**PURPOSE:** The purpose of this Standard Operating Procedure (SOP) is to establish a standard procedure for safe and proper collection of study blood samples at the CRC via venipuncture.

**SCOPE:** This SOP applies to designated research personnel who have received appropriate phlebotomy training.

**RESPONSIBILITY:** The Principal Investigator is responsible for ensuring that all staff involved with the collection of study blood samples are experienced and proficient in venipuncture.

The research designee is responsible for following this SOP when obtaining blood samples for clinical trials.

**DEFINITIONS:**

**Antecubital fossa:** The hollow or depressed area at the bend of the elbow. The median cubital

vein runs superficially midline of the antecubital fossa. The median cubital vein is the best choice for venipuncture as it is least likely to roll, large and easy to access, unlikely to clot during blood collection, and presents the least risk of nerve damage.

**Brachialcephalic vein:** The superficial vein running lateral to the median cubital vein. This is the second best choice for venipuncture and presents like the median cubital vein with a low risk of nerve damage.

**Hemolysis:** The destruction of red blood cells with liberation of hemoglobin, the iron-containing protein.

**Laboratory Requistion:** Form that serves as order and source documentation of laboratory tests.

**Palpate:** To feel or examine by hand.

**Personal Protective Equipment (PPE):** Specialized clothing or equipment worn by a healthcare worker for protection against infectious materials ). Examples include gloves, gowns, masks and goggles.

**Sharps Container:** A sturdy, liquid-proof container utilized to collect used needles or other sharp objects necessary for puncturing the skin or tissue.

**Tourniquet:** A tight encircling band-like device used to forcibly compress a blood vessel.

**Universal Precautions:** Infection control measures used to reduce the risk of transmission of

bloodborne pathogens through exposure to blood or other body fluids. These preventative measures treat all blood and body fluids as infected or disease carrying.

**DEFINITIONS (cont.):**

Measures include:

* Use of single-use disposable injection or percutaneous equipment, or sterilized, if single-use equipment is not available
* Discarding sharps, such as needles, scalpels, etc. without recapping, in rigid, liquid-proof containers that is sealed and destroyed prior to being completely full
* Washing hands with soap and water before and after procedures
* Use of barriers such as gloves, gowns, goggles, or face mask to prevent contact with blood or body fluids
* Disinfecting instruments and contaminated equipments and work space

**Vacutainer:** Plastic or glass tubes used to collect blood samples. Vacutainers may contain various additives that act to separate components of blood or keep blood.

**Venipuncture:** The transcutaneous, sterile procedure used to puncture a vein in order to

withdraw a specimen of blood, or to initiate infusion therapy.

**PROCEDURE:**

1. Perform hand hygiene frequently.
2. Assemble blood collection equipment; place equipment away from study subject.
3. Explain procedure to subject.
4. Ask subject to remove restrictive clothing.
5. Position the subject arms comfortably and safe. Consider lowering extremity to allow veins to fill.
6. Apply tourniquet approximately 3-4 inches above planned puncture site. Do not place too tightly or leave on more than 2 minutes.
7. Palpate for a suitable vein with index finger. The medial cubital vein or brachiocephalic vein are used most frequently.
8. Prepare venipuncture site with alcohol prep. Cleanse in a circular fashion, beginning at the site and working outward. Allow to dry. Do not palpate area after cleansing.
9. Don gloves and other appropriate PPE, if necessary.

**PROCEDURE (cont):**

1. Perform venipuncture using appropriate size needle.
2. If necessary, place each successive tube in vaccutainer to initiate flow.
3. When blood collection is complete, release tourniquet and remove last tube from vacutainer holder.
4. Place a cotton ball or gauze over site, and withraw needle in smooth, cautious manner to avoid bruising the vein.
5. Apply and hold pressure to the cotton ball or guaze over the puncture site until bleeding stops. May ask subject to hold pressure if able.
6. Secure cotton ball or guaze with paper tape or bandaid.
7. Discard needle into red, shaprs container without recapping needle. Dispose any used, remaining equipment in appropriate receptacle.
8. Invert each tube gently if instructed per the protocol. Do not shake as vigorous mixing may cause hemolysis.
9. Label each tube with subject ID, date and time of draw. If requested by sponsor, may need to include location of site draw (i.e: left antecubital, etc).

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| **REFERENCES:** | CDC Universal Precautions for Preventing Transmission of Bloodborne InfectionsOSHA Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens |
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| **RELATED POLICIES:** |  |
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| **APPENDICES:** | None |
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| **REVISION HISTORY:** Keep a running history of all revision dates |
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| **Approval Date** | **Effective Date** |  **Review/Revision Date** |
| **01/01/2015** | **01/01/2015** | **06/01/2016** |
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