TERMS OF REFERENCE

A. Statement of Institutional Authority for Research Ethics Boards

The University of Waterloo has two Research Ethics Boards (REBs): the Clinical Research Ethics Committee and the Human Research Ethics Committee. As constituted sub-committees of the University of Waterloo’s Senate Graduate and Research Council, both of the University of Waterloo’s REBs are established and empowered under the authority of the University of Waterloo Senate.

B. Mandate and Accountability of the Research Ethics Boards

The REBs’ mandate, on behalf of the University, is to protect the rights and welfare of human participants who take part in research conducted under the auspices of the University. The University of Waterloo’s REBs review such research to ensure that it meets ethical principles and that it complies with all applicable regulations, guidelines and standards pertaining to human participant protection. These include but are not limited to 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). For clinical trials, the REBs follow Health Canada’s Food and Drugs Act, the International Conference on Harmonization (ICH) Good Clinical Practice: Consolidated Guideline, and where applicable, U.S. federal regulations. The University of Waterloo’s REBs also operate under applicable laws and regulations of the Province of Ontario and of Canada.

The University of Waterloo requires that all research involving humans or human biological materials conducted in its jurisdiction or under its auspices, undergo ethics review and clearance by one of its two REBs prior to initiation of any research related activities, including recruitment and screening activities.

The Clinical Research Ethics Committee (CREC) has jurisdiction over clinical trials research (i.e., involving a drug or natural health product or is medical device testing) conducted under the auspices of the University of Waterloo and any research involving a “controlled act” as defined under the Regulated Health Professionals Act of Ontario, 1991. The Human Research Ethics Committee (HREC) has jurisdiction over all other research involving humans with which the University is affiliated.

C. Membership of the CREC

Membership shall be consistent with the requirements for REB composition specified in Article 6.4. of the TCPS 2 and ICH Good Clinical Practice: Consolidated Guideline. All Committee members shall be competent to judge the ethical acceptability of research ethics applications they review. In accordance with Article 6.3 and Chapter 8 of the TCPS 2, in the interest of fostering a collaborative spirit and appropriate levels of information sharing between both committees, and to facilitate timely and effective reviews for researchers, members of CREC may be required to serve as reviewers, in either a delegated or ad-hoc sub-committee capacity,
for applications made to HREC if, in the judgment of the Chair of HREC and Director, ORE, the application requires expertise which the CREC member has been judged to possess.

The CREC shall consist of a minimum of 9 voting members including both men and women:

- one faculty member from each of Optometry, Pharmacy, and Kinesiology (see also D3)
- one member knowledgeable about clinical trials research from any of: clinician, a Pharmacologist or an Immunologist/Toxicologist
- two clinical physicians knowledgeable about clinical trials research
- one lawyer preferably knowledgeable about clinical trials research
- one member knowledgeable in ethics
- one community member who has no affiliation with the institution

The following additional members are ex-officio (non-voting):
- Chief Ethics Officer, Office of Research Ethics
- Senior Manager/Manager, Office of Research Ethics
- Research Ethics Advisor, Office of Research Ethics

D. Terms of Office for the CREC

1. Members of the CREC shall be nominated by the Chief Ethics Officer following consultation with the respective Faculty Deans and Department Chairs/School Directors and Chair, CREC.

2. Members of the CREC shall be appointed by Senate Graduate and Research Council.

3. The Chair and Vice Chair will be selected from among the membership of CREC by the Vice-President University Research. The Chair will have a minimum of one term’s prior experience as a member of the CREC. In the event the Chair is either the member from Optometry, Pharmacy, or Kinesiology, an additional member may be appointed from the same area as the Chair. The Vice Chair may discharge the responsibilities of the Chair when the Chair is unable to do so, discharge responsibilities assigned by the Chair and assist in the overall operation of the REB, as requested.

4. Members of the CREC, except the ex-officio members, will serve for a three-year term, normally renewable once. Terms will be overlapping to preserve experience and continuity of function.

E. Meetings of the CREC

1. The CREC normally will meet face to face eleven times per year. In the absence of any business, meetings may be cancelled by the Chief Ethics Officer (or delegate) in consultation with the Chair.

2. Additional meetings of the CREC, or of a sub-committee of its members, may be called by the Chief Ethics Officer (or delegate) and/or Chair, as necessary.

3. Each meeting will require the involvement of a quorum defined as half the total voting membership plus one. Quorum must also meet membership criteria specified by
relevant research ethics guidelines and regulations. Every effort will be made to ensure that each meeting includes the community member.

4. Members shall normally attend CREC meetings with at least 70% attendance per year. When unexpected circumstances arise that prevent a regular member from attending a CREC meeting in person, arrangements will be made where feasible with the member to participate through use of technology (e.g., telephone or video link). In cases where a regular member cannot attend CREC meetings for a protracted period (e.g., during a 6 month’s sabbatical), a substitute member from the same discipline may be appointed to serve during the regular member’s absence.

5. Members shall notify the ORE of an anticipated absence at least one day prior to a meeting. Members who cannot attend a meeting are expected to provide written comments to the ORE for each of the protocols under review at the respective meeting. This information is provided to other members of the CREC and becomes part of the discussion and meeting minutes.

6. Any real, perceived or potential conflict(s) of interest related to the applications under review at a specific meeting shall be declared by the member(s) at the outset of the meeting. Examples of conflicts of interest include but are not limited to applications on which they are listed as principal investigator or co-investigator; current or past research collaborations with investigators listed on the application; applications on which students they supervise are listed. Other members of the CREC will decide whether the member with the conflict of interest should recuse him/herself from related discussions.

7. The CREC will reach its decisions concerning the ethical acceptability of research that is undergoing ethics review through a process of open discussion and consensus. Where consensus cannot be reached, a vote of the quorum present may be taken and recorded.

8. The CREC’s deliberations and decisions will be documented in comprehensive, confidential minutes that are securely maintained in the ORE. The Research Ethics Advisor, ORE, shall serve as Secretary to the CREC.

9. Detailed written feedback from the CREC including its decision on the ethical acceptability of the research shall be communicated to the researcher(s) by the Senior Manager/Manager or Research Ethics Advisor, ORE, following consultation with the Chair, CREC, in an efficient and timely manner according to ORE standard operating procedures. Feedback is based on minutes of discussion of the research project.

10. The CREC may, where appropriate, request that the Principal Investigator (PI) or his/her designate attend a meeting to provide further information about and/or to discuss his/her research. The CREC will also accommodate reasonable requests from a PI to attend a meeting to participate in discussions about his/her research.

11. The CREC may seek the confidential opinion or advice of an ad hoc advisor/reviewer from among UW faculty or from a confidential external consultant on a particular application to ensure it has the necessary background information and knowledge to review the ethical acceptability of the application.
F. **Responsibilities and Mandates of the CREC**

1. To ensure that all research under CREC jurisdiction, involving human participants conducted by students, staff, and faculty affiliated with the University of Waterloo, and all clinical trials research conducted at Waterloo by unaffiliated students, staff, and faculty researchers, undergo ethics review and clearance prior to being conducted. This research may be conducted on- or off-campus and may be funded or unfunded.

2. To review the ethical acceptability of all research projects, under CREC jurisdiction, (involving human participants on behalf of the institution including, but not limited to, those that):
   - may pose greater than minimal risk to participants (i.e., physiological, psychological, economic, social, or other);
   - involve recruitment of persons who may be vulnerable as research participants in the context of a specific study, and/or cannot legally give free and informed consent
   - include ethically sensitive issues, topics and/or procedures; and
   - represent applications to certain granting agencies that stipulate full REB review.

   In so doing, the CREC may:
   - Grant ethics clearance to
   - Propose modifications to
   - Disapprove
   - Terminate

   proposed or ongoing research conducted within the jurisdiction of the University or under its auspices to ensure that a proportionate review of risks and benefits has occurred in accordance with the ethical framework proposed under the TCPS 2 (Chapter 1).

**Delegation of CREC Authority Related to Ethics Review and Clearance**

The CREC delegates to the Chief Ethics Officer, Senior Manager/Manager, and Research Ethics Advisor(s), ORE, by virtue of their membership on the CREC, and according to ORE Standard Operating Procedures, authority to conduct:

3. Initial ethics review and clearance of research under its jurisdiction that poses minimal risk to research participants, and includes provision of comprehensive and timely written feedback.

4. Ethics review and clearance of modifications to ongoing research under its jurisdiction that poses minimal risk to research participants, and includes provision of comprehensive and timely written feedback.

5. Annual ethics review and clearance of all research under its jurisdiction that continues beyond one year.

6. Ethics review and clearance of all revised materials and related documents associated with the ethics review feedback process involving minimal and greater than minimal risk research.
Delegation of CREC Responsibility for Record Keeping and Research Ethics Education

The CREC ensures through the ORE, that:

7. CREC members are provided with opportunities for research ethics education during their tenure on the CREC beginning with a new member orientation session.

8. Comprehensive, accurate records (i.e., paper and electronic) of the initial and continuing (i.e., modifications, annual) ethics review and clearance processes are securely maintained in the ORE for all research under its jurisdiction. This includes all revised materials associated with initial and continuing ethics review.

9. CREC meeting dates and submission deadlines are easily accessible by researchers through information posted on the ORE website.

10. A monthly report is received on minimal risk research that has undergone ethics review and clearance through the delegated ethics review process by the Chief Ethics Officer, Senior Manager/Manager, and Research Ethics Advisor(s).

11. Timely information and regular reports are received on any unanticipated issues (events) that have occurred in association with research under its jurisdiction.

12. UW guidelines, procedures and sample materials related to the conduct of research with humans are reviewed and updated on a regular basis (e.g., annually) to ensure that they remain current in an evolving research ethics environment.

13. Educational activities (e.g., in-class presentations, seminars and workshops) are provided to UW students, faculty and staff involved in research with human participants.

14. Legal or other advice is sought by the Chief Ethics Officer, as required, on matters related to the protection of human participants in research.

15. Timely information on guidelines, procedures, and other matters related to the conduct of research with human participants is provided to the CREC as well as student, staff and faculty researchers who conduct research with humans.

* In Section F, it is understood that the Chief Ethics Officer has overall responsibility for the mandates and operation of the ORE.

G. Reconsideration and Appeal of CREC Decisions

1. Reconsideration Process

A Principal Investigator may make a written request for reconsideration of a CREC decision when ethics clearance is not granted, or when ethics clearance is conditional on revisions that the Principal Investigator (PI) believes may jeopardize the feasibility or integrity of the research. The Chief Ethics Officer will refer such a request, including documentation and supporting materials received for reconsideration from the PI, to other members of the CREC for discussion at its next meeting. The CREC will review the written documents, and where appropriate, will request an informal meeting with the PI (or his/her designate). Following consideration of all additional information (verbal and written), the CREC will reach a final decision with respect to its position on the original
decision. Every attempt will be made by the Chief Ethics Officer and CREC, in consultation with the PI to reach a resolution by this informal route.

2. Appeal Process

In the event the matter cannot be resolved through a reconsideration or informal process, the institution shall provide the PI with prompt access to an established appeal process through which the PI may appeal the CREC’s decision. An appeal can be requested for procedural or substantive reasons. An appeal committee shall be appointed through the same authority that established the REB, ensuring that members of the appeal committee will have expertise and knowledge to be able to competently judge the ethical acceptability of the research ethics application under review. Members of the CREC whose decision is under appeal shall not serve on the appeal committee. The appeal committee will act impartially in its review of documentation provided by the CREC and the PI (or designate), and will consult with others as required, including but not limited to, members of the CREC and the PI (or designate). The appeal committee will issue a written report with its decision on the matter with copies to the PI and CREC. It may approve, reject or request modifications to the research proposal. The appeal committee’s decision will be final.

Approved Senate Graduate & Research Council, February 2009; Revised CREC Oct. 2011; approved Senate Graduate & Research Council, Nov. 14, 2011
Revised CREC August 2012, approved Senate Graduate & Research Council, Sept. 10, 2012
Revised ORE August 2013; approved Senate Graduate & Research Council, September 9, 2013;
Revised ORE August 2016; approved Senate Graduate & Research Council, September 12, 2016