Purpose:
To provide standards for phlebotomy and retrieval of blood samples, in a manner which ensures the delivery of safe, competent, and effective care, and to meet study goals.

Policy:

- All clinical research nurses or research project assistants must be certified in the performance of phlebotomy before performing this procedure without supervision.

- A signed IRB approved consent and a physician’s order are necessary for the initiation of phlebotomy and for blood sampling.

- A phlebotomy certified clinical research nurse may initiate a venipuncture for phlebotomy utilizing the upper extremities.

- A Butterfly needle set will be used for all phlebotomy in the CTRC. The gauge is determined by the nurse, based upon protocol requirements, condition of veins, and amount of blood to be drawn, using the largest gauge feasible.
• Phlebotomy will not be attempted if the nurse cannot locate an appropriate site, and/or if the subject expresses the desire to exit from the study.

• If the nurse is unable to phlebotomize a subject after a thorough assessment and/or two attempts another nurse should be requested to assess and attempt.

• The nurse will attempt up to two venipunctures. If unsuccessful, another nurse or the nurse manager may attempt to phlebotomize with the verbal permission of the subject. If unsuccessful or lacking the permission of the subject the Principal Investigator will be notified of the difficulty and the study procedure will be aborted.

• Lidocaine patch or Spray and Stretch may be used as a local anesthetic prior to phlebotomy in children.

• A new butterfly set will be used for each attempt.

• Phlebotomy will be initiated after verification of subject ID, physician order and sample requirements of protocol.

• Sample vacutainer tubes to be filled shall be properly labeled prior to use with the subject ID number, date of birth and date of draw.

PROCEDURE:

A. Prior to initiation of phlebotomy for purpose of blood sampling

1. Check for signed, dated approved consent form, signed physician’s orders, and completed inclusion/exclusion criteria form.

2. Ascertain the subject’s ID, name, date of birth. Assess the subject’s understanding of the study and the procedure to be done at this visit.

3. Explain procedure to subject.

4. Wash hands thoroughly or use hand sanitizer.

5. Prepare study procedure equipment.
B. Prepare study procedure equipment:

1. Inspect the integrity of equipment.
2. Butterfly set, largest bore suitable for subject’s veins
3. Vacutainer holder
4. Labeled vacutainer tubes per protocol
5. Alcohol swabs
6. Clean gloves
7. 2x2 sterile gauze pads
8. Tourniquet
9. Squeeze ball

C. Initiation of Phlebotomy

1. Assess the condition of the subject’s veins by palpation concentrate on the anticubital veins
   
   a. Apply tourniquet above intended IV site

   a. Apply tightly enough to impede venous flow, without occluding arterial flow.

   b. Tie tourniquet in a manner to allow release with one hand.

   c. Application of heat in the form of heat packs may be indicated for promotion of venous dilatation.

2. Prepare the insertion site:

   a. Cleanse skin by cleaning with an alcohol prep using aseptic technique starting from center of proposed site and in a circular motion away from site for 30 seconds.

   b. Do not touch the prepped area with your fingers. If palpable reassessment of the vein needs to be done, re-prep the skin prior to venipuncture.

3. Don clean gloves.

4. Insert Butterfly needle at the prepared site, ascertain blood “flash” in needle hub.
5. Push vacutainers into vacutainer holder piercing stopper with needle.

6. Order of draw for vacutainers:
   - Red
   - Gold (serum separator)
   - Blue
   - Green
   - Yellow
   - Lavender

7. Gently agitate lavender, blue, green and yellow top vacutainers after filling.

8. After filling the last vacutainer release tourniquet.

9. Retract needle of Butterfly

10. Apply a pressure dressing of sterile 2X2 gauze and Coban

References: State of California Business and Professions Code, Division 2, Chapter 3, Sections 1242.5 and 1246 (b) as well as the California Administrative Code, Title 17, Chapter 2, Subchapter 1, Group 2, Article 1, Section 1034.

Appendices: All RNs who have successfully completed the Intravenous Therapy Course including post-test and clinical component involving three (3) venipunctures and (3) blood component administrations under direct supervision of an I.V. trainer, may:
   1. Initiate I.V. therapy by primary and secondary infusion lines,
   2. Administer I.V. medications as noted in the I.V. Therapy Manual,
   3. Administer blood and blood products, and
   4. Perform phlebotomy.

Note: RNs previously IV certified in another institution, including blood administration, must challenge the I.V. Therapy Certification Program exam and a supervised clinical venipuncture experience involving (3) venipunctures and (3) blood component administrations.