Buffy Coat into prelabeled 1.5 mL cryovial: 13D with clear cap
- Store in -80°C within 2 hours of collection

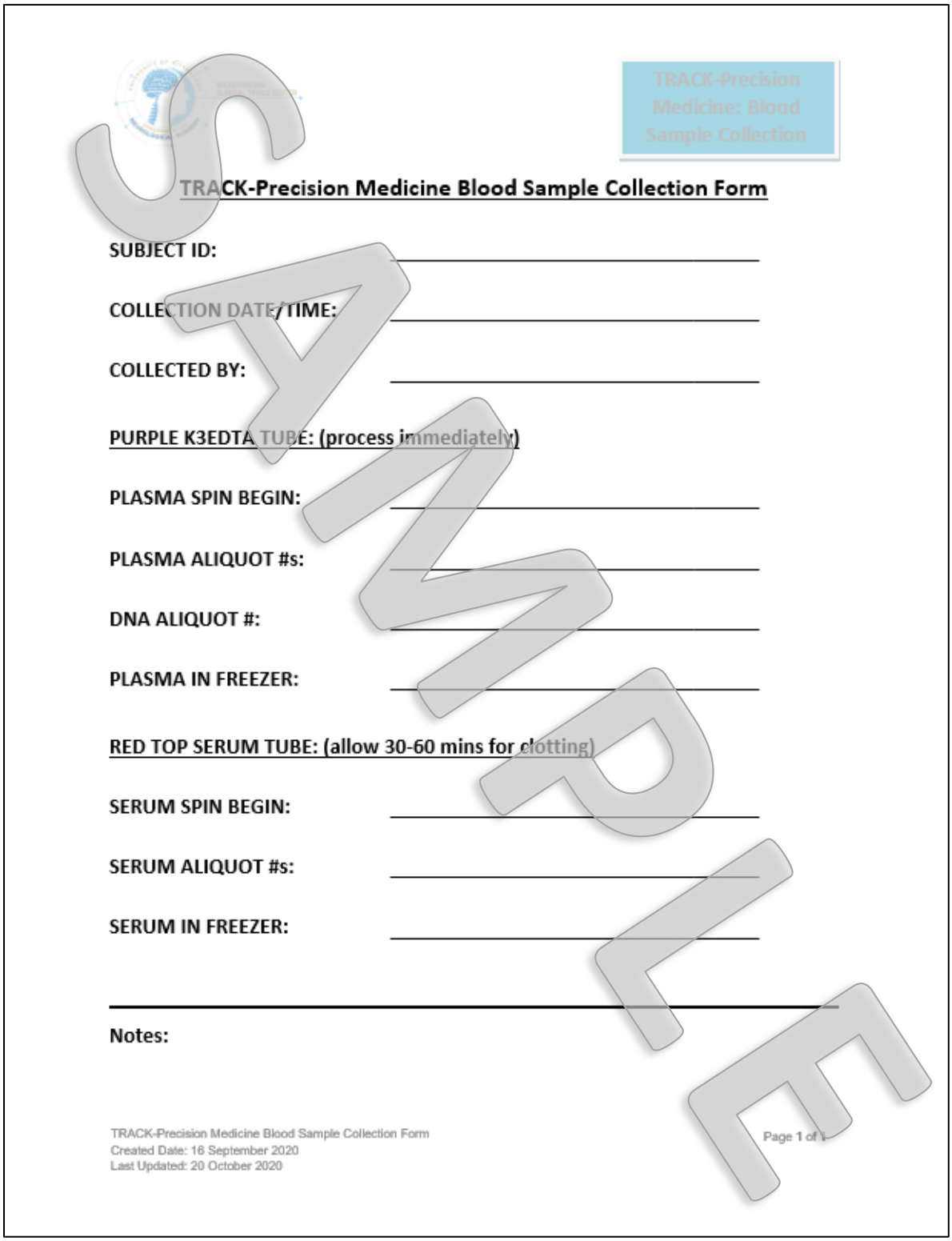
1 Red Top Serum Clot Activator Tube

- Allow to clot 30-60 mins.
- Spin for 15 Mins. @ 1500 RCF within 1 hour of collection
- Aliquot Serum into prelabeled 1.5 mL cryovials: 07S-12S
- Aliquot in portions of at least 500 uL (0.5 mL)
- Store in -80°C within 2 hours of collection

1 Blue Top Polypropylene Conical Tube

- Spin for 15 Mins. @ 1500 RCF within 1 hour of collection
- Aliquot CSF into prelabeled 1.5 mL cryovials: 01C-05C
- Aliquot in portions of at least 500 uL (0.5 mL)
- Store in -80°C within 2 hours of collection

12.3 Appendix C: Blood Sample Collection Form



TRACK-Precision Medicine: Blood Sample Collection

TRACK-Precision Medicine Blood Sample Collection Form

SUBJECT ID: _____

COLLECTION DATE/TIME: _____

COLLECTED BY: _____

PURPLE K3EDTA TUBE: (process immediately)

PLASMA SPIN BEGIN: _____

PLASMA ALIQUOT #s: _____

DNA ALIQUOT #: _____

PLASMA IN FREEZER: _____

RED TOP SERUM TUBE: (allow 30-60 mins for clotting)

SERUM SPIN BEGIN: _____

SERUM ALIQUOT #s: _____

SERUM IN FREEZER: _____

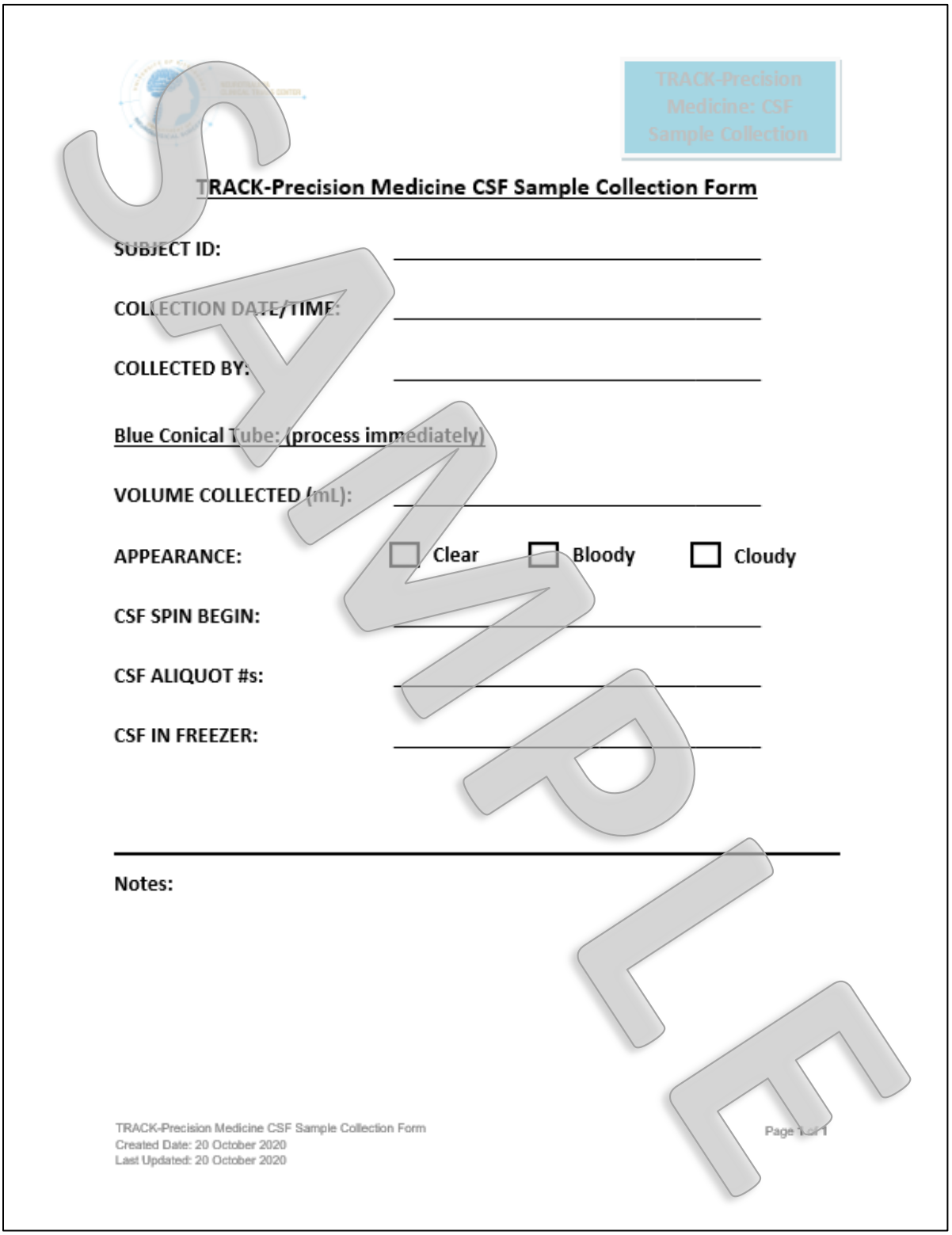
Notes:

TRACK-Precision Medicine Blood Sample Collection Form
Created Date: 16 September 2020
Last Updated: 20 October 2020

Page 1 of 1

SAMPLE

12.4 Appendix D: CSF Sample Collection Form



TRACK-Precision Medicine: CSF Sample Collection

TRACK-Precision Medicine CSF Sample Collection Form

SUBJECT ID: _____

COLLECTION DATE/TIME: _____

COLLECTED BY: _____

Blue Conical Tube: (process immediately)

VOLUME COLLECTED (mL): _____

APPEARANCE: ☐ Clear ☐ Bloody ☐ Cloudy

CSF SPIN BEGIN: _____

CSF ALIQUOT #s: _____

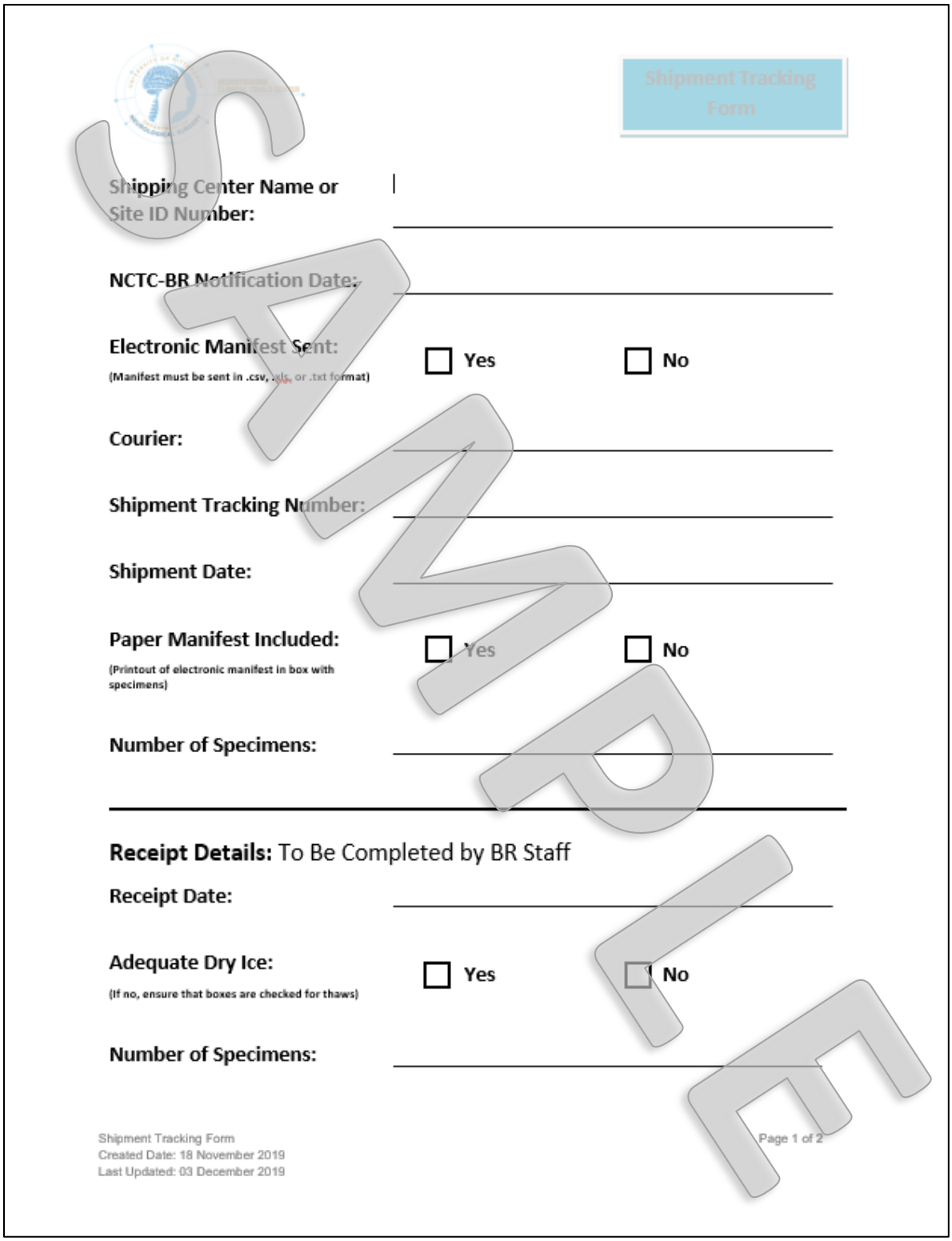
CSF IN FREEZER: _____

Notes:

TRACK-Precision Medicine CSF Sample Collection Form
Created Date: 20 October 2020
Last Updated: 20 October 2020

Page 1 of 1

12.5 Appendix E: Shipment Tracking Form



Shipment Tracking Form

Shipping Center Name or Site ID Number: _____

NCTC-BR Notification Date: _____

Electronic Manifest Sent: ☐ Yes ☐ No
(Manifest must be sent in .csv, .xls, or .txt format)

Courier: _____

Shipment Tracking Number: _____

Shipment Date: _____

Paper Manifest Included: ☐ Yes ☐ No
(Printout of electronic manifest in box with specimens)

Number of Specimens: _____

Receipt Details: To Be Completed by BR Staff

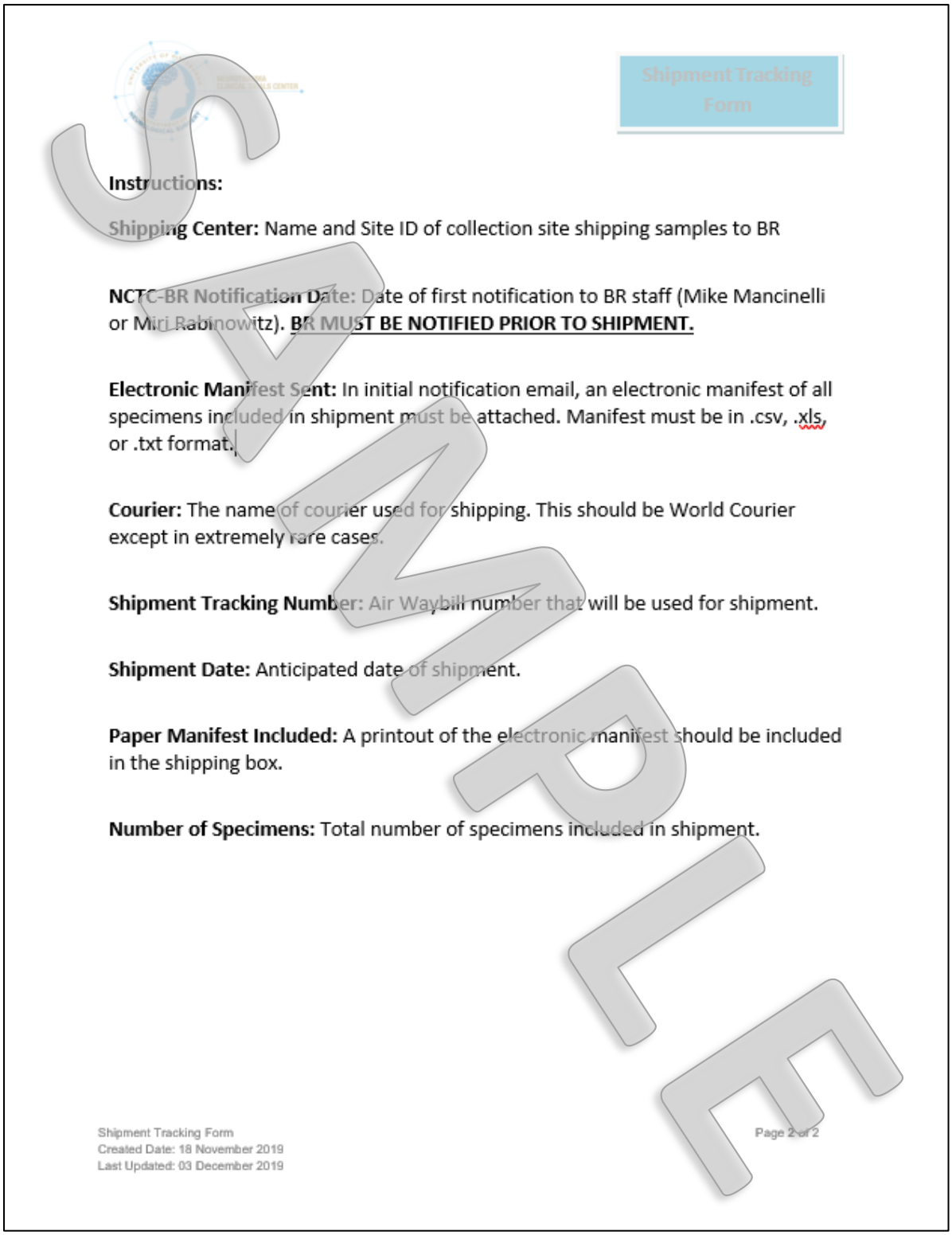
Receipt Date: _____

Adequate Dry Ice: ☐ Yes ☐ No
(If no, ensure that boxes are checked for thaws)

Number of Specimens: _____

Shipment Tracking Form
Created Date: 18 November 2019
Last Updated: 03 December 2019

Page 1 of 2



Shipment Tracking Form

Instructions:

Shipping Center: Name and Site ID of collection site shipping samples to BR

NCTC-BR Notification Date: Date of first notification to BR staff (Mike Mancinelli or Miri Rabinowitz). **BR MUST BE NOTIFIED PRIOR TO SHIPMENT.**

Electronic Manifest Sent: In initial notification email, an electronic manifest of all specimens included in shipment must be attached. Manifest must be in .csv, .xls, or .txt format.

Courier: The name of courier used for shipping. This should be World Courier except in extremely rare cases.

Shipment Tracking Number: Air Waybill number that will be used for shipment.

Shipment Date: Anticipated date of shipment.

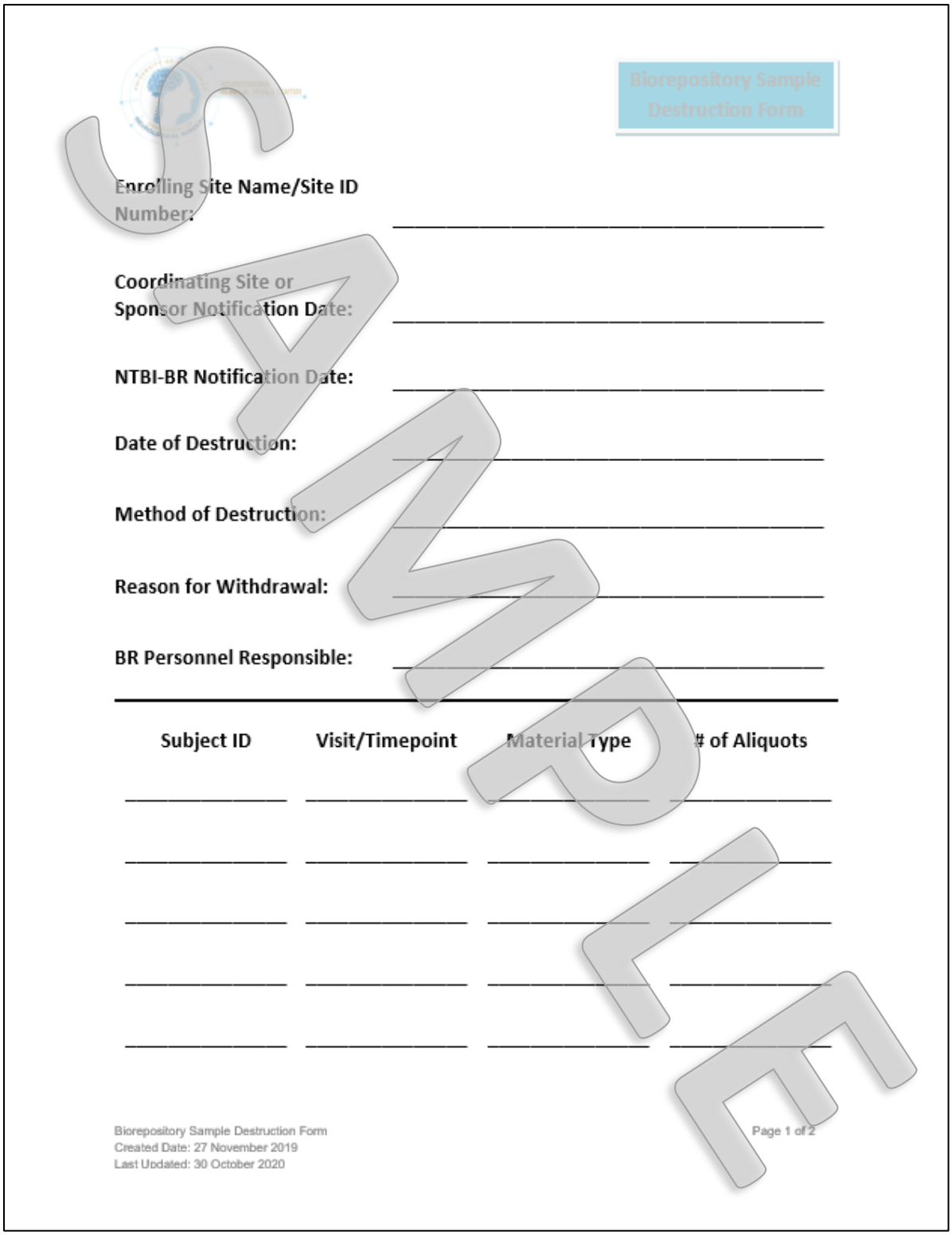
Paper Manifest Included: A printout of the electronic manifest should be included in the shipping box.

Number of Specimens: Total number of specimens included in shipment.

Shipment Tracking Form
Created Date: 18 November 2019
Last Updated: 03 December 2019

Page 2 of 2

12.6 Appendix F: Biorepository Sample Destruction Form



Biorepository Sample Destruction Form

Enrolling Site Name/Site ID Number: _____

Coordinating Site or Sponsor Notification Date: _____

NTBI-BR Notification Date: _____

Date of Destruction: _____

Method of Destruction: _____

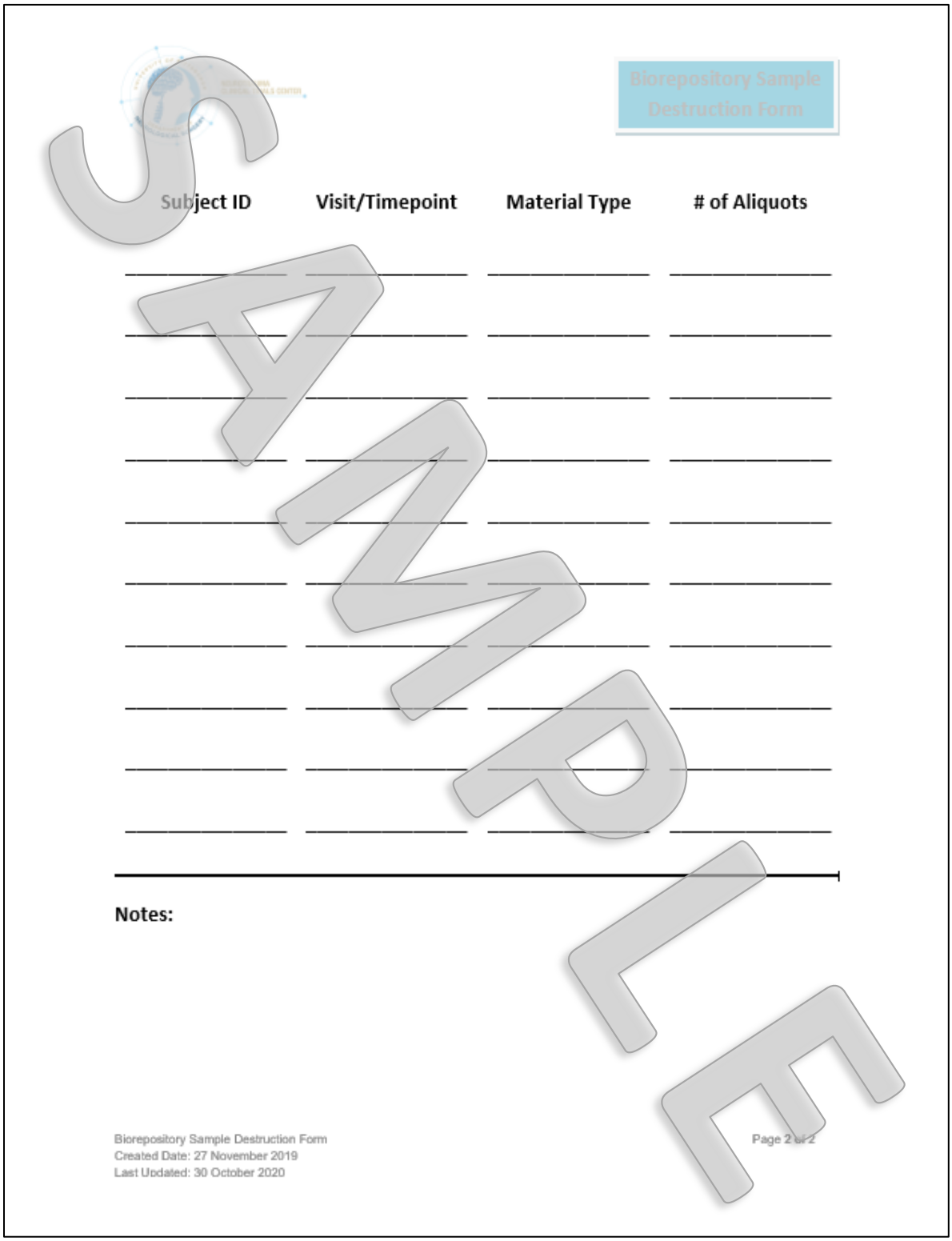
Reason for Withdrawal: _____

BR Personnel Responsible: _____

Subject ID	Visit/Timepoint	Material Type	# of Aliquots

Biorepository Sample Destruction Form
Created Date: 27 November 2019
Last Updated: 30 October 2020

Page 1 of 2



Biorepository Sample Destruction Form

Subject ID	Visit/Timepoint	Material Type	# of Aliquots

Notes:

Biorepository Sample Destruction Form
Created Date: 27 November 2019
Last Updated: 30 October 2020

Page 2 of 2

12.7 Appendix G: Biorepository Electronic Manifest Spreadsheet

Box Label	Sample ID (Subject)	Visit	Material Type	Material Modifier	Date/Time Drawn	Date/Time Processed	Date/Time Frozen	Date/Time Shipped	Site
PM-03 P+S Box 1	PM-03-3001-A-01P	<6 Hours	Plasma	EDTA	1/3/2020 9:00	1/3/2020 9:20	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-A-02P	<6 Hours	Plasma	EDTA	1/3/2020 9:00	1/3/2020 9:20	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-A-03P	<6 Hours	Plasma	EDTA	1/3/2020 9:00	1/3/2020 9:20	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-A-04P	<6 Hours	Plasma	EDTA	1/3/2020 9:00	1/3/2020 9:20	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-A-05P	<6 Hours	Plasma	EDTA	1/3/2020 9:00	1/3/2020 9:20	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-A-06P	<6 Hours	Plasma	EDTA	1/3/2020 9:00	1/3/2020 9:20	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-A-07S	<6 Hours	Serum	SCA	1/3/2020 9:00	1/3/2020 9:42	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-A-08S	<6 Hours	Serum	SCA	1/3/2020 9:00	1/3/2020 9:42	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-A-09S	<6 Hours	Serum	SCA	1/3/2020 9:00	1/3/2020 9:42	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-A-10S	<6 Hours	Serum	SCA	1/3/2020 9:00	1/3/2020 9:42	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-A-11S	<6 Hours	Serum	SCA	1/3/2020 9:00	1/3/2020 9:42	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 BC Box 1	PM-03-3001-A-13D	<6 Hours	Buffy Coat	EDTA	1/3/2020 9:00	1/3/2020 9:20	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 CSF Box 1	PM-03-3001-A-01C	<6 Hours	CSF	Polypropylene	1/3/2020 9:10	1/3/2020 9:20	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 CSF Box 1	PM-03-3001-A-02C	<6 Hours	CSF	Polypropylene	1/3/2020 9:10	1/3/2020 9:20	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 CSF Box 1	PM-03-3001-A-03C	<6 Hours	CSF	Polypropylene	1/3/2020 9:10	1/3/2020 9:20	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 CSF Box 1	PM-03-3001-A-04C	<6 Hours	CSF	Polypropylene	1/3/2020 9:10	1/3/2020 9:20	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 CSF Box 1	PM-03-3001-A-05C	<6 Hours	CSF	Polypropylene	1/3/2020 9:10	1/3/2020 9:20	1/3/2020 10:06	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-B-01P	12 Hours	Plasma	EDTA	1/3/2020 21:15	1/3/2020 21:32	1/3/2020 21:58	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-B-02P	12 Hours	Plasma	EDTA	1/3/2020 21:15	1/3/2020 21:32	1/3/2020 21:58	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-B-03P	12 Hours	Plasma	EDTA	1/3/2020 21:15	1/3/2020 21:32	1/3/2020 21:58	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-B-04P	12 Hours	Plasma	EDTA	1/3/2020 21:15	1/3/2020 21:32	1/3/2020 21:58	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-B-05P	12 Hours	Plasma	EDTA	1/3/2020 21:15	1/3/2020 21:32	1/3/2020 21:58	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-B-06P	12 Hours	Plasma	EDTA	1/3/2020 21:15	1/3/2020 21:32	1/3/2020 21:58	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-B-07S	12 Hours	Serum	SCA	1/3/2020 21:15	1/3/2020 21:48	1/3/2020 22:12	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-B-08S	12 Hours	Serum	SCA	1/3/2020 21:15	1/3/2020 21:48	1/3/2020 22:12	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-B-09S	12 Hours	Serum	SCA	1/3/2020 21:15	1/3/2020 21:48	1/3/2020 22:12	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-B-10S	12 Hours	Serum	SCA	1/3/2020 21:15	1/3/2020 21:48	1/3/2020 22:12	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-B-11S	12 Hours	Serum	SCA	1/3/2020 21:15	1/3/2020 21:48	1/3/2020 22:12	8/1/2020 11:00	UCSF
PM-03 P+S Box 1	PM-03-3001-B-12S	12 Hours	Serum	SCA	1/3/2020 21:15	1/3/2020 21:48	1/3/2020 22:12	8/1/2020 11:00	UCSF