Requirements for the Practice of Human Blood Drawing (Phlebotomy) for Research Conducted at Virginia Tech

Environmental Health and Safety requires the following guidelines for implementation and ongoing operation of human blood drawing (phlebotomy) for use in research at Virginia Tech.

Research groups at Virginia Tech may implement more stringent requirements than those outlined below.

General Guidelines

1. Phlebotomists must comply with all aspects of OSHA BBP regulations.

2. Anyone working in an area where phlebotomy will be conducted must have awareness training of the risks from blood exposure and the consequences of poor infection prevention.

3. There must be no contraindications for blood withdrawal that would injure the subject or contraindications that would undermine the research goals. This can be confirmed by a simple questionnaire drawn up by the PI or designee.

4. All blood draws are performed by personnel who are proficient in both phlebotomy and safe handling of blood and human tissues.

   Proficient personnel includes:

   a. Medical or Nursing license
   b. Medical Technologist license or certification
   c. Phlebotomist license or certification
   d. Advanced EMS certification
   e. Documentation of training provided by a trained instructor

5. Any phlebotomy instructor is deemed qualified to train a new phlebotomist if he/she meets the certification or licensure requirements above. Training parameters and determination of a trainee's competence is at the discretion of the qualified trainer.

6. Proficiency evaluation and the need for refresher training will be at the discretion of the department if there has been an occupational break in blood drawing for the phlebotomist.

7. Informed consent is obtained prior to any blood withdrawal procedure. The initial IRB-approved informed consent form signed by a study participant is sufficient for the duration of the research project. The PI is responsible for complying with all IRB

requirements. Unless the phlebotomist is part of the research group, there is no need for the phlebotomist to track consent documentation.

8. No undue coercion may be used to acquire cooperation for subject participation. PI must ensure that the phlebotomist understands this.

9. Ample time must be allowed for the participant to consider whether to participate in the study (as deemed by IRB).

10. Prospective collection for genetic research ALWAYS requires signed informed consent; counseling services may be advised or required.

11. Written protocol with diagrammed instructions must be available if the subject would like to review the document.

12. All blood samples must not exceed the minimal amount necessary. This amount must be approved by the IRB.

13. Incident reporting requirements must be followed, and forms must be available for the phlebotomist (see Appendix A.)

14. The phlebotomist must be aware that the research subject may refuse to participate in the blood draw at any time during the research project.

Safety

Appropriate Location

1. Blood draws must be conducted in an appropriate location.

2. Floors must not be carpeted. If the only option is a carpeted space, plastic or other impervious and cleanable material must be used to cover the carpet.

3. One or more comfortable chairs must be available. Chair covers must be non-porous or a cleanable and impervious cover will be used. Chairs must be used for the subject unless mid-exercise samples are required by the research. Chairs must be available in case the exercise subject becomes light-headed. The phlebotomist may prefer to use a rolling stool for blood draws.

4. A dedicated space must contain a hand washing basin and sterile/nonporous work surface. Standard Operating Procedures (SOPs) for hand hygiene and equipment/area decontamination must be developed by research personnel for blood draws that will take place in spaces that are not dedicated blood draw rooms.

5. Phlebotomies must not occur in a space where pathogens are being manipulated.

6. Space should have a curtain or door for privacy if possible.

7. Space must not be used for eating or drinking.

Infection Prevention

1. The employer must provide hepatitis B immunization, or documentation that it was offered; post-exposure services must be provided to phlebotomist.

2. A Hand Hygiene Protocol must be in place for all persons performing phlebotomies.

3. Personal Protective Equipment must be available and used.

4. Single-use gloves must be worn during all blood withdrawal procedures. Gloves must be changed between subjects. Avoid using latex gloves.

5. Tourniquets must be single-use or cleaned before the next use; latex must be avoided in case of subject or phlebotomist allergy to latex.

6. Only single-use/one-hand cap devices must be used for blood withdrawal.

7. An SOP for pre-phlebotomy skin disinfection must be in place. The phlebotomist must be trained on the skin disinfection SOP for any research specific requirements.

8. A Sharps container must be no more than 4 feet from the phlebotomy chair.

9. Work surfaces must be decontaminated/disinfected for the appropriate contact time immediately after work is complete. Suitable disinfectants[5] include:
    a. A 1:10 dilution of 5.25%-6.15% sodium hypocholorite (i.e., household bleach) for 10 min contact time. NOTE: A dilution of 70% Ethanol may be used to remove chlorine residue following disinfection to reduce the wear on metal surfaces.
    b. An EPA–registered tuberculocidal disinfectant, used for contact time listed on the disinfectant.

Transportation of Blood Samples

Blood samples that are to be transported outside the building will be sealed in appropriately labeled, leak-proof primary tubes/flasks/containers and disinfected on the outside before being placed into a durable, leak-proof secondary transport container. A biohazard symbol will be placed on the primary container. The secondary container will be disinfected and secured for transport.

Equipment

a. Chairs
b. Vacutainer® system/extraction tubes or other appropriate blood collection equipment
c. Tourniquets (avoid latex)
d. Skin disinfectant
e. Hand washing basin
f. Specimen storage equipment
g. Transportation bags/containers
h. Labeling equipment
i. Cotton gauze & tape/bandages
j. Single-use gloves, latex must be avoided

Records Management

1. PI must maintain copies of all active protocols (including: letters of approval, consent forms, informative documents & responsible party information) and SOPs.

2. The PI is responsible for maintaining original signature documents and consent forms per IRB requirements.

3. Phlebotomists must follow PI requirements for blood draw documentation such as: date, time, site and amount of draw, etc.

4. Phlebotomy related SOP's must be reviewed annually and updated as needed.

References

WHO Guidelines on drawing blood: best practices in phlebotomy. 2012. World Health Organization (WHO).

Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards. 2012. Office for Human Research Protections (OHRP). U.S. Department of Health and Human Services.

Blood Drawing for Human Subject Research. 2008. Duke University Health System.

Research Studies Involving the Collection of Blood Samples. 2008. Wayne State University, Human Investigation Committee.

Guideline for Disinfection and Sterilization in Healthcare Facilities. 2008. Center for Disease Control and Prevention (CDC).

Appendix A: Incident Response and Reporting

Response Procedures

Exposure Incident:

1. Immediately report any incident, accident or potential exposure to the PI, Lab Manager or other emergency contact for the laboratory. That person will advise and direct the appropriate course of action.
2. Elapsed time following exposure can be critical, so act quickly. In some instances, prophylactic medications can be given within the first few hours of exposure which will significantly lessen infection risk.
3. If deemed appropriate, treatment must be obtained in the Emergency Room of the nearest hospital. The appropriate response: DIAL 911.

Physical Injury:

1. Provide immediate first-aid: stop bleeding of wounds and, if appropriate, wash the affected area with disinfectant/soap.
2. If the incident is a medical emergency, DIAL 911 immediately.

Eye Exposure:

1. Immediately flush eyes for 5-10 minutes using an eyewash station.

Needle Stick:

1. Clean and wash area thoroughly, using antimicrobial soap or mild disinfectant, for a minimum of 5 minutes. Gently massage the area to make it bleed during this time.

Mucous Membrane Exposure:

1. Immediately flush membranes if possible. Go to an appropriate healthcare provider for treatment (Emergency Room, primary care physician, Student Health Services, etc.).

Reporting Procedures

1. As soon as any initial response is complete and incident is stable, *immediately notify* the Lab Director and/or Lab Manager, the Animal Facility or greenhouse Manager (if applicable), and the University Biosafety Officer (UBO).

    a. The UBO will acknowledge receipt of notification via email (to document notification) to the reporting person and other appropriate personnel.
    b. If UBO does not acknowledge receipt of notification within two (2) hours, notify an Associate Biosafety Officer (ABO).

    c. If email is not available, the UBO/ABO will acknowledge receipt via phone call to the reporting person and other appropriate personnel.

2. Reporting person and Lab Director/ Lab Manager/Animal Facility Manager must complete the VT Lab Incident Report and submit it to the UBO/ABO via email immediately.

   a. The VT Lab Incident Report can be downloaded from the following URL: http://www.ehss.vt.edu/detail_pages/document_details.php?category_id=18&document_id=320

   b. If an injury or exposure has occurred, an Employer's Accident Report must be completed immediately by the supervisor per directions found at: https://www.hr.vt.edu/benefits/health-insurance/workers-compensation/employers-instructions.html

Contact	Primary Method (cell phone)	Secondary Method (email)
UBO-Charlotte Waggoner	540-320-5864	ren@vt.edu
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Annual Document Review/Revision Status

Date	Revision #	Comments	Reviewer