STANDARD OPERATING PROCEDURE (SOP)
Phlebotomy Stations Outside of Clinical Care Areas

1. Scope

This SOP was designed to establish a standardized procedure for establishing a safe and appropriate location and method for obtaining human blood and human blood products for research purposes. Human blood draws conducted outside of clinical care areas at the University of Pittsburgh must follow the guidelines of this SOP. Areas utilized for blood draws should follow the requirements listed in Section 4.4 of this SOP. This SOP incorporates regulations and recommendations from the *Occupational Safety and Health Administration Needlestick Safety and Prevention Act* (29 CFR 1910.1030), *the University of Pittsburgh Bloodborne Exposure Control Plan*, University of Pittsburgh General Counsel, the University Biohazards Committee, University of Pittsburgh Institutional Review Board (IRB) and the Department of Environmental Health and Safety (EH&S).

Blood draws conducted outside of University of Pittsburgh or University of Pittsburgh Medical Center (UPMC) spaces are not covered by this SOP. Blood donation drives conducted by outside entities are covered by other University polices.

2. Purpose

To provide options for obtaining human blood and human blood products for research purposes. To provide recommendations for safely conducting blood draws in spaces outside of clinical care areas.

3. Blood Draw Locations

Human blood samples required for laboratory research work should be obtained from the Central Blood Bank or human donors should donate blood through the Clinical and Translational Research Center (CTRC) at the University of Pittsburgh or other approved locations registered through the University of Pittsburgh EH&S Department.

3.1 Central Blood Bank

The Central Blood Bank offers human blood and human blood products for purchase. Whole blood, white blood cells and salvage plasma are available through the Blood Bank and these products can be delivered to the research laboratory (transportation fee included) or picked up by research personnel. Any blood or blood product picked up by research personnel is required to be transported to the laboratories according to all Biosafety Level 2 practices for BSL-2 agent transport. The following is contact information for the Blood Bank:

Central Blood Bank
Five Parkway Center 875 Greentree Road
Pittsburgh, PA 15220
Phone – (412)-209-7000
Website – www.centralbloodbank.org

Contact Personnel – Darrell Rodgers
Phone – (412)-209-7194 (Research Request Line)
Email – drodgers@itxm.org

3.2 Clinical and Translational Research Center (CTRC)

The CTRC offers the University of Pittsburgh School of Medicine faculty and staff a clinical research environment. CTRC facilities are located at Children's, Montefiore, Magee Women's Hospital, Hillman Cancer Center and Western Psychiatric Institute and Clinic. Information on the CTRC can be found at the following website, http://www.muhctrc.pitt.edu/content.asp?id=294.

The following is contact information for the CTRC:

Phone – (412)-648-6691
Email – muhctrc@upmc.edu

3.3 Other Approved Locations

Research groups that establish other approved locations for the purpose of conducting human blood draws are required to follow the established guidelines as defined by this SOP in section (4) below and register with the University of Pittsburgh Environmental Health and Safety Department. The EH&S Department can be contacted via departmental email (safety@ehs.pitt.edu) or office phone (412)-624-9505.

4. Requirements

4.1 Safety-Engineered Sharps Devices

The OSHA Bloodborne Pathogen Standard, *29 CFR 1910.1030* (supported by the University of Pittsburgh Bloodborne Exposure Control Plan) defines the required usage of Safety-Engineered Sharps Devices for any clinical research (including blood draws and injections).

University personnel conducting human blood draws are required to use Safety-Engineered Sharps Devices effective **March 1, 2006.** Any blood draws planned to be conducted in spaces outside of clinical care areas initiated after the effective date (March 1, 2006) are required to contact the EH&S Department to register the location of the blood draws and Safety-Engineered Devices used in the study prior to the start of the blood draws.

4.2 IRB Protocol

All research studies involving human subject blood draws are required to obtain IRB approval of the research protocol prior to initiating blood draws. Investigators must comply with all IRB requirements, including training requirements.

4.3 Consent Forms

All persons donating blood are required to sign consent forms per Pennsylvania state regulations prior to initial blood draws. If the blood draw is part of a research protocol, an IRB approved consent form must be completed and utilized.

If the blood draw is for control usage / equipment calibration purposes, the researcher should contact the Office of General Counsel to obtain a template consent form prior to conducting the blood draw.

4.4 Location of Laboratory Phlebotomy Stations

Blood draws in spaces outside of clinical care areas should be conducted in a room that is separated by a door from bench space, biological safety cabinets or other laboratory equipment that is used to handle or store biological or infectious agents. Space utilized for blood draws should be separate from active manipulation of infectious biological agents and active work with hazardous chemical agents prior to the blood draw (for area disinfection purposes), at the time of the blood draw, and until disinfection procedures have been completed after the blood draw.

Blood draw areas must follow all BSL-2 work practices including:

4.4.1 *Furniture* – Blood draw chair or table should be made of a material that can easily be disinfected (Ex. vinyl or plastic furniture).

4.4.2 *Sharps containers* – An approved Sharps disposal container should be available in the blood draw area at the point of use. All glass items and needles must be disposed in an approved Sharps container.

4.4.3 *Disinfectant* – Bleach solution or an EPA registered disinfectant should be available in the blood draw area in the event of a spill.

4.4.4 *Spill or Emergency Procedure* – A procedure to handle spill cleanup or emergency response information should be posted at the point of use.

4.4.5 *Biohazardous Waste Disposal* – Biohazardous waste bags and boxes must be used to dispose of all plastic ware and personnel protective equipment.

4.4.6 *Biohazardous Signage and Labeling* – All clinical laboratory spaces must be labeled with a biohazardous door sign designating the space as BSL-2. All equipment used to store and handle human blood and blood products must be labeled with a biohazardous sticker.

4.4.7 *Personnel Protective Equipment* - Personnel conducting blood draws are required to wear the appropriate personnel protective equipment (PPE). This includes liquid barrier gloves (latex or nitrile), face protection (full face shield or surgical mask and safety glasses) and lab coat or lab gown that can be laundered or disposed in event of a blood splash or spill.

4.5 Personnel Conducting Blood Draws

The principal investigator is responsible for verifying that laboratory personnel performing blood draws have sufficient training and experience in conducting human blood sampling. Qualifications may include prior experience as a trained phlebotomist, nurse or emergency medical technician. All research personnel conducting human blood draws or work with human blood and blood products must complete bloodborne pathogen training on an annual basis. Information on training is available at the following site: