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1 Purpose

The document herein outlines the recommended health and safety guidelines for performing phlebotomy on human subjects for research purposes at the University of Saskatchewan.

2 Applicable To

The *Phlebotomy Guidelines for Human Subjects in Research* applies to all staff, students, contractors, and visitors engaged in phlebotomy on humans at the university.

The Phlebotomy Guidelines for Research do not apply to phlebotomy for animals.

3 Definitions

Biohazardous Material: Materials of biological origin that have the capacity to produce deleterious effects on humans and/or animals. Examples, but not limited to, include:

- Recombinant DNA molecules that are transferred into human research participants (human gene transfer);
- Recombinant DNA that is introduced into animals (transgenic animals);
- Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or pharmacologically active agent);
- Microorganisms where there is a deliberate transfer of a drug resistant trait or of recombinant DNA containing genes for the biosynthesis of products potentially toxic for vertebrates;
- Microorganisms classified as Risk Group 2 (RG-2) or Risk Group 3 (RG3) agents (Risk Group 4 agents are not allowed on the University of Saskatchewan campuses) whether infectious or defective;
- Microorganisms where more than two-thirds of the DNA from RG-2 or RG-3 agents is cloned into other nonpathogenic agents;
- Biological products derived from RG-2 or RG-3 microorganisms;
- Clinical/medical waste (e.g., diagnostic specimens), that are used in research and known, or reasonably expected to contain pathogens classified as RG-2, RG-3, or toxins;
- Prions;
- Human bodily fluids, blood, tissues, and cell lines; and/or
- Large scale cultures of a biological material.

Biological Material: Pathogenic and non-pathogenic microorganisms, proteins, and nucleic acids, as well as any biological matter that may contain microorganisms, proteins, nucleic acids, or parts thereof. Examples include, but are not limited to, bacteria, viruses, fungi, prions, toxins, genetically modified organisms, nuclei acids, tissue samples, diagnostic specimens, live vaccines, material derived synthetically, and isolates of a pathogen (e.g. pure culture, suspension, purified spores).

Biosafety Permit: A biosafety permit is a formal authorization granted by the Biosafety Group or the Biosafety Protocol Approval Committee (BPAC) to individuals requesting approval for the acquisition, use, storage, transportation and disposal of select Risk Group 2 and 3 biological materials. A biosafety permit is only granted to individuals meeting the requirements as stipulated in the *Biosafety Code of Practice*.

Capillary: The smallest of the human body's blood vessels.

Containment Level 2: The primary exposure hazards associated with organisms requiring containment level 2 are through the ingestion, inoculation and mucous membrane route. Agents requiring containment level 2 facilities are not generally transmitted by airborne routes, but care must be taken to avoid the generation of aerosols (aerosols can settle on bench tops and become an ingestion hazard through contamination of the hands) or splashes. Primary containment devices such as BSCs and centrifuges with sealed rotors or safety cups are to be used as well as appropriate personal protective equipment. As well, environmental contamination must be minimized by the use of hand washing sinks and decontamination facilities (autoclaves).

Immunization: The process by which an individual's immune system becomes fortified against an agent.

Organism: Any living entity (e.g. animals, plants, cell (tissue) cultures, microorganisms).

Phlebotomy: The practice of drawing or collecting blood from a venous blood source (venipuncture) or capillary blood source.

Universal Precautions: Are a set of strategies developed to prevent transmission of blood borne pathogens. The focus of universal precautions is on blood and selected body fluids such as cerebrospinal fluid, pleural fluid, and amniotic fluid. Body secretions such as urine, vomitus, feces, or sputum are not controlled under universal precautions, and are instead usually covered under a set of guidelines called body substance isolation.

Venipuncture: The drawing or puncture of a vein through the skin in order to withdraw blood.

Venous Source: Refers to blood being drawn from a vein.

4 Training Requirements

4.1 Venipuncture

Only trained health care professionals (physicians, registered nurses, or phlebotomists) shall be permitted to draw human blood from a venous source for research purposes.

4.2 Capillary Source

Individuals intending to draw blood from a capillary source shall be appropriately trained on the procedure, the associated hazards, and protective measures. Training by a health care professional, or an individual with experience with capillary source procedures is considered acceptable.

Records of training, theoretical and practical, shall be maintained by the supervising researcher overseeing the work.

5 Ethics

Researchers intending to perform phlebotomy must ensure that all required ethics approvals from the University Biomedical Research Ethics Board (Bio-REB) are in place prior to engaging in phlebotomy on humans.

The Bio-REB is responsible for the review of all ethics applications involving human subjects that include medically invasive procedures, physical interventions and therapies (including exercise and diet interventions), administration and testing of drugs, natural products or devices, or physiological imaging and measures (e.g. MRI or CT scans, heart rate, blood pressure). A project that is based solely on the use of medical charts or health records (no other research method is being used) will be reviewed by the Biomedical Research Ethics Board. For more information on the human ethics approval process and requirements, please refer to the University [Research Ethics website](#).

All prospective donors are to be recruited in accordance with good ethical principles. A signed consent form is required from all donors.

6 Biosafety

Under the university's *Biosafety Code of Practice*, all individuals working with biological materials require a biosafety permit. The permitting process ensures that appropriate administrative and operational procedures and controls are in place to safely conduct research, academic or other work involving organisms, biological materials and biohazardous materials.

All human blood is treated as potentially infectious and must be handled at biosafety containment level 2 physical and operational procedures as described in the Public Health Agency of Canada's (PHAC) *Canadian Biosafety Standards and Guidelines (2nd edition, respectively)*.

All individuals shall adhere to universal precaution strategies when performing phlebotomy (<http://www.ccohs.ca/oshanswers/prevention/universa.html>).

7 Phlebotomy Hazards

By its nature, phlebotomy has the potential to expose workers to blood from other people, putting them at risk from bloodborne pathogens. These pathogens include human immunodeficiency virus, hepatitis B virus, hepatitis C virus, and those causing viral haemorrhagic fevers (Crimean Congo haemorrhagic fever, West Nile, Ebola, Lassa and Marburg) and dengue. Diseases such as malaria and syphilis may also be transmitted via contaminated blood. Poor infection control practices may lead to bacterial infection where the needle is inserted and contamination of specimens.

8 Immunizations

It is the responsibility of the biosafety Permit Holder (supervisor) to ensure staff and students are offered recommended immunizations prior to performing phlebotomy. The Public Health Agency of Canada (PHAC) recommends that individuals performing phlebotomy receive immunization for Hepatitis B. Other vaccinations, including tetanus, diphtheria, influenza, measles, mumps, and rubella, may also be indicated depending on the research protocol. For more information on recommended immunizations in Canada refer to the PHAC *Canadian Immunization Guideline*, (7th Edition, 2007).

If the individual refuses immunization, a *Vaccination Waiver Form* shall be completed. The waiver form is available on the Safety Resources website, <http://safetyresources.usask.ca/>.

Copies of all immunization records and immunization waiver forms shall be maintained by the biosafety Permit Holder.

9 Phlebotomy Equipment and Materials

Areas designated for venipuncture and capillary phlebotomy are to include the following equipment and materials:

- Sink for hand washing;
- Soap and/or hand sanitizer;
- Impervious work surface;
- Emergency eye wash station;
- Phlebotomy chair or suitable seating;
- Tourniquet;
- Prepackaged alcohol wipes;
- Clean cotton balls;

- Safety-engineered blood collection needles (venipuncture);
- Safety-engineered lancets (capillary source);
- Vacutainers (blood collection tubes);
- Absorbent waterproof pad;
- Test strip and/or capillary tubes;
- Sterile gauze and bandages;
- Disinfectant and supplies for decontamination;
- Bleach or 70% ethanol;
- Paper towels;
- Sharps container;
- Autoclave bag or biohazard disposal container;
- First Aid kit; and
- Spill kit.

New phlebotomy materials (e.g. needles, lancets, collection tubes, alcohol wipes, cotton balls, gauze) shall be used for each individual undergoing phlebotomy procedures. Never reuse phlebotomy materials.

10 Personal Protective Equipment

The minimum personal protective equipment (PPE) required when performing phlebotomy and when handling human blood are:

- Clean lab coat;
- Safety glasses;
- Disposable non-latex gloves (e.g. nitrile gloves);
- Pants; and
- Closed toe/heel shoes.

New gloves shall be worn for each individual undergoing phlebotomy procedures.

11 Venipuncture Procedure

Only health care professionals (physicians, registered nurses, or phlebotomists) shall be permitted to draw human blood from a venous source for research purposes.

Venipuncture procedures shall be carried out in accordance with accepted best practices of the health care profession in Saskatchewan and Canada.

12 General Capillary Source Phlebotomy Procedure

Following is the general procedure when performing human capillary source phlebotomy on fingertips.

1. Prepare all necessary materials prior to performing the procedure so that they are easily assessable. Keep work area organized and clean.
2. Wash hands thoroughly (30 seconds).
3. Don lab coat, safety glasses and nitrile gloves. Set aside a second pair of gloves for cleanup procedure. If gloves have to be removed for any reason, a new pair should be used. If gloves are damaged, replace them before proceeding. Wash hands before putting on new gloves.
4. Work over an absorbent paper with plastic backing. If soiled, dispose of all contaminated material in an autoclave bag or biohazard disposal container.
5. Select the non-dominant hand and ring finger tip of the donor. Hold the finger nail down firmly on the table surface. Select a site that is about 1/3 of the nail length from the end of the finger, slightly off centre.
6. Wipe the fingertip with an alcohol wipe. Allow to air dry thoroughly.
7. Retrieve a new safety-engineered lancet. Never use a surgical blade to perform capillary source phlebotomy.
8. Puncture the disinfected finger tip with one quick, continuous and deliberate stroke, to achieve a good flow of blood and to prevent the need to repeat the puncture. Safety-engineered lancets require only gentle pressure on the side of the end of the finger. Do not puncture the skin more than once with the same lancet or use the same site more than once. This can lead to bacterial contamination or infection.
9. Dispose of the used lancet in a sharps container.
10. Wipe away the first drop of blood because it may be contaminated with tissue fluid or debris (sloughing skin).
11. Squeeze out a single blood drop and transfer it to the test strip or capillary tube.
12. Wipe off finger with a new cotton ball. Discard the cotton ball in the autoclave bag or biohazard disposal container.
13. If bleeding has not completely stopped, cover wound with cotton ball, sterile gauze, or a bandage.
14. Dispose of all test strips or capillary tubes when finished in the sharps container.
15. Disinfect the work area with bleach (e.g. fresh dilution of 10% bleach with a contact time of 15 minutes, or a 70% ethanol with contact time of 5 minutes). Wipe area thoroughly with paper towel.
16. Remove all PPE, and wash hands thoroughly after phlebotomy. PPE should not be worn outside of phlebotomy area. The laboratory coat should go straight to laundry on site, or be placed in a plastic bag for transfer to a laundry facility.
17. Ensure all samples collected are stored in appropriate storage units such as a refrigerator or freezer. All storage locations must be listed on the biosafety permit.

13 Incidents

If an individual performing phlebotomy has been injured or exposed to human blood (e.g. cut, puncture, exposure to eyes or mucous membranes), the following steps are to be followed by the individual.

1. Remove any contaminated clothing and personal protective equipment.
2. Flush contaminated areas with soap and water. If eyes are exposed, flush eyes for 15 minutes using an emergency eyewash station. If there is an open wound to the skin (cuts, punctures), encourage bleeding, flush area with water, apply an antiseptic, and cover with gauze.
3. Notify the supervising researcher and the biosafety permit holder (if different from the supervising researcher).
4. As required, seek professional medical attention immediately.

If an individual performing phlebotomy acquires an infection that is suspected of being linked to performing phlebotomy procedures, the individual must notify the supervising research and the biosafety permit holder (if different from the supervising researcher) immediately. The individual should seek medical attention immediately.

All incidents shall be reported to Safety Resources using its online reporting system (<http://safetyresources.usask.ca/>). For assistance reporting an incident, please contact Safety Resources at safetyresources@usask.ca.

14 Hazardous Waste

All hazardous waste shall be collected and disposed of in accordance with the Safety Resources *Hazardous Waste Disposal Standard*. The manual is available on the Safety Resources website, <http://safetyresources.usask.ca/>.

If you have questions about the disposal of biohazardous waste, or other hazardous waste, please contact Safety Resources at safetyresources@usask.ca.

15 References

- Public Health Agency of Canada, *Canadian Immunization Guideline*, 7th Edition, 2007.
- Public Health Agency of Canada, *Canadian Biosafety Standards*, 2nd Edition, 2015.
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- Canadian Centre for Occupational Health and Safety (CCOHS), *Routine Practices*, <http://www.ccohs.ca/oshanswers/prevention/universa.html>.
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