KILIMANJARO CHRISTIAN MEDICAL CENTRE (KCMC)
AIDS RESEARCH UNIT (ARU)
Standard Operating Procedure

TITLE: VENIPUNCTURE	

PURPOSE: To establish a standard procedure for safe and appropriate collection of study blood samples via venipuncture conducted under the KCMC ARU. To ensure proper technique and handling necessary for specimen integrity and to safeguard subject and phlebotomist and data quality.

POLICY: The Principal Investigator designates the collection of blood for study laboratory procedures via venipuncture to the clinical trials phlebotomist(s).

RESPONSIBILITY:

Principal Investigator: The Principal Investigator will assure that all staff involved with venipuncture are experienced and proficient in the collection of study blood samples.

Clinical Trials Phlebotomist/Clinical Research Nurse: The clinical trials phlebotomist/clinical research nurse will follow policy and procedure in the collection of clinical trials blood samples collected via venipuncture. The clinical trials phlebotomist will assure that: 1) all blood samples collected are correctly labeled, 2) that source patient is verified against requisition and labels, 3) that time and date of draw are recorded, 4) that correct order of vascutainer fill, determined by vaccutainer additive and medical laboratory standards are followed, 5) that the site of venipuncture is adequately prepared and sterilized, 6) that the work station where venipuncture is done is clean, stocked with necessary supplies, and organized, and, 7) that equipment needed for venipuncture is available.

Clinical Research Coordinator: The clinical research coordinator or research nurse designee will assure that informed consent has been obtained prior to any clinical trials blood collection via venipuncture occurs. The clinical research coordinator (or designee) will assure that laboratory kits or at minimum labels, including requisition for visit specified protocol laboratory testing accompany study participant to phlebotomy draw station.

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 presents a low risk of nerve damage.

Hemolysis: The destruction of red cells with liberation of hempoglobin, the iron-containing pigment.

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

ordered for specific study subject and visit. Included on the form are the patient identification number (PID), study identification number (SID), time and date of draw, and phlebotomist drawing sample(s) initials.

Palpate: To feel or examine by hand.

Sharps Container: A sturdy, liquid-proof container used to collect used needles or other sharp objects used 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 body fluids. These preventative measures treat all blood and body fluids as infected or disease carrying. Measures include: 1) use of single-use disposable injection or precutaneous equipment, or sterilized if single-use equipment is not available; 2) discard sharps, such as needles, scalpels, etc. without recapping, in rigid, liquid-proof containers that is sealed and destroyed prior to being completely full; 3) wash hands with soap and water before and after procedures; 4) use of barriers such as gloves, gowns, goggles, or face mask to prevent contact with blood or body fluids; and 5) disinfect instruments and contaminated equipments and work space.

Vaccuatiner: Plastic or glass tubes used to collect blood samples. Vaccutainers may contain various additives that act to separate components of blood, or keep blood from clotting.

Venipuncture: The transcutaneous, sterile procedure used to punctures a vein in order to withdraw a specimen of blood, or initiate infusion therapy. For purposes of this SOP, only withdrawal of blood is defined.

PROCEDURE:

Blood collection is to be drawn according to protocol specifics for all study subjects or screen potentials who have provided written informed consent to participate in a study and employing techniques of universal precautions. Sterile needles and vaccutainer collection systems or syringes will be used for all blood collections. Blood collection tubes must be drawn in a specific order to avoid cross-contamination of additives between tubes. The recommended order of draw is:

First - blood culture tube (yellow-black stopper
Second - non-additive tube (red stopper or SST)
Third - coagulation tube (light blue stopper). If just a routine coagulation assay is the only test ordered, then a single light blue stopper tube may be drawn. If there is a concern regarding contamination by tissue fluids or thromboplastins, then one may draw a non-additive tube first, and then the light blue stopper tube.
Last draw - additive tubes in this order:
1. SST (red-gray, or gold, stopper). Contains a gel separator and clot activator.
2. Sodium heparin (dark green stopper)
3. PST (light green stopper). Contains lithium heparin anticoagulant and a gel separator.

4. EDTA (lavender stopper)
5. ACDA or ACDB (pale yellow stopper). Contains acid citrate dextrose.
6. Oxalate/fluoride (light gray stopper)

NOTE: Tubes with additives must be thoroughly mixed. Erroneous test results may be obtained when the blood is not thoroughly mixed with the additive.

NOTE: For plastic tubes, the order of draw for tubes 2 and 3 is reversed.

1) Equipment and Supplies: a) Sterile vaccutainers and evacuated collection tube system (butterfly or needles with holder/adapter), or 21 gauge needle or less, with 20 mL syringe), b) tourniquet, c) alcohol wipes, alcohol applied with clean cotton, gauze or sponge, or betadine/iodine to disinfect the area of draw, d) labels, e) permanent ink, f) gloves, and g) sharps container for disposal of used needles, syringes and vaccutainers (if applicable). Sharps container must never be filled greater than ¾ prior to destruction in order to avoid accidental needle sticks. The container should be labeled as biohazard.

2) Selection of Vein: Selection of vein is individual preference though the median cubital vein located midline to the antecubital fossa is an excellent choice. If the median cubital vein or brachialcephalic vein are unacceptable, the write or hand veins may be used. Never perform venipuncture from an infected area or from an arm receiving intravenous therapy. Avoid sites with extensive scarring, hematomas, and swelling.

3) Drawing Blood: a) Verify study subject to be drawn against requisition and blood collection tube labels. b) Wash hands with soap and water. c) Arrange vaccutainers in order of fill. d) Place tourniquet approximately 3-4 inches/7.5-10 cm above venipuncture site. Tourniquet should be tight enough to distend the vein but not so tight that it causes arterial occlusion. Instruct patient to clench and unclench fist of arm to be accessed several times in order to trap blood in vein and distend for venipucnture. e) Clean venipuncture site to be accessed and allow to dry. If using betadine, confirm whether subject has an allergy to iodine prior to use. f) Remove protective cover from needle. With free hand, stretch skin at site and stabilize vein to be drawn. Align needle with the vein and pierce skin with bevel edge of needle up at 15 to 30 degree angle. Decrease angle until almost paralell to skin surface, then pierce vein wall. Use a firm forward motion. If using a vaccutainer draw system, allow vaccutainer to fill naturally from vacuum pressure provided. If blood flow stops during draw, rotate needle slightly or advance, or withdraw needle slightly. g) When the last vaccutainer is filling and prior to removing the needle from the site, remove the tourniquet. This prevents hematomas from forming. If using a needle and syringe system, remove the tourniquet directly prior to withdrawal of the needle from the site. h) Once blood collection is complete, withdraw needle and dispose of in sharps container. Apply firm pressure to venipuncture site until site stops bleeding. Elevate site and avoid bending to prevent hematoma from forming. i) If using a needle and syringe to draw blood, pull syringe plunger gently back to establish vacuum. Pulling too vigorously will cause frothing of the blood sample and hemolysis. Immediately after drawing transfer whole blood into correct vaccutainers for test to be performed. Allow the vacuum of the vaccutainer to transfer blood from the syringe to the tube. Pushing blood

from the syringe into the vaccutainer may cause hemolysis of the sample. If vaccutainer contains an additive to prevent blood coagulation, such as EDTA, ACD, or heparin, invert the vaccutainer gently back and forth 10 times. ji) Remove and dispose of gloves and wash hands with warm water and soap. k) Document date and time of draw and initials of person erforming venipuncture blood collection on laboratory requistion form.

Additional Precautions: a) Roll all garments above the site of venipuncture. b) A limit of two tries by a phlebotomist to obtain samples should be followed before allowing someone else to attempt blood collection. If unable to obtain specimen from the study subject, notify the study coordinator and document the process. c) Some people may have allergic reaction to latex containing barriers, such as gloves and to the latex bands used as tourniquets. Non-latex products are available for subjects or employees who are allergic. These include rubber and vinyl gloves and fabric bands.

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4) Distribution of Study Blood Specimens to Receiving Laboratory

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a) Samples obtained by clinical research nurses are walked over to the receiving laboratory at least once daily, before 3 PM. All study chemistries are drawn at the hospital phlebotomy laboratory in order to eliminate time of draw until processing. b) The distribution of the study specimen is logged by the clinical research nurse distributing the samples by date, time, subject identification number, person distributing the sample, and the person receiving the sample in the laboratory. c) The log book accounting for distribution of study samples remains in the clinical research office, in a locked file cabinet.