OHRP has ruled that for all Federally sponsored research, informed consent must be obtained before identifiable specimens may be collected for research purposes. This applies to any research that is done at an institution that receives Federal funding. The following guidance and the new Blood Drawing Protocol form have been developed to help standardize procedures to establish safe practices in the collection of human blood and human blood products for research purposes.

Submission of the Blood Drawing Protocol for review and approval will assist the IRB in ensuring that donors’ who are participating are protected.

**Blood Drawing in Non-Clinical Settings**

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 infectious agents. Space utilized for blood draws should be separated 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:

1. Furniture – Blood draw chair or table should be made of materials that can easily be disinfected (example vinyl or plastic furniture)
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 of in an approved Sharps container.
3. Disinfectant – Bleach solution or an EPA registered disinfectant should be available in the draw area in the event of a spill.
4. Spill or Emergency Procedure - A procedure to handle spill cleanup or emergency response information should be posted at the point of use.
5. Biohazardous Waste Disposal - Biohazardous waste bags and boxes must be used to dispose of all plastic ware and personnel protective equipment.
6. Biohazardous Signage and Labeling – All clinical laboratory spaces must be labeled with a biohazardous door sign designating the space as BLS-2. All equipment used to store and handle human blood and blood products must be labeled with a biohazardous sticker.
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.

**Personnel Conducting Blood Draws**

The principal investigator is responsible for verifying that 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 on the University Environmental Safety website or is part of the UVMMC mandates.

**Approved Standard Practices for Obtaining Blood**

1. Healthy adults individuals will be asked to participate in this minimal risk procedure. Education and review of the consent will be performed.
2. After the consent is signed, the volunteer will be brought to

   3. **Phlebotomy of a peripheral arm vein** will be performed by ___________ using sterile procedures and seated position. A sterile bandage will cover the phlebotomy site after the procedure and the arm will be elevated to ensure that bleeding has stopped.
4. The volunteer will be observed for any lightheadedness, bruising or bleeding during and after the procedure.
5. If the volunteer is lightheaded, he/she will be reclined and monitored until symptoms resolve.
6. If the volunteer is asymptomatic after the phlebotomy procedure, he/she will be released.
7. Any volunteer with any side effects during or after phlebotomy will not be used again to obtain the blood products. In addition, any volunteer that requires more than three attempts to access a vein will also not be used as a volunteer.