

Biomedical Research Techniques Performed in a Non-Clinical Setting

The IRB formulated these guidelines for investigator qualifications to minimize risk to participants. Documentation of qualifications must be submitted to the IRB with the IRB request for review unless it is already on file with Research Protections. Many of the qualifications for biomedical research techniques include a competency assessment which is described in detail below.

The IRB recognizes the need for periodic reassessment of competency and/or training to ensure that techniques minimize risk to participants. If an individual has not performed procedures within 2 years, the individual must have their competency reassessed.

Finger Sticks: Non-medically certified individuals must be trained and have their competency evaluated by an appropriate instructor (e.g., experienced faculty member, registered nurse) prior to performing finger sticks.

Standard Venipuncture: An individual performing standard venipuncture must meet the following criteria:

- 1) possess a certification for standard venipuncture; or complete documented training (a venipuncture course; or training in topics covered by a venipuncture course by an individual who has met the IRB qualifications for standard venipuncture) and supervised experience (20 successful attempts); and
- 2) have a competency assessment for the target population completed by a NC licensed physician or registered nurse.

Peripheral Venous Catheter: An individual inserting, maintaining or withdrawing blood from a peripheral venous catheter must be approved for standard venipuncture; licensed if required by law; and meet the following criteria:

- 1) possess a certification to insert, maintain, and withdraw a peripheral venous catheter; or complete documented training (i.e., a peripheral venous catheter course) and supervised experience (25 successful attempts); **and**
- 2) have a competency assessment for the target population completed by a NC licensed physician or registered nurse.

A faculty member approved to use the technique, a NC licensed physician, or a registered nurse must supervise any students that are approved by the IRB to insert, maintain, or withdraw blood from a peripheral venous catheter. "Supervision" entails that the faculty member or medical professional is readily available to respond to questions or concerns.

Risk Language of ASU Performed Biomedical Research Techniques-Consent Form

a. Standard Venipuncture: The risks of collecting a blood sample from you include the possibility of requiring more than one attempt to obtain the blood sample, local discomfort (pinch when the needle enters your skin), minor bruising or bleeding at the site (10%), possible temporary lightheadedness, infection (<0.01%), or development of a blood clot (<0.01%). The amount of blood being withdrawn is about [state as X teaspoons or tablespoons] and will not affect your ability to participate in normal daily activities [explain if otherwise]. A trained and experienced individual will perform the technique and your blood will be collected in a hygienic setting with sterile materials and biohazard protection measures to minimize these risks. In the rare case of exposure

of your blood or tissue to research personnel, your blood will be tested for HIV and hepatitis (a positive HIV or hepatitis test will be reported to you).

b. Catheterization: The risks of collecting a blood sample from you include the possibility of requiring more than one attempt to obtain the blood sample, local discomfort (pinch when the needle enters your skin), minor bruising or bleeding at the site (10%), or possible temporary lightheadedness, infection (<0.01%), or development of a blood clot (< 0.01%). These risks are slightly increased compared to a standard blood draw. The amount of blood being withdrawn is about [state as X teaspoons or tablespoons] and will not affect your ability to participate in normal daily activities [explain if otherwise]. A trained and experienced individual will perform the technique and your blood will be collected in a hygienic setting with sterile materials and biohazard protection measures to minimize these risks. In the rare case of exposure of your blood or tissue to research personnel, we will analyze your blood for HIV and hepatitis (a positive HIV or hepatitis test will be reported to you).

c. DEXA: The risks associated with a DEXA scan include exposure to small amounts of radiation. DEXA scanning utilizes radiation to obtain an image of your body. Everyone receives a small amount of unavoidable radiation from the environment each year. Some of this radiation comes from space and some from naturally-occurring forms of radioactive water and minerals. The DEXA scan technique gives your body the equivalent of about 4 extra days' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this study only and does not include any exposure you may have received or will receive from other tests. If you are pregnant or trying to get pregnant, you should not participate in a DEXA scan.