

## **POLICIES AND PROCEDURES**

SECTION: Research and Compliance			NUMBER: CLN-29.00	
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/4/2009	REV. B: 8/30/2010	REV. C:
TITLE: Obtaining a Blood Sample			Page 1 of 4	

### **1. PURPOSE**

To describe the technique and duties for performing venipuncture (collection of a venous blood sample).

### **2. SCOPE**

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

### **3. RESPONSIBILITIES**

The PI is responsible for the training of the SCs and other designated site personnel for the collection and at least the initial processing of laboratory samples, including blood.

### **4. BACKGROUND**

The collection of blood sample(s) as required by the study protocol should consistent between all study visits.

Few processes are more used in clinical research than the drawing of a blood sample and few are more critical in terms of timing, especially on pharmacokinetic (PK) studies. Great care must be taken to maintain Study Participants' (SPs') comfort, integrity of the SPs' veins, and good aseptic technique and universal precautions to minimize the transfer of micro-organisms.

### **5. PROCEDURE**

#### 5.1. Equipment

- 5.1.1. Vacutainer collection tubes as needed per study protocol (verify expiration date)
- 5.1.2. Central lab kit as needed per study protocol (verify expiration date)
- 5.1.3. Vacutainer holder (disposable with each venipuncture)
- 5.1.4. Needle (either safety device butterfly with connector or straight safety device venipuncture needle)
- 5.1.5. 4x4 gauze pads or cotton balls
- 5.1.6. Tourniquet (disposable with each venipuncture)
- 5.1.7. Alcohol pads
- 5.1.8. Exam gloves (non-latex gloves will be needed for use with SPs who are allergic to latex)
- 5.1.9. Band-Aid, tape, and/or Coban wrap

#### 5.2. Preparation

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TITLE: Obtaining a Blood Sample			Page 2 of 4	

- 5.2.1. Ensure working area is clean and good hand washing technique is used both before and after the blood draw.
  - 5.2.2. Introduce self and verify SP's identity (name and date of birth).
  - 5.2.3. Escort SP to the site where the blood draw will be collected.
  - 5.2.4. Explain the procedure to the SP, asking whether he/she gets lightheaded when having his/her blood drawn, and if so, place patient in supine or near supine position.
  - 5.2.5. Inquire about SP's allergies (e.g., latex and/or Band-Aids).
  - 5.2.6. Wash hands.
  - 5.2.7. Open alcohol swab and Band-Aid in preparation for the blood draw.
  - 5.2.8. Place SP's arm out, palm up on a flat surface, arm extended all the way out. Place a tourniquet around one of the SP's arms (approximately 3 inches above the elbow or wrist area). When wrapping the tourniquet, instead of tying it completely, only pull one end part of the way through as to create a loop. This will allow for quick one hand release of the tourniquet.
  - 5.2.9. With tourniquet on, ask SP to make a fist and hold tightly. Locate the best palpable vein by feeling for a "firm, bouncy, or spongy" feeling above the vein. If necessary, repeat 5.2.8 on other arm to locate best vein for the venipuncture by feeling for a "firm, bouncy, and/or spongy" feeling of a vein. Some individuals may need to squeeze and make a tight fist several times before a vein is palpable.
  - 5.2.10. Put on protective gloves.
  - 5.2.11. Palpate vein again with gloved hand.
  - 5.2.12. Cleanse area with alcohol using a circular motion moving from venipuncture site outward approximately 2 inches.
  - 5.2.13. Allow alcohol to air dry or wipe with cotton ball.
- 5.3. Drawing blood
- 5.3.1. Blood will be drawn with a straight needle or a butterfly needle.
    - 5.3.1.1. **Straight Needle.** If you are using a straight needle, simply take the lower cap off the needle and screw it into the Vacutainer holder. Next, place the collecting tube into the Vacutainer holder lightly. Place the Vacutainer holder to the side of the patient's arm with collection tube lightly inside. With a firm grip on the Vacutainer holder, insert needle, bevel side up, at a 10- to 20-degree angle to the surface of the arm and make a smooth entrance into the arm. Insert the needle just past the length of the bevel. While holding the Vacutainer holder steady with a firm grip, push the collection tube into the Vacutainer holder as far as

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TITLE: Obtaining a Blood Sample			Page 3 of 4	

it will go, making sure to puncture the collection tube in the center of the rubber cap. At this point you will know whether you have a blood return. If blood is not flowing freely into the tube, adjust the venipuncture site and/or needle carefully.

- 5.3.1.2. **Butterfly Needle.** If you use a butterfly needle, take the lower cap off the adapter and screw the needle side into the Vacutainer holder. Put the cap that is at the end of the needle's tubing over what is now the end of the Vacutainer holder. Insert the butterfly needle into the arm, ( $\frac{1}{4}$  to  $\frac{1}{3}$  of the needle should be in the arm). Blood return will be seen in the tubing once the needle is within the vein. If blood is not flowing freely into the tubing, adjust the venipuncture site and/or needle carefully
- 5.3.2. Once you have a blood return, let each Vacutainer tube fill to the maximum amount. Blood should stop flowing when the tube is completely filled.
- 5.3.3. When the blood sample is completely obtained, pull one end of the tourniquet with your free hand to remove it. Place the gauze pad or cotton ball lightly over the needle insertion area. With one motion, apply pressure to the gauze as the needle is withdrawn from the access site. Cap needle with safety device.
- 5.3.4. Apply pressure to the gauze with the patient's contra-lateral hand for a full minute or longer if patient is on anticoagulant therapy (e.g., coumadin, heparin, and/or aspirin).
- 5.3.5. Discard all biohazardous materials in the correct container directly after the removal of the needle.
- 5.3.6. Have the SP apply firm pressure over a gauze pad at the venipuncture site for several minutes to prevent swelling and bruising.
- 5.3.7. Apply a Band-Aid over fresh gauze or cotton ball. If SP is sensitive to tape or Band-Aid, use Coban wrap over cotton ball/gauze.
- 5.3.8. Prepare blood for transport to the lab (label tubes, complete requisitions and/or shipping materials as needed per study protocol).
- 5.3.9. Remove gloves and wash hands.

## 6. TERMS & ABBREVIATIONS

<b>PI</b>	Principal Investigator
<b>PK</b>	Pharmacokinetic
<b>SC</b>	Study Coordinator
<b>SP</b>	Study Participant

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TITLE: Obtaining a Blood Sample			Page 4 of 4	

**7. REFERENCES**

None

**8. ATTACHMENTS**

None