

Clinical and Translational Research Center TraCS Institute	Approved by: Medical Director and Director of Nursing
SOP Title and #: Phlebotomy	Revisions: 11/10/2009, 8/13/2013, 8/23/2015, 8/20/2016
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- I. **Purpose:** This Standard Operating Procedure (SOP) describes the activities that will take place to ensure the seamless flow of study participants requiring phlebotomy.
- II. **Scope:** This SOP applies to the procedures for drawing and handling blood specimens at the CTRC.
- III. **Applicability:** Accurate specimen collection and proper handling of such specimens is imperative for all research studies in order to avoid any errors or protocol deviations that may potentially occur. Study coordinators and principal investigators (study staff) rely on the phlebotomist or nurse to obtain the study specimens following universal precautions, proper aseptic technique, and labeling practices. These parties will need to understand the CTRC procedure to complete this process in a timely, accurate manner.
- IV. **Responsible Parties:** Principal Investigator, study staff, CTRC phlebotomist, CTRC nursing staff, and CTRC front desk staff. Blood drawing in the CTRC is done primarily by a phlebotomist and at other times by licensed nurses.
- V. **Procedures:**
 - A. **Blood Draw Frequency and Volume:** The frequency and volume of blood drawn during a study visit will be detailed in the IRB approved study. The Principal Investigator assumes responsibility for ensuring the frequency and volume of blood drawn is ordered as outlined in the approved protocol.
 - B. **Ordering the Labs:**
 1. The study coordinator or member of the study team will be responsible for ensuring the signed lab orders are correctly entered in Epic prior to notifying CTRC staff that a blood draw is needed.
 2. If needed, the CTRC receptionist will be responsible for printing subject labels with appropriate CSN number for the current EPIC encounter upon check in to CTRC. These labels may be used if necessary for the specimens delivered to McLendon labs in the event that the hospital lab label printer is not responding. Epic labels with the current visits CSN number are to be used for that day's visit only and not for future visits.
 3. Unless the research subject must be drawn in a room, the subject should be seated in the "Blood Collection Waiting" area.
 4. A member of the study team will notify CTRC staff that a blood draw is needed by completing the "blood draw half sheet" and indicating whether kit labs, hospital labs or both are needed. If applicable, the room number should also be designated and whether or not the subject is on contact precautions. A minimum of 1 Epic subject label must be attached to record the draw on the "Clinical Research Blood Drawing Log."
 5. If kit labs (blood tubes not being sent to McLendon Lab) are needed, the coordinator will ensure that all tubes are pre-packaged in a clear bio-hazard plastic bag or other suitable container, all tubes and outside of bag have been labeled correctly with proper identifier, and are placed in the "kit lab" wall holder across from Blood Collection (room 1037A) prior to subject being called for the blood draw. A label with the subject's name, date of birth and medical record number must be placed on the outside of the plastic biohazard bag.
 6. The study coordinator will place the completed "blood draw half sheet" into the filing tray on the wall across from the Blood Collection door from front to back to ensure the subject is drawn in order of the request. This action will signify to CTRC staff that all procedures above have been completed and that the subject is ready to be drawn.

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7. Although not required, it is highly recommended that the study coordinator remain on the unit until the blood draw is completed in the event questions arise and to prevent delays in subject being drawn.

C. Collecting Specimens:

1. The phlebotomist or nurse will ensure that signed orders are in Epic prior to drawing labs. On rare occasions, labs may be drawn without a signed order in Epic if the Charge Nurse is actively in communication with the licensed provider to obtain an order.
2. Once orders have been verified and the amount of blood/tubes has been established and confirmed, the phlebotomist or nurse will begin the blood drawing procedure by releasing the orders in EPIC. Epic lab labels will print from the hospital lab label maker. The CTRC phlebotomist or nurse will make sure the lab label is placed on the correct tube.
3. The phlebotomist or nurse will prepare the necessary lab drawing supplies and will confirm any kit lab tubes are properly labelled per study requirements. If a discrepancy is found, the study coordinator will be notified prior to escorting subject to the lab.
4. The phlebotomist or nurse will escort the subject into Blood Collection (or draw in designated room) and will follow all health and safety regulations regarding the checking of subject's identification and according to study protocol. After greeting the subject and having the subject seated, the CTRC phlebotomist or nurse will verify the subject's name and date of birth using the pre-printed Epic labels provided with the subject.
5. Only the CTRC staff drawing the blood and the subject should be in the Blood Collection room. Study staff and family members should remain outside of the lab unless otherwise directed by CTRC staff.
6. The phlebotomist or nurse will explain all procedures to the subject and answer any questions.
7. The phlebotomist or nurse will use aseptic technique to obtain all required specimens while following all health and safety regulations.
8. The phlebotomist or nurse will ensure all tubes are completely filled according to manufacturer's fill line on the tube and will notify study staff immediately if unable to fill tube(s) correctly.
9. The phlebotomist or nurse will ensure that all tubes are properly labeled with the correct date, time and initials.

D. Difficult or Unsuccessful Venipunctures:

1. If the venipuncture is unsuccessful on the first attempt, the phlebotomist or nurse will search for an alternate site in the opposite arm or below the first site.
2. The CTRC phlebotomist or nurse should utilize the AccuVein® vein visualization equipment on any subject deemed a "difficult draw" or if a subject states prior history of unsuccessful venipunctures.
3. Each phlebotomist or nurse is permitted two unsuccessful venipunctures per subject at each visit. After the second attempt, one additional attempt may be made by a different trained staff member if directed to do so by the study team. On rare occasions, additional attempts may be made at the discretion of the study physician or Principal Investigator and the CTRC Charge Nurse or Director of Nursing. This

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determination will be made on a case by case basis and with consent of the research subject. CTRC staff will document subject's consent and the study staff reasoning for additional attempts in a note in the subject's Epic chart.

E. Upon Completion of Specimen Collection:

1. The study staff will be notified immediately if all samples cannot be obtained.
2. The phlebotomist or nurse will record the date and time the sample(s) were drawn as well as other required fields in Epic. The phlebotomist or nurse will also record the date, time and their initials on each tube being sent to McLendon Labs.
3. For kit labs, the phlebotomist or nurse will record the date, time, initials and total volume on the label on the outside of the biohazard bag. If applicable, the phlebotomist or nurse will also record the date, time and initial on kit lab slips provided by the study team.
4. Specimens to be sent to the McLendon Laboratory are to be placed in biohazard bags taking care to close the bag tightly and ensuring that all samples are enclosed securely and are free of contaminants. The phlebotomist or nurse will then tube the labs to the appropriate laboratory tube station. In the event the tube station is "offline," the phlebotomist or nurse will transport the specimens to the lab.
5. If kit labs are obtained, the tubes will be placed on the "Completed Kit Labs" bucket located in the Specimen Processing & Storage room for the coordinator to pick up and/or process.
6. The study coordinator will be responsible for utilizing the centrifuge to spin specimens for kit labs and ensure specimens are mailed as needed.
7. The phlebotomist or nurse should then chart that a subject's blood draw occurred on the "Clinical Research Blood Drawing Log" by using a provided label or writing the subject's full name and date of birth on the log with the date and time the sample was collected. The phlebotomist or nurse's initials should also be noted as well as the volume drawn and the number and type of tubes. This log will be kept for 2 years from the date of service and then placed in the Shred-It Bin.

- F.** Any deviations from these phlebotomy procedures must be reported to the Charge Nurse or the Director of Nursing so appropriate documentation can be filed.

VI. Related documents:

- A.** SOP titled "Pediatric Blood Draw"