**Supplemental Information**

**Day before scheduled appointment**

*Study Coordinator Duties*

1. Reminder call to participant and answer questions regarding fasting.
2. Instruct participant to drink plenty of water and continue to take medications as directed.
3. Create appointment schedule for each Phlebotomist.
   1. Include participant’s date of birth for identification purposes.
   2. Print maps to participant’s homes.
4. Notify Processing Laboratory of anticipated quantity and time of deliveries.
5. Prepare Phlebotomist supplies.
   1. Place filled Black document folder and empty green and red document folders in carrying cases.
   2. Routine Supplies.
   3. Surplus supplies.
6. Double check that each Phlebotomist has sufficient specimen collection kits (at least 2 additional kits as surplus).
7. Triple check that all collection kits and supplies are prepped for appointments
   1. Ice packs in freezer
   2. Phlebotomist bags filled
   3. Courier bags are prepped
   4. Inventory lists reviewed
8. Secure all Phlebotomist’s bags in a locked cabinet.

**Day of scheduled appointment**

*Courier Duties*

1. Pick up supplies from Study Coordinator.
2. Meet Phlebotomist(s) for transfer of specimens and kits following blood draw.

*Phlebotomist Duties*

1. Pick up supplies from Study Coordinator.
2. Wash hands with soap and warm water.
3. 15 minutes before scheduled appointment call participant to notify them you are en route.
4. Take all supplies into the home.
5. At the door, knock and ask to speak to the participant.
   1. Introduce yourself and ask to go to a quiet location with seating and a flat surface.
6. Ask the participant to verify their date of birth to confirm identity.
7. Read the entire consent form to the participant.
8. Ask if they have any questions – ensure all inquiries are addressed.
9. Print the full name of the participant on the consent forms.
10. Ask the participant to sign both copies of the consent form.
11. Give one copy of the consent form to the participant.
12. Open the collection kit and affix the Consent Form Label to the second signed consent form. Place in Red document folder. This form will be returned to the Study Coordinator at the end of the day.
13. Affix the Specimen Log Label to the Specimen Log (Additional file 2).
14. Affix the Tracking Sheet Label to the Tracking Sheet (Additional file 1).
15. Return additional labels to collection kit bag.
16. Ask the participant the date and time they last ate or drank anything other than water.
17. Complete Section 1 of Specimen Log:
    1. Phlebotomist name.
    2. Date/Time.
    3. Date and time of last food/drink.
    4. Fasting status (at least 8-12 hours since last food/drink).
    5. Results requested?
    6. Consent given AND retained.
    7. Consent form labeled.
18. Complete medication portion of specimen log.

**Blood draw procedure (in participant’s home):**

1. Sanitize hands and dawn gloves
2. Gather and prepare supplies from Specimen Collection Kit
   1. Insert Eclipse vacutainer needle with safety lock into vacutainer holder.
   2. Remove Biotransport container from carrying case
      1. Set on flat surface
      2. Open and set aside lid
   3. Place timers around neck
   4. Position biohazard waste/sharps container nearby
   5. Set out:
      1. Tourniquet
      2. Gloves
      3. Alcohol prep pad
      4. Sterile gauze
      5. Cotton ball
      6. Band-aid
      7. Hand sanitizer/purell hand wipe
      8. Specimen log
      9. Tracking sheet
3. Assess the participant’s arm to determine the phlebotomy site
4. Apply tourniquet
5. Wipe participant’s skin at the phlebotomy site with alcohol pad starting in the center and moving in a circular motion outward
6. While allowing skin to dry completely, set timer to 60 minutes
7. Insert Eclipse needle into chosen site
   1. “Hard stick” special instructions (attempt up to 2 sticks using a fresh needle each time from surplus supplies):
      1. Insert winged needle into chosen site
      2. Using a surplus DISCARD serum vacutainer, initiate blood draw so that the plastic tubing of winged needle set fills with blood.
      3. As soon as blood begins to flow from the plastic tubing into the vacutainer, pull off that vacutainer and proceed with standard blood draw protocol.
      4. Dispose of DISCARD serum vacutainer in the biohazard container.
8. Collect 1 serum vacutainer.
   1. All blood collection tubes have a vacuum and should automatically fill to the line on the label to get the correct ration of blood to coagulant/additive
   2. In the event the vacutainer loses its vacuum another tube from the surplus supplies should be labeled and used in its place.
9. Once collected, immediately invert the vacutainer 10 times to initiate clotting.
10. Place the serum tube in Biotransport rack. The sample should remain upright and undisturbed at room temperature for 30-60 minutes.
11. Ontracking sheet record timeof first draw.
12. Onspecimen log:
    1. Record start timein rack for tube
    2. Circle appropriate comment on draw
13. While the serum tube is sitting to clot, collect the first ficoll containing vacutainer.
14. Once collected, immediately invert the tube 10 times to mix anticoagulant additive with blood.
15. Place the filled ficoll containing tube in the Biotransport rack. The sample should remain upright and undisturbed at room temperature until processing at the laboratory.
16. Onspecimen log**:**
    1. Record start timein rack for tube
    2. Circle appropriate comment on draw
17. Collect the second ficoll containing vacutainer.
18. Once collected, immediately invertthe tube 10 times to mix anticoagulant additive with blood.
19. Place the second filled ficoll containing tube in the Biotransport rack. The sample should remain upright and undisturbed at room temperature until processing at the laboratory.
20. Onspecimen log**:**
    1. Record start timein rack for tube
    2. Circle appropriate comment on draw
21. Collect the firstK2 EDTA vacutainer
22. Once collected, immediately invert the tube 10 times.
23. Place the tube temporarily in the Biotransport rack at room temperature.
24. Next, collect the second K2 EDTA vacutainer
25. Once collected, immediately invert the tube 10 times.
26. Working quickly, undo tourniquet.
27. Place the tube temporarily in Biotransport rack within at room temperature.
28. Working quickly, apply pressure with cotton ball over venipuncture site and withdraw needle, dispose immediately in biohazard waste/sharps box.
29. Working quickly, apply Band-Aid to venipuncture site.
30. Immediately, transfer both K2 EDTA vacutainers to the Biotransport rack inside the cooler with the ice packs.
31. Close Biotransport containers.
32. Immediately zip closed the carrying cases.
    1. It is important that a minimal amount of cold air escape the cooler.
33. On specimen log:
    1. Record start time in black cooler with ice packs for both purple tubes.
    2. Circle appropriate comment on draws.
34. Dispose of all non-sharps trash in Ziploc biohazard bag.
35. Make sure to carry all trash with you out of the home (return all trash to Processing Laboratory for disposal.)
36. Give participant snack to eat if requested.
37. Ensure Section 2 of Specimen Log and Tracking Sheet are completed, place in Green document folder.
38. Instruct participant to drink plenty of water and avoid rigorous exercise for two hours.
39. Collect all supplies and thank participant.
40. When back in car, immediately plug the cooler into cigarette lighter/cell phone charger.
41. If the timer goes off, signaling that 60 minutes have elapsed since the serum tube was collected, transfer the serum tube only to the Biotransport rack within the cooler with ice packs. (Note: the ficoll containing tubes remain at room temperature.)
42. Record time of transfer on specimen collection log
43. Set second timer for 60 minutes.
44. Proceed to next appointment or Processing Laboratory for delivery.
45. NOTE: All tubes must be transported to Processing Laboratory within 1.5 hours of collection to allow processing of samples within two-hour window.

**Transfer of Specimens to Courier**

1. Phlebotomist should complete tracking sheet from green folder, record staff ID#, initial, and hand off to the courier.
2. Wearing gloves, phlebotomist should transfer all specimens to the courier and exchange timers.
   1. If serum tubes have been at room temperature for at least 30 minutes from the time of collection and have not already been transferred to cold, they should be transferred from the room temperature case to the cold temperature cooler for transport to the lab.
      1. Record the time the tubes are transferred from room temperature to cold on the specimen log.
   2. Ficoll containing tubes should remain at room temperature from the time of collection to the arrival at the lab.
   3. K2 EDTA tubes should be transferred directly from each phlebotomist’s cooler to the courier’s cooler.
3. In addition to specimens, phlebotomist should transfer all remaining components of used collection kits (containing kit logs, cryovials, extra labels, etc.) and specimen logs to the courier.
4. Courier should confirm that all specimens and kit supplies are accounted for, initial tracking sheet, and proceed to the Processing Laboratory.

**Transfer of Specimens from Courier to Processing Lab**

1. Courier should transfer all specimens, collection kits, and specimen logs to the lab.
2. Courier should complete tracking sheets, record staff ID#, initial, and hand off to the lab.
3. Lab should confirm that all specimens and kit supplies are accounted for, initial tracking sheet, and begin processing of samples.

**Return of collection supplies to Study Coordinator**

* + - 1. Following transfer of specimens to the Courier, the Phlebotomist returns all specimen collection supplies and waste to Study Coordinator.
      2. Study Coordinator verifies accuracy and quantity of consent forms according to appointment schedule.
      3. Following transfer of specimens to the Processing Laboratory, the Courier returns transport supplies to Study Coordinator.

**Consent Form Procedure**

1. Survey Coordinator provides participant names (and survey IDs) to the Study Coordinator for appointment scheduling.
2. Phlebotomist takes 2 blank consent forms to participant’s home during the appointment.
3. Once signed by participant, Phlebotomist affixes Consent Form Blood Draw ID Label and writes participant’s name and survey ID on one of the two forms to return to the Study Coordinator. The participant retains the other signed Consent Form.
4. Study Coordinator receives the signed, labeled consent form.
5. Study Coordinator copies the completed consent form, secures the copy in a locked file cabinet and returns the original consent form to the Survey Coordinator.
6. Survey Coordinator verifies that the participant’s name corresponds to the survey ID and records the blood ID in a database to link all records.

**Courier supplies:**

*Specimen transport supplies*

1. Two carrying cases
2. Two test tube racks
3. Two biotransport sealed containers
4. Two ice packs

**Phlebotomist supplies:**

*Specimen transport supplies*

1. Two carrying cases
2. Two test tube racks
3. Two biotransport sealed containers
4. Two ice packs

*Black document folder:*

1. Routine Supplies Inventory Sheet
2. Surplus Supplies Inventory Sheet
3. Two blank consent forms (2 copies per participant)
4. Appointment schedule and maps
5. Protocol
6. Blank Specimen logs
7. Blank Tracking sheets

*Empty Red document folder (at the end of the day deliver this folder containing the following completed documents to the Study Coordinator):*

* + - 1. Completed Routine Supplies Inventory Sheet
      2. Completed Surplus Supplies Inventory Sheet
      3. Consent forms (1 completed copy per participant)
      4. Appointment schedule and maps
      5. Protocol

*Empty Green document folder (at the end of the day deliver the following completed documents in this folder to the Processing Laboratory):*

Specimen logs

Tracking sheets

*Routine Supplies*

1. Specimen collection kits
   1. Large plastic kit bag
   2. Small plastic kit bag (with cryovials)
   3. Specimen Kit Log (bar-coded)
   4. Printed, bar-coded labels
      1. Consent form label
      2. Tracking sheet label
      3. Specimen log label
      4. Large kit bag label
      5. Small kit bag label
      6. Cryobox labels
      7. 1 serum vacutainer label
      8. 2 ficoll containing vacutainer labels
      9. 2 K2 EDTA vacutainer labels
      10. extra label
   5. Vacutainers (1 serum, 2 ficoll containing, 2 K2 EDTA)
   6. Single use vacutainer holder
   7. Eclipse vacutainer needle with safety lock
   8. Alcohol wipe
   9. Sterile gauze
   10. Cotton ball
   11. Band-Aid
   12. Bar-coded cryovials for endpoint biological specimens prior to analysis
2. 20 Genie Lancets (Fisher)
3. 2 Timers
4. Purell hand wipes
5. Tourniquet
6. Ziploc biohazard bags for non-sharps trash disposal
7. Biohazard waste/sharps disposal container
8. Gloves
9. Hand sanitizer
10. Pens
11. Participant snack
12. Face masks wrapped in plastic bags

*Surplus supplies*

1. 10 Alcohol prep pads
2. 5 tourniquets
3. 5 vacutainer holders
4. 5 Eclipse needles
5. 10 sterile gauze
6. 10 Lancets
7. 1 pack cotton balls
8. 1 pack Band-Aids
9. Surplus unlabeled vacutainers (2 serum, 2 ficoll containing, 2 K2 EDTA)
10. 2 Winged needles (21¾Gx12”)
11. 2 Winged needles (23G)
12. 2 serum starter vacutainer labeled DISCARD

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Table S1: Cryovial Numbering System** | | | | | |
| **Option** | **Blood ID (Participant ID) for kit bags, consent form, tracking sheet and specimen log** | | | | |
| 1 | xxxxxx00 |  |  |  |  |
| 2 | xxxxxx25 |  |  |  |  |
| 3 | xxxxxx50 |  |  |  |  |
| 4 | xxxxxx75 |  |  |  |  |
|  | **Serum 2ml cryovials (4 per participant)** | | | | |
| 1 | xxxxxx01 | xxxxxx02 | xxxxxx03 | xxxxxx04 |  |
| 2 | xxxxxx26 | xxxxxx27 | xxxxxx28 | xxxxxx29 |  |
| 3 | xxxxxx51 | xxxxxx52 | xxxxxx53 | xxxxxx54 |  |
| 4 | xxxxxx76 | xxxxxx77 | xxxxxx78 | xxxxxx79 |  |
|  | **DNA 2ml cryovials (4 per participant)** | | | | |
| 1 | xxxxxx05 | xxxxxx06 | xxxxxx07 | xxxxxx08 |  |
| 2 | xxxxxx30 | xxxxxx31 | xxxxxx32 | xxxxxx33 |  |
| 3 | xxxxxx55 | xxxxxx56 | xxxxxx57 | xxxxxx58 |  |
| 4 | xxxxxx80 | xxxxxx81 | xxxxxx82 | xxxxxx83 |  |
|  | **PBMC 2ml cryovials (5 per participant)** | | | | |
| 1 | xxxxxx09 | xxxxxx10 | xxxxxx11 | xxxxxx12 | xxxxxx13 |
| 2 | xxxxxx34 | xxxxxx35 | xxxxxx36 | xxxxxx37 | xxxxxx38 |
| 3 | xxxxxx59 | xxxxxx60 | xxxxxx61 | xxxxxx62 | xxxxxx63 |
| 4 | xxxxxx84 | xxxxxx85 | xxxxxx86 | xxxxxx87 | xxxxxx88 |
|  | **PBMC plasma residual 5ml cryovials (1 per participant)** | | | | |
| 1 | xxxxxx22 |  |  |  |  |
| 2 | xxxxxx47 |  |  |  |  |
| 3 | xxxxxx72 |  |  |  |  |
| 4 | xxxxxx97 |  |  |  |  |
|  | **PBMC RBCs and granulocytes residual 5ml cryovials (1 per participant)** | | | | |
| 1 | xxxxxx23 |  |  |  |  |
| 2 | xxxxxx48 |  |  |  |  |
| 3 | xxxxxx73 |  |  |  |  |
| 4 | xxxxxx98 |  |  |  |  |