UNIVERSITY OF WATERLOO
HUMAN RESEARCH ETHICS BOARD

TERMS OF REFERENCE

A. Statement of Institutional Authority for Research Ethics Boards

The University of Waterloo has two Research Ethics Boards (REBs): the Human Research Ethics Board and the Clinical Research Ethics Board. 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 Board (HREB) has jurisdiction over research involving humans conducted under the auspices of the University of Waterloo with the exception of research that is reviewed by the Clinical Research Ethics Board (CREB). CREB has jurisdiction over clinical trials research (i.e., involving a drug or natural health product or medical device testing),research involving a "controlled act" as defined under the Regulated Health Professionals Act of Ontario, 1991, and other research activities as defined under approved standard operating procedures.

C. Membership of the HREB

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. Members of HREB may be required to serve as reviewers, in either a delegated or an ad-hoc sub-committee capacity for applications made to CREB. This is in accordance with Article 6.3 and Chapter 8 of the TCPS 2, encouraging collaboration and information sharing between both REBs, and facilitating timely and effective reviews for researchers. The CREB

chair will determine if the application requires expertise that the HREB member has been judged to possess.

To fulfill the mandate of the Board, the membership will be comprised of both voting and non-voting members.

The HREB shall consist of a minimum of 12 voting members

- six faculty members including:
  - one member with expertise in clinical psychology
  - one member with expertise in the science of human movement
  - one member with expertise in the methods or processes used in engineering/technology research for the conduct of research with humans
  - one member with expertise in statistical methodologies
  - one member with expertise in qualitative methodologies
  - Chair of the Delegated Ethics Review Committee (DERC)[1] from the Department of Psychology (ex-officio)
- 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
- Medical Director, University of Waterloo Health Services (ex-officio)

The committee must reflect gender diversity, including at minimum both men and women.

Non-voting members of the Board act as resource support, offer expertise and assistance on matters under consideration by the Board, and share information as needed[2]. The following additional members are ex-officio, non-voting:

- Director, Research Ethics; Senior Manager/Manager, Research Ethics
- Research Ethics Advisor
- Research Experiences Group (REG) Coordinator and Ethics Administrator for DERC

Faculty members of DERC also serve on HREB as alternate members. When serving as an alternate member they may vote and count in quorum.

D. Terms of Office of the HREB

1. Following consultation with the respective Faculty Deans and Department Chairs/School Directors and HREB , the Director will nominate members of the HREB.

2. The Senate Graduate and Research Council shall appoint members of HREB.

3. The Vice-President Research and International will appoint the Chair and Vice Chair from the HREB members. The Chair will have a minimum of one-year prior experience as a member of the HREB. 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

[1] DERC (Psychology) operates under the auspices of HREB with the sole purpose of conducting delegated reviews within Psychology under the Delegated Ethical Review Committee (Psychology) terms of reference.

[2] TCPS 2, Article 6.4 stipultes “where research ethics administration staff have the requisite experience, expertise and knowledge comparable to what is expected of REB members, instituions may appoint them (based on written polices and procedures of the institution) to serve as non-voting members on the REB.

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 HREB, except ex-officio members, will serve for a three-year term, when possible, normally renewable once. Terms will be overlapping to preserve experience and continuity of function.

E. Meetings of the HREB

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

2. Additional meetings of the HREB, or of a sub-committee of its members, may be called by the Manager in consultation with the 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 HREB meetings with at least 70% attendance per year. When unexpected circumstances arise that prevent a regular member from attending an HREB 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 HREB 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 Manager of an anticipated absence at least one day prior to a meeting. Members who cannot attend a meeting are expected to provide written comments for each of the protocols under review at the respective meeting. This information is provided to other members of the HREB and becomes part of the discussion and meeting minutes.

6. At the outset of each meeting, members shall declare any real, perceived or potential conflict(s) of interest related to the applications under review. 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 HREB will decide whether the member with the conflict of interest should recuse themselves from related discussions.

7. The HREB will reach its decisions concerning the ethical acceptability of research that is undergoing ethics review through a process of open discussion and consensus. When members are unable to reach consensus a vote of the quorum present will be taken and recorded.

8. The HREB's deliberations and decisions will be documented in comprehensive, confidential minutes that are securely maintained. The Research Ethics Advisor, shall serve as secretary to the HREB.

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

10. The HREB 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 HREB will also accommodate reasonable requests from a PI to attend a meeting to participate in discussions about their research.

11. The HREB may seek the confidential opinion or advice of an ad hoc advisor/reviewer from among University of Waterloo 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 HREB

1. To ensure that all research under HREB 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 HREB 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
    - stipulate full REB review as required by certain granting agencies.

    The HREB may grant ethics clearance, propose modifications, disapprove, or 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.

G. Delegation of HREB Authority Related to Ethics Review and Clearance

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

1. 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.

2. 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.

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

4. 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 with the exception of applications that have been categorized as requiring a review by a sub-committee of the HREB or the full HREB.

H. Delegation of HREB Responsibility for Record Keeping and Research Ethics Education

The HREB ensures through the ORE that:

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

2. 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 for all research under its jurisdiction. This includes all revised materials associated with initial and continuing ethics review.

3. HREB meeting dates and submission deadlines are easily accessible by researchers through information posted on the Research Ethics website.

4. HREB members receive a monthly report on minimal risk research that has undergone ethics review and clearance through the delegated ethics review.

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

6. University of Waterloo 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.

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

8. Legal or other advice is sought, as required, on matters related to the protection of human participants in research.

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

I. Reconsideration and Appeal of HREB Decisions

1. Reconsideration Process

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

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