

**UNIVERSITY OF WATERLOO
HUMAN RESEARCH ETHICS COMMITTEE**

Delegated Ethical Review Committee (Psychology)

TERMS OF REFERENCE

A. General - Statement of Institutional Authority for Research Ethics Boards

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

B. General - 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.

HREC has jurisdiction over research involving humans conducted under the auspices of the University of Waterloo with the exception of clinical trials research reviewed by CREC. CREC also reviews other types of research (e.g. "controlled acts") specified in the Terms of Reference for CREC.

C. Relationship between DERC (Psychology) and HREC

HREC may allow delegated reviews to occur for minimal risk research falling within its jurisdiction. Delegated reviews are conducted on behalf of HREC in accordance with ORE SOPs # 203 – 209. As specified by these SOPs, delegated review can occur either by using delegated reviewers who are ORE Office staff (e.g. Managers, Director) or by using a Delegated Ethical Review Committee (DERC) comprised of faculty members within a department¹.

¹ Any delegated reviewers must be current or past HREC members (RCR Secretariat Interpretation).

Members of the DERC (Psychology) operate under the auspices of HREC with the sole purpose of conducting delegated reviews within Psychology within the review categories which have been specifically approved for delegated review and delegated to DERC (Psychology) by HREC.

Members of the DERC (Psychology) are accountable to HREC for their decisions since they are reviewing applications on behalf of HREC. The HREC can request reports, periodic audits, records or other documentation from DERC (Psychology) reviewers to ensure the quality and consistency of decision-making and ethical review conducted on its behalf. The ORE will provide a monthly report to HREC which summarizes the decisions made by DERC (Psychology) delegated reviewers on behalf of HREC. This report will clearly identify which applications have undergone delegated review by DERC (Psychology) members.

D. Relationship between DERC (Psychology) and the ORE

The ORE provides administrative support to the DERC (Psychology) members in the form of guidelines, standards, computer systems and forms to be used in fulfilling their responsibilities. Members of the DERC (Psychology) are responsible for ensuring that their decisions are consistent with other HREC decisions and for using the ORE provided processes.

Although the DERC (Psychology) members will conduct the initial review of the application, the review of annual progress reports for minimal risk studies originally reviewed by DERC (Psychology) is undertaken by the Research Ethics Officer in the ORE.²

E. Membership of the DERC

All DERC (Psychology) members shall be competent to judge the ethical acceptability of delegated 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 DERC (Psychology) 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 DERC (Psychology) member has been judged to possess.

- DERC (Psychology) will be comprised of five standing members (i.e. three faculty members plus a DERC Administrative Officer) plus the Chair of HREC who will be an ex-officio member of the DERC (Psychology). One member of DERC (Psychology) who is also a current member of HREC may be appointed Chair/leader of DERC (Psychology).
- The specific operational responsibilities of the DERC (Psychology) Chair with respect to the DERC (Psychology) are to: ensure DERC (Psychology) responsibilities are fulfilled appropriately and in conformity with its Terms of Reference, ensure ORE and HREC policies and practices are used and ensure the competency of the delegated reviewers to review specific applications. Together with the DERC (Psychology) Administrative Officer (DAO), the DERC Chair should also ensure the delegated reviews are distributed appropriately and fairly to DERC (Psychology) standing committee members to review. The HREC Chair may also participate as a DERC (Psychology) reviewer.
- Normally DERC (Psychology) standing members will review applications independently and provide independent feedback to the researchers using standard ORE provided forms and guidelines.

² The review of annual progress reports for studies reviewed by HREC (i.e. above minimal risk) is undertaken by one of the two ORE Managers.

- Together with members of the ORE, the HREC Chair, the DAO and the three standing faculty members of DERC (Psychology) will develop and maintain a Standard Operating Procedure which details the specific categories of applications (e.g., DERC - A, DERC - B) which have been delegated to the DERC (Psychology) by HREC. This SOP should also detail the processes to be used to review these delegated applications.
- Although most reviews will normally be conducted independently by either the DAO or the standing faculty members, the DERC (Psychology) Chair may ask one or more members of the DERC (Psychology) to meet as a group to review a specific application or to sequentially review an application.
- Standing faculty members of DERC (Psychology) will represent specific disciplines. These disciplines should be selected to represent the areas in which the majority of applications are expected to arise. Initial faculty standing members will be drawn from the six research areas within psychology. In addition to three standing faculty members, standing members will also include the DAO who has personal experience and expertise with both the Research Experiences Group and SONA. The psychology graduate student member of HREC may be invited to be a standing member of DERC (Psychology) at the discretion of the HREC Chair after consultation with the Director, ORE.
- The DAO may be assigned a specific category of applications to review (e.g. DERC - A) and independently approve.
- Standing members of DERC (Psychology) will include both men and women.
- Ad hoc experts may be asked to participate in DERC (Psychology) discussions on a case by case basis as determined by the DERC (Psychology) Chair and DAO. The role of the ad-hoc experts will be to offer advice and technical expertise to standing members in situations where standing members have judged this expertise to be necessary. Ad hoc experts may include faculty members from other uW departments. Without limiting the generality of the foregoing, ad hoc experts providing advice to DERC (Psychology) may include experts from other psychology departments including: developmental psychology, cognition and industrial/organizational psychology.
- Ad hoc experts cannot provide feedback directly to researchers nor can they approve an application.
- Only standing members can approve an application and provide feedback to applicants.
- Standing members of DERC (Psychology) must be either current or former members of HREC.
- The DAO may be asked to participate in the ethical review of applications as judged appropriate by the DERC (Psychology) Chair.
- Standing members should possess broad expertise in the research methodologies involved with the applications under review.

F. Terms of Office of the DERC

1. Members of the DERC (Psychology) shall be nominated by the Chair of DERC (Psychology) to the Chair of HREC and approved by HREC at one of its monthly meetings following consultation with the respective Dean, psychology department chairs or other senior administrative personnel as appropriate.
2. Members of the DERC (Psychology) shall have been previously appointed as HREC members by Senate Graduate and Research Council and shall normally have served at least one term on HREC before being appointed as a DERC (Psychology) standing members.

3. The HREC Chair, in consultation with the Faculty Dean and Department Chairs/Senior Administrators as appropriate, shall serve as Chair of the DERC (Psychology) subcommittee to maintain appropriate levels of communication, quality assurance and consistency between the operations of the two committees.
4. Members of the DERC (Psychology) will serve for a three-year term, normally renewable once. Terms will be overlapping to preserve experience and continuity of function. The DAO shall be cross-appointed as an ex-officio member of HREC for an unlimited number of terms.
5. Required professional development will include: reading the TCPS 2nd edition, completion of the TCPS 2nd edition online tutorial, reviewing TCPS interpretations on a regular basis, reviewing the Terms of Reference for DERC (Psychology), developing familiarity with all current uW guidelines, forms, procedures and SOPs used in the ethics review process.
6. DERC (Psychology) members may be asked to participate in ongoing professional development activities. These optional activities might include: attendance at CAREB seminars, attending some HREC meetings, attending workshops sponsored by other universities, participating in training sponsored by the Tri-agencies, participating in webinars as identified by the ORE, attending face to face meetings with ORE staff members.

G. Decisions of the DERC

1. The DERC (Psychology) Chair, in consultation with the DAO, will assign delegated reviews to DERC (Psychology) members so as to ensure that the requirements of articles 6.4 and 6.5 of the TCPS 2nd ed. are met as well as to ensure a fair and equitable workload is achieved.
2. Face to face meetings of the DERC (Psychology), or of a sub-committee of its members, may be called by the Director ORE, the HREC Chair, the DERC (Psychology) Chair or a standing committee member as necessary.
3. Standing members of DERC (Psychology) may be invited to attend all or part of HREC monthly meetings as observers to provide professional development opportunities and also to ensure consistency of decision making. Copies of HREC minutes will be made available to DERC (Psychology) on Sharepoint if issues are discussed which, in the opinion of the HREC Chair and Director ORE are felt to be relevant to the types of reviews conducted by the DERC (Psychology).
4. At least one DERC (Psychology) member should review each application using the forms, guidelines and and resources provided by the ORE.
6. Any real, perceived or potential conflict(s) of interest related to the applications under review shall be declared by the member(s) when they are first asked to review an application. Examples of conflicts of interest may 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. If a conflict of interest has been declared, the HREC Chair will decide, after consultation with the DAO and/or Director ORE as

appropriate, whether the member with the conflict of interest should recuse him/herself from related discussions.

7. Members of the DERC (Psychology) will reach an independent decision concerning the ethical acceptability of research that is undergoing ethics review. If a decision cannot be reached, or the application cannot be approved, the application will be referred to HREC.
8. Members of the DERC (Psychology)'s deliberations and decisions will be documented in a comprehensive, confidential manner and securely maintained in the DAO's office or other Psychology offices as deemed appropriate by the HREC Chair. ORE staff or HREC members should be provided with prompt access to DERC (Psychology) files on an "as needed" basis.
9. Detailed written feedback from the DERC (Psychology) including its decision on the ethical acceptability of the research shall be communicated to the researcher(s) by the DERC (Psychology) reviewer in an efficient and timely manner, according to ORE standard operating procedures. Feedback is based on the discussions or comments provided by the delegated reviewer.
10. Members of the DERC (Psychology) 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. Members of the DERC (Psychology) will also accommodate reasonable requests from a PI to attend a meeting to participate in discussions about his/her research.
11. The DERC (Psychology) 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.

H. Responsibilities and Mandates of the DERC (Psychology)

1. To ensure that all research under HREC jurisdiction, which has been specifically assigned to the DERC (Psychology) is ethically reviewed. 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 which have been specifically assigned to DERC (Psychology), involving human participants on behalf of the institution including, but not limited to, those that:
 - clearly pose less than minimal risk to participants (i.e., physiological, psychological, economic, social, or other);
 - do not involve recruitment of persons who may be vulnerable as research participants in the context of a specific study, and can legally give free and informed consent
 - do not include ethically sensitive issues, topics and/or procedures; and
 - do not represent applications to certain granting agencies that stipulate full REB review.

In so doing, the DERC (PSYCHOLOGY) may:

- grant ethics clearance to or

- propose revisions to

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). **The DERC (Psychology) cannot disapprove or terminate research.** When delegated reviewers consider a negative decision, this decision shall be referred to HREC for review and endorsement. HREC will be responsible for communicating the decision to the researcher.³

I. Delegation of HREC Authority Related to Ethics Review and Clearance

The HREC delegates the DERC (Psychology) standing members, by virtue of their current or past membership on the HREC, and according to ORE 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. Ethics review and clearance of all revised materials and related documents associated with the ethics review feedback process involving minimal risk research.

J. Delegation of HREC Responsibility for Record Keeping and Research Ethics Education

The HREC ensures through the ORE that:

1. DERC (Psychology) members are provided with opportunities for research ethics education during their tenure on the DERC (Psychology) beginning with a new member orientation session.
2. Comprehensive, accurate records (i.e., paper and electronic) of the initial and continuing (i.e., modifications) ethics review and clearance processes for applications reviewed by the DERC (Psychology) are securely maintained either in the ORE or by the DERC (Psychology) DAO for all research under the jurisdiction of the DERC (Psychology). This includes all revised materials associated with initial and continuing ethics review.
3. DERC (Psychology) procedures are easily accessible by researchers through information posted on the ORE website or Sharepoint site.
4. A monthly report is received by HREC on minimal risk research that has undergone ethics review and clearance through the delegated ethics review process by the DERC

³ TCPS 2nd edition, p. 78.

(Psychology). DERC (Psychology) delegated reviews should be indicated clearly on the monthly report.

5. Timely information and regular reports are received by HREC on any adverse events or protocol deviations that have occurred in association with research under the DERC (Psychology)'s jurisdiction.
6. 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. DERC (Psychology) members agree to use these required forms, guidelines and processes when conducting reviews.
7. Educational activities (e.g., in-class presentations, seminars and workshops) are provided to uW students, faculty and staff involved in research with human participants.
8. Legal or other advice is sought by the Director, ORE 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 DERC (Psychology) as well as student, staff and faculty researchers who conduct research with humans.

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

K. Reconsideration and Appeal of DERC (Psychology) Decisions

1. Reconsideration Process

A Principal Investigator may make a written request for reconsideration of a DERC (Psychology) feedback when ethics clearance is conditional on revisions that the Principal Investigator (PI) believes may jeopardize the feasibility or integrity of the research. Such a request should be made directly to the Director, ORE. The Director, ORE, will refer such a request, including documentation and supporting materials received for reconsideration from the PI and DAO to 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 DERC (Psychology) decision or feedback. Every attempt will be made to reach a resolution using an informal route. Failing this, HREC's decision will be final.