



Office of Research Compliance

THE TEXAS A&M UNIVERSITY SYSTEM

GUIDELINES FOR THE COLLECTION OF BLOOD SPECIMENS VIA VENIPUNCTURE FOR HUMAN RESEARCH PURPOSES

1. GUIDING PRINCIPLES

1.1. Safety of Research Participants and Research Personnel

These guidelines were established to enhance the safety of blood draws for human participants and staff performing phlebotomy by promoting best practices in phlebotomy. For the purposes of this guidance, the term phlebotomy means blood sampling for the purposes of laboratory tests and blood collection for donation.

System members must ensure that any person performing phlebotomy as a part of a research protocol is well-trained and confident in the technique and has access to the necessary supplies and materials needed to protect the participants in any research protocol requiring a blood draw.

1.2. Best practices in phlebotomy involve the following factors:

- Appropriate training in phlebotomy;
- Use of an appropriate location; and
- Use of appropriate supplies and protective equipment.

1.3. Flexibility in Establishing Standard Operating Procedures

Each System member conducts different kinds of research with different protocols. The phlebotomist performing the blood draw must be well-trained, but a variety of ways exist for the phlebotomist to obtain that training. What is most important is that the phlebotomist be able to demonstrate competency in the technique and perform it with minimal negative effect on research participants.

This guidance is meant to provide system members and their researchers flexibility in establishing standard operating procedures for blood collection from human participants and donors.

2. SCOPE AND APPLICABILITY

- 2.1. These guidelines are intended to provide a framework for system members to mitigate the risks associated with the collection of blood specimens for research purposes, to identify the minimum qualifications for those engaged in collecting blood specimens from individuals, and to outline

phlebotomy best practices. System members have discretion to implement additional requirements.

3. MINIMUM QUALIFICATIONS FOR THOSE COLLECTING BLOOD SPECIMENS

3.1. Personnel performing phlebotomy for research must demonstrate appropriate education and training to reduce risks of exposure to blood and adverse events for participants and donors. At least one of the minimum standards set forth below must be met:

- Completion of a Phlebotomy Certification from a qualified program or institution; documentation required;
- Maintain a valid state license for which phlebotomy is within the scope of practice such as a nurse (RN or LVN), physician assistant, paramedic, etc.; proof of licensure required;
- Be properly trained and qualified and acting under a licensed physician's supervision; written documentation of supervision required; or
- Be appropriately trained and qualified employee of a contract organization that provides clinical or phlebotomy services.

3.2. Training should include techniques that ensure that the specimen collected will be adequate, measures that reduce the risk of contamination, infection, injury and error. Training should also include both theory and supervised hands-on specific skill(s) demonstration.

3.3. Minimum Training Standards

The minimum training standards recommended below were obtained from surveying National Training Commonalities and World Health Organization guidelines on blood drawing. Before undertaking phlebotomy, those performing blood draws should

- demonstrate proficiency for, the blood collection procedures on the population that will be within their scope of practice
- be at least 18 years of age
- complete bloodborne pathogen training and enroll in an occupational health program;
- review the System member's Bloodborne pathogens exposure control plan;
- have knowledge in anatomy of the sites from which blood access is authorized;
- demonstrate proficiency in standard practices such as:
 - Selection and use of PPE
 - Coaching patients through process
 - Selecting and assembling phlebotomy equipment
 - Labeling and documentation
 - Locating veins for venipuncture,
 - Palpation
 - Tourniquet application
 - Disinfection of venipuncture site (alcohol wipes, etc.)
 - Applying gauze and bandages
 - Proper use of syringes, butterfly needles and vacuum blood collection tubes
 - Sample preparation for lab transfer
 - Disposal of potentially infectious material (sharps, blood contaminated gauze, towels, etc.)
 - Process for disinfecting reusable items such as scissors, tourniquets, specimen carriers, etc.

- demonstrate knowledge in participant protection practices
 - Participant rights and informed consent
 - Proper participant identification
 - Procedures for unsuccessful draws
 - Awareness of special considerations related to health history (for example prohibitions on drawing on the same side as a mastectomy, through infected tissue, through scar tissue, history of fainting, etc.)
 - First aid, CPR, and emergency response procedures

4. LOCATION

4.1. Phlebotomy should be performed in a clinical setting or a dedicated phlebotomy room that allows for privacy and contains or has access to:

- a clean surface with chairs that have armrests for the donor;
- a table or counter for supplies and documentation purposes;
- a hand wash basin with soap, running water and paper towels;
- alcohol hand rub
- a puncture-resistant sharps container; and
- a phone for emergency use

4.2. The System member's Institutional Biosafety Committee (IBC) / Research Compliance office should be consulted about the suitability of nonclinical locations or field sites under consideration for particular human research projects.

5. SUPPLIES AND PROTECTIVE EQUIPMENT

5.1. The phlebotomist should collect all the equipment needed for the procedure and place it within safe and easy reach on a tray or trolley, ensuring that all the items are clearly visible.

5.2. The required equipment includes:

- a supply of laboratory sample tubes, which should be stored dry and upright in a rack; blood can be collected in
- vacuum-extraction blood tubes; or
- glass tubes with screw caps;
- well-fitting, non-sterile gloves;
- an assortment of blood-sampling devices needles and
- syringes of different sizes;
- a tourniquet;
- alcohol hand rub;
- 70% alcohol swabs for skin disinfection;
- gauze or cotton-wool ball to be applied over puncture site;
- laboratory specimen labels;
- writing equipment;
- laboratory forms;
- leak-proof transportation bags and containers; and
- a puncture-resistant sharps container.