

Guidelines for the Collection of Blood Samples in Research Involving Humans

This document provides the University of Manitoba Research Ethics Boards (REBs) and researchers with the information they need to make an informed judgement on the ethical and participant safety issues involved in the collection of blood samples in the research setting with human participants. Phlebotomy is described by the World Health Organization (2013) in the [World Health Organization \(WHO\) guidelines on drawing blood: best practices in phlebotomy](#) as *blood sampling* for purposes of laboratory tests and *blood collection* for donation. These guidelines are intended to clarify who should perform phlebotomy, including capillary blood collection, with human research participants within the University of Manitoba research setting.

Research participant and staff safety are of paramount importance. Sample size and integrity is also important considerations when drawing blood for research purposes. Phlebotomy involves risks to both the participant and the health worker through potential injury or exposure to contaminated blood or equipment. Training related to safe collection and handling of the blood products is essential. Training should include information on infection control procedures as they pertain to phlebotomy. According to the WHO, special training is required for those working with children and infants. Training should include opportunities for theoretical learning and practical skills review and assessment.

Scope of Practice for Phlebotomy

Scopes of practice provide broad, yet meaningful safety parameters on health-related activities. [The Canadian Society for Medical Laboratory Science position statement, Support for Regulation: Medical Laboratory Assistants \(MLAs\)](#) (2012) outlines the regulatory responsibilities of a health worker trained and certified to complete a wide variety of laboratory skills, including phlebotomy.

Phlebotomy procedures (involving human participants) for research approved by any of the University of Manitoba Research Ethics Boards (REBs) will be completed by health workers trained and certified in this procedure. This may include **Certified Medical Laboratory Assistants (MLAs)**, and other job titles, as recognized as equivalents by the National Competence Profile, some of which are noted as follows: **clinical laboratory assistant, medical laboratory technician, MLS/T (medical laboratory assistant/technician), medical laboratory aide, laboratory helper and phlebotomist** (as per the Canadian Society for Medical Laboratory Science (CSMLS) position statement, March 2013).

The University of Manitoba recognizes that **Registered Nurses** and **Licensed Medical Physicians** may perform phlebotomy as a task within their general scope of practice if the individual has the current necessary knowledge and practical skills to judge him or herself as capable of providing phlebotomy-related care in a safe and competent manner.

Scope of Practice for Blood Glucose testing

Blood glucose testing is commonly done by health care workers and patients by accessing a sample by finger stick (fingerprick) and using a blood glucose testing machine (i.e. glucometer). Blood glucose testing may be done independently or with the assistance of someone else (i.e. a health care worker or other person who has been trained in the safe practice of blood glucose testing).

The training and procedures may take place at home or at a clinic (or other), as long as the test itself can be conducted safely and infection control practices can be upheld. Training on the procedure is typically provided by members of health care teams (i.e. nurses, physicians, Diabetes Educators) through health and clinical practice. Adequate training should take place before patients or research participants initiate the procedure independently. Blood glucose testing procedures (and related scope of training) must be documented. The qualifications of the trainer should also be included in the documentation.

Fingerprick lancets/devices and glucometer machines should not be shared. Training should include information on adequate infection control practices that are appropriate to the testing procedures (i.e. not sharing single-use lancets and glucometers, proper hand-washing technique, appropriate clean-up and disinfection of the test site (i.e. blood droplets). Glucometer users should clean and disinfect their machines according to manufacturer directions. Finally, untoward effects of blood glucose testing should be documented and reported. This may include the Research Ethics Board (REB), the study sponsor, the health care/research institution and/or regulatory body.

Canadian Standards Association (CSA) *Toolkit for Sample Collection Facilities and Medical Laboratories.*

The Canadian Standards Association (CSA) provides a *Toolkit for Sample Collection Facilities and Medical Laboratories*: [Z316.7-12 - Primary sample collection facilities and medical laboratories - Patient safety and quality of care - Requirements for collecting, transporting, and storing samples](#)

Clinical researchers may find the information within the standard useful when considering how to appropriately establish procedures for collecting and processing primary biological samples in research.

An excerpt from the website reads “*This tool kit has been created to provide concise and user-friendly templates to assist users by providing guidance in applying the provisions of Z316.7-12 Primary sample collection facilities and medical laboratories – Patient safety and quality of care – Requirements for collecting, transporting, and storing samples. This kit contains templates and examples of manuals, procedures, policies, checklists, forms and instructions in an electronic format (Microsoft Word) that can be adapted by each user to facilitate the application of this standard.*”

The Toolkit is available through CSA Stores at the following link: <http://shop.csa.ca/en/canada/medical-laboratory-systems/z3167-12/invt/27034862012>

Relevant policies and guidance documents

The University upholds the principles of and follows the [Tri-Council Policy Statement Version 2 \(2014\)](#) guidelines. The core principles of TCPS2 (Respect for Persons, Concern for Welfare, and Justice) and the institutional policy [Ethics of Research Involving Humans](#) (2011) provide general guidance for REB and Researcher roles in the ethical and safe conduct of research.

Noted within University of Manitoba policy, [The Ethics of Research Involving Humans](#) (2011), item 2.2 ***Applicable Ethics Principles***, *The University of Manitoba hereby affirms The Tri-Council Policy Statement "Ethical Conduct for Research Involving Humans", as embodying principles that apply in the discharge of its responsibilities for protecting the rights and welfare of human participants. The TCPS 2 articulates minimal standards, however, and this University policy, or those of a sponsoring agency, discipline, or a category of research may have more applicable or more restrictive requirements for the protection of human participants. In such cases, the more applicable or restrictive requirements shall apply and take precedence in the review and approval of research projects conducted at the University of Manitoba.*

[ICH Guidance: Good Clinical Practice](#) (2004) broadly implies that the REB, the Principal Investigator, the Sponsor and Monitor all share in the responsibility of protecting research participants by assuring that members of the research team are properly qualified and trained in their duties.

Institutional Review Board/Independent Ethics Committee (IRB/IEC)

3.1 Responsibilities

3.1.1 An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects

4. Investigator

4.1 Investigator's Qualifications and Agreements

4.1.5 *The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.*

4.2.3 *The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.*

5.18.4 Monitor's Responsibilities

(b) Verifying that the investigator has adequate qualifications and resources (see 4.1, 4.2, 5.6) and remain adequate throughout the trial period, that facilities, including laboratories, equipment, and staff, are adequate to safely and properly conduct the trial and remain adequate throughout the trial period.

(h) Verifying that the investigator and the investigator's trial staff are performing the specified trial functions, in accordance with the protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.

8. Essential Documents for the Conduct of a Clinical Trial.

8.2.10 Curriculum Vitae and /or Other

To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects

The [World Health Organization, WHO guidelines on drawing blood: best practices in phlebotomy](#) (2013) provides additional guidance on the education and training required by someone designated to complete the collection of blood samples in research. WHO guidelines (8.3 Phlebotomy training) suggest that the health worker have training that includes infection control procedures so as to protect the participant and him/herself. Training should also include both theory and supervised hands-on specific skill(s) demonstration and finally, certification of training and regular in-service support is encouraged.

WHO guidelines - 2.1.4 Training in phlebotomy

- *All staff should be trained in phlebotomy, to prevent unnecessary risk of exposure to blood and to reduce adverse events for patients.*
- *Groups of health workers who historically are not formally trained in phlebotomy should be encouraged to take up such training; lax infection prevention and control practices result in poor safety for staff and risk to patients (20, 37).*
- *The length and depth of training will depend on local conditions; however, the training should at least cover the essentials (see Annex E) (38).*
- *Supervision by experienced staff and structured training is necessary for all health workers, including physicians, who undertake blood sampling.*

Sources:

- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014. Retrieved from http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf
- University of Manitoba, The Ethics of Research Involving Humans, December 7, 2011. Retrieved from http://umanitoba.ca/admin/governance/media/Ethics_of_Research_Involving_Humans_Policy_-_2013_07_02.pdf
- World Health Organization. WHO guidelines on drawing blood: best practices in phlebotomy. Geneva, Switzerland: WHO Press; 2013. 125 p. Retrieved from http://whqlibdoc.who.int/publications/2010/9789241599221_eng.pdf
- Canadian Society for Medical Laboratory Science, Position Statement, Support for Regulation: Medical Laboratory Assistants (MLAs), approved April 2002, revised March 2013. Retrieved from

http://csmls.org/csmls/media/documents/position_statements/CSMLS-Certification-and-Entry-Level-Requirements-for-MLAs_EN.pdf

- International Conference on Harmonization. (2004). ICH Guidance E6: Good Clinical Practice: Consolidated guideline, February 2, 2004. Retrieved from http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/e6-eng.pdf
- Centers for Disease Control and Prevention, CDC - Blood Glucose Monitoring - Injection Safety, February 6, 2013. 8 p. Retrieved from <http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>
- **Biological Safety at the University of Manitoba, Environmental Health and Safety Office (EHSO), University of Manitoba**, December 19, 2013. [Biosafety Training](http://umanitoba.ca/admin/vp_admin/risk_management/ehso/bio_safety/biotraining.html) available at http://umanitoba.ca/admin/vp_admin/risk_management/ehso/bio_safety/biotraining.html
- Canadian Standards Association. (2012). Z316.7-12 - Primary sample collection facilities and medical laboratories - Patient safety and quality of care - Requirements for collecting, transporting, and storing samples. Retrieved from <http://shop.csa.ca/en/canada/medical-laboratory-systems/z3167-12/inv/27034862012>