A. Statement of Institutional Authority for Research Ethics Boards

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

C. Membership of the HREC

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 HREC may be required to serve as reviewers, in either a delegated or ad-hoc sub-committee capacity, for applications made to CREC if, in the judgment of the Chair of CREC and Director, ORE, the application requires expertise which the HREC member has been judged to possess.
The HREC shall consist of a minimum of 12 voting members including both men and women:

- seven faculty members with broad expertise in qualitative and quantitative methodologies selected from across the faculties (i.e., Arts, Applied Health Sciences, Engineering and Mathematics) including
  - two members from Psychology, one of whom may be from Clinical Psychology
  - one member from Kinesiology
  - one member with expertise in statistical methodologies
  - one member who is knowledgeable in the relevant law
- two graduate students with experience in the conduct of research with humans
- two members of the community who have no affiliation with the institution
- Director, Health Services (ex-officio)

The following additional members are ex-officio, non-voting:

- Director, Office of Research Ethics
- Senior Manager, Office of Research Ethics

D. Terms of Office of the HREC

1. Members of the HREC shall be nominated by the Director, Office of Research Ethics (hereafter, the Director) following consultation with the respective Faculty Deans and Department Chairs/School Directors.

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

3. The Director, in consultation with other members of the HREC, shall select one faculty member to serve as Chair. The Chair will have a minimum of one year prior experience as a member of the HREC.

4. Members of the HREC, except 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 HREC

1. The HREC normally will meet face to face eleven times per year. In the absence of any business, meetings may be cancelled by the Director in consultation with the Chair.

2. Additional meetings of the HREC, or of a sub-committee of its members, may be called by the Director 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 at least one community member.

4. Members shall normally attend HREC meetings with at least 70% attendance per year. When unexpected circumstances arise that prevent a regular member from attending an HREC 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 HREC 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 HREC 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 HREC will decide whether the member with the conflict of interest should recuse him/herself from related discussions.

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

9. Detailed written feedback from the HREC including its decision on the ethical acceptability of the research shall be communicated to the researcher(s) by the Director, ORE, on behalf of the HREC, 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 HREC 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 HREC will also accommodate reasonable requests from a PI to attend a meeting to participate in discussions about his/her research.

11. The HREC 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 HREC

1. To ensure that all research under HREC jurisdiction or teaching projects involving human participants and conducted by students, staff and faculty affiliated with the University of Waterloo, and all research conducted at Waterloo by unaffiliated students, staff and faculty researchers, undergo ethics review and clearance prior to being conducted. These activities may be conducted on- or off-campus and may be funded or unfunded.
2. To review the ethical acceptability of all research projects, under HREC 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 HREC 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 HREC Authority Related to Ethics Review and Clearance

The HREC delegates to the Director and Managers, ORE, by virtue of their membership on the HREC, 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 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 HREC Responsibility for Record Keeping and Research Ethics Education

The HREC ensures through the ORE that:

7. HREC members are provided with opportunities for research ethics education during their tenure on the HREC 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. HREC 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 Director and Managers, ORE.

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 Director, 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 HREC as well as student, staff and faculty researchers who conduct research with humans.

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

G. Reconsideration and Appeal of HREC Decisions

1. Reconsideration Process

A Principal Investigator may make a written request for reconsideration of an HREC 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 Director, ORE, will refer such a request, including documentation and supporting materials received for reconsideration from the PI, to other members of the HREC for discussion at its next meeting. The HREC 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 HREC will reach a final decision with respect to its position on the original decision. Every attempt will be made by the Director and HREC, 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 HREC’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 HREC 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 HREC and the PI (or designate), and will consult with others as required, including but not limited to, members of the HREC 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 HREC. It may approve, reject or request modifications to the research proposal. The appeal committee’s decision will be final.
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