University of Waterloo Statement on Human Research

The University of Waterloo, a research-intensive institution, regards the conduct of research involving humans as a privilege requiring a balance between scientific inquiry and the protection of the welfare of those involved as research participants. At the same time, it is committed to promoting the conduct of well-designed, responsible research with humans and recognizes its value in advancing knowledge, technology and training.

The University of Waterloo has two Research Ethics Committees (RECs)*, referred to as the Human Research Ethics Committee (hereafter, the HREC), and the Clinical Research Ethics Committee (hereafter, the CREC) or collectively, as the RECs. Both RECs are committees of Senate Graduate and Research Council. The RECs are empowered to ensure that all research involving humans with which it is affiliated is ethical, and is conducted in accordance with the University of Waterloo's Statement on Human Research; its Guidelines for Research with Human Participants (Guidelines); and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition (TCPS 2). In addition, for clinical trials, the RECs follow Health Canada's Food and Drug Regulations and the ICH Good Clinical Practice: Consolidated Guideline, and endeavor to facilitate compliance with the requirements of two U.S. federal agencies: The Food and Drug Administration and the Office for Human Research Protections, the U.S. Department of Health and Human Services. The RECs operate under applicable laws and regulations of the Province of Ontario and of Canada. The RECs are also empowered to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants with which the University of Waterloo is affiliated that does not comply with these guidelines and regulations.

The University of Waterloo's Office of Research Ethics (ORE)** works in close association with, and administers, the RECs. The ORE operates under the same requirements as the RECs including the University of Waterloo's Statement on Human Research, its Guidelines for Research with Human Participants (Guidelines) and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS), and in addition for clinical trials, Health Canada's Food and Drug Regulations and the ICH Good Clinical Practice: Consolidated Guideline; The Food and Drug Administration and the Office for Human Research Protections, the U.S. Department of Health and Human Services. It also operates under applicable laws and regulations of the Province of Ontario and of Canada. The Director and Managers, ORE, conduct ethics review of all human research applications that pose no greater than minimal risk to participants. The ORE provides centralized administration associated with the RECs and for the research ethics operation at the University of Waterloo. In addition, the ORE is responsible for developing guidelines and procedures for the ethics review process, and revises the guidelines and procedures regularly to ensure consistency with evolving provincial, federal and international research ethics requirements, and responsiveness to changing societal values and evolution in the area of research ethics. Within the ORE, and consistent with its education mandate, educational programs and materials are developed and delivered to students, staff and faculty involved in research with humans.

At the University of Waterloo, and consistent with Article 2.1 of the TCPS 2, the following research requires ethics review: a) research involving living human participants; and b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells from living and deceased individuals. The TCPS 2, defines research as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation" (TCPS 2, p. 15). At Waterloo, activities requiring ethics review include, but are not limited to, interviews, questionnaires (web-based or paper format), focus groups, oral histories, unobtrusive observations on individuals or groups where there is no expectation of privacy, physiological assessments and measurements, clinical trials, analysis of secondary data not in the public domain and not anonymous, program evaluation, quality assurance and quality improvement activities for research purposes. It includes research conducted by University faculty, undergraduate and graduate students and staff with human participants. These activities may be conducted on- or off-campus and may be funded or unfunded.

The ethics review process is intended to offer a level of assurance to research participants, the investigators and the University that research participants will be involved in ethically sound and well-designed research, and will be engaged in a prior consent process that is fully informed and voluntary. The ethics review process also ensures adequate protection of individuals' privacy as well as confidentiality of information they provide. In addition, the ethics review process increases the probability that all known and anticipated risks associated with the research are identified and adequately communicated to participants prior to participation. Moreover, it ensures that the known and potential risks are judged to be outweighed by potential benefits from conducting

the research. Procedures used to recruit participants are examined to ensure they are free of explicit or implicit coercion and enable participants to withdraw their consent at any time without fear of reprisal.

The ORE and the RECs are committed to assisting researchers in identifying, considering and addressing any ethical issues inherent in their research, recognizing that all members of the University community share a common commitment to maintaining high standards in research with humans. The University, through the ORE and the RECs, endorses the importance of the ethics review and clearance processes as a mechanism to facilitate and ensure the conduct of ethical research with humans.

** May also be referred to as Research Ethics Boards (REBs)*
*** Established in 1971 as the Office of Human Research, expanded in 1991 to the Office of Human Research and Animal Care and again in 1996 to the Office of Research Ethics*

Approved by Senate Research Council, Sept. 1995; Oct. 1999
Approved by Senate Graduate and Research Council, May 2005; June 2011