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1) Preamble

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) (Article 1.4) requires that Research Ethics Boards (REBs) be established at the highest levels of the institution and cover as broad a range of research as possible. A multiplicity of REBs with small workloads in the same institution is discouraged. However, the TCPS does recognize that large institutions may find it necessary to create more than one REB and recommends a proportionate approach to ethics assessment. (Article 1.6) The TCPS requires that if institutions decide to authorize research ethics review by other than the full REB, it must require that such approvals be reported in appropriate ways to the full REB. At UWO there are two main REBs 1) the Research Ethics Board for the Review of Health Sciences Research Involving Humans Subjects (HSREB) and 2) the Research Ethics Board for the Review of Non-Medical Research Involving Human Subjects (NMREB).

For many years UWO has had a process of proportionate review that has generally served the research community well. The balance of this document describes the proportionate review process at The University of Western Ontario and the attendant guidelines and procedures. **All questions and clarifications concerning the interpretation of these guidelines should be directed to the Office of Research Ethics 661-3036 or ethics@uwo.ca.**

The proportionate review mechanism was created to provide a level of flexibility in the research ethics review process of proposals presenting minimal risk of harm to subjects. It also allows researchers to respond to sudden research opportunities where data collection must begin before the full REB's regular meeting. The term 'expedited review' has proven to be quite controversial in the Canadian research ethics community and has given rise to numerous debates and to confusion. From the perspective of the researcher, the term often creates an expectation that expedited review process will mean a 'speedy' review with less administrative burden.

To more accurately represent the process of proportionate review, this guideline has instituted a change in proportionate review terminology from "Expedited Review" to "Delegated Review". The Delegated Review process refers to a research ethics review by other than the full REB. Delegated Review allows an REB to ensure that all research under its jurisdiction is assessed according to a consistent standard. It also provides the authority for the REB to intervene should the delegated review process need adjustment. The REB maintains high-level (not project-by-project) oversight, and it is ultimately responsible for ensuring that decisions made by delegated review adequately protect the research subjects and reflect the standards of the presiding REB.

As per the TCPS, Western and its REBs have authorized a Delegated Review process that requires that the actions and decisions of the delegated reviewer(s) be formally reported to the full REB in a timely manner, thus, permitting the REB to maintain surveillance over the decisions made on its behalf. To ensure that the Delegated Review does not compromise institutional accountability, the delegated reviewer(s) are accountable to the primary REB that appointed them. The delegated reviewer(s) must

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maintain an ongoing and strong link to their REB by regular reporting about their activities and decisions. The REBs retain the authority to accept the report as presented or to request a more rigorous review process. Regardless of the review process, the primary REB is responsible for the ethics approval of all research involving humans carried out under its jurisdiction.

2) Types of Research that may eligible for Delegated review

- a) The research projects must be no more than minimal risk. (TCPS C1) The standard of minimal risk is defined as follows:
If potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk.
- b) The research participants must be drawn from the general adult population, capable of giving free and informed consent, and may not include vulnerable subjects such as children, persons who are not legally competent to consent, mentally incompetent persons, prisoners, legal wards or the therapeutically dependent. *(In the case of children, the REB may agree that some exceptions are acceptable for Delegated Review if the research carries absolutely no risk.)*
- c) In general, the projects should not involve any highly personal, sensitive or incriminating topics or questions which could place participants at risk or cause embarrassment. *(In the case of medical chart reviews refer to the HSREB Guidelines ~ Categories of Review)*
- d) The projects must not manipulate behaviour of participants beyond the range of “normal” classroom activity or daily life.
- e) In general, the projects should not involve physically invasive contact with the research participants. *(For exceptions see the HSREB Guidelines ~ Categories of Review)*
- f) The projects should not withhold key information that could influence a participant’s decision to participate in the research.
- g) The projects should not involve the kind of deception that had a participant known about it in advance they likely would not have agreed to participate.

3) Mandate & Types of Sub-REBs

All Sub-REBs are under the jurisdiction of either the NMREB or the HSREB depending upon the nature of research that is reviewed. Departments or faculties wanting to establish a Sub- REB must have the approval of the main REB prior to setting up the committee. The main REBs are required to maintain surveillance over their Sub-REBs

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and the decisions made on behalf of the main REB. (Check the Office of Research Ethics web site (<http://www.uwo.ca/research/ethics/>) for a list of active Sub-REBs)

- a) NMREB Delegated (institution-wide) – individuals appointed by the NMREB to undertake delegated review of minimal risk protocols for researchers in departments or faculties without Sub-REBs;
- b) HSREB Delegated Levels 1 & 2 (institution-wide) – individuals appointed by the HSREB to undertake delegated review of minimal risk protocols for researchers in departments, faculties or institutions without Sub-REBs;
- c) Faculty or Department Sub-REB (faculty or department specific) – Authorized to review minimal risk protocols for faculty, staff and students whose primary affiliation is with that department or faculty. This committee may also review Undergraduate projects. Please note however that approval by one Faculty or Department Sub-REB does not guarantee access to another department's or faculty's resources e.g. the Psychology Student Pool. In the case of the Psychology Student Pool, researchers from outside the department of Psychology who wish to access the Pool to conduct minimal risk research should apply for Delegated Review by the Psychology Sub-REB rather than their own department or the NMREB.
- d) Undergraduate Sub-REB – Authorized to review only undergraduate projects and course-based research assignments within a specific department (*see also Guidelines for Ethics Review of Undergraduate Research Projects Involving Humans*);

4) Sub-REB Membership

- a) A Faculty or Departmental Sub-REB must:
 - i) have at least five members;
 - ii) have at least two faculty members who are experienced researchers;
 - iii) identify one faculty member who will assume a leadership role for the Sub-REB and final approval and sign-off responsibilities;
 - iv) have at least one member who is a current or recent (within past 2 years) member of either the UWO NMREB or HSREB;
 - v) meet face-to-face at least once a year;
 - vi) ensure the members are familiar with the relevant UWO REB Guidelines (NMREB or HSREB) and the TCPS.
- b) An Undergraduate Sub-REB must:
 - i) have as members, at least two faculty members from the Department who are experienced researchers;
 - ii) have at least one member who is a current or recent (within past 2 years) member of either the UWO NMREB or HSREB;

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- iii) identify one faculty member who will assume a leadership role for the Sub-REB and final approval and sign-off responsibilities;
 - iv) ensure the members are familiar with the relevant UWO REB Guidelines (NMREB or HSREB) and the TCPS.
- c) At a minimum, the NMREB Delegated reviews will be conducted by:
- i) A current member (or members) of the NMREB. In most instances this will be the Chair, Deputy Chair or Senior Ethics Officer of the NMREB;
 - ii) other reviewers may be recruited as needed.
- d) At a minimum, the HSREB Delegated Level 1 and 2 reviews will be conducted by:
- i) A current member (or members) of the HSREB. In most instances this will be the Chair, Deputy Chair or Senior Ethics Officer of the HSREB;
 - ii) other reviewers may be recruited as needed.

5) Guidelines & Procedures for Sub-REBs

The Sub-REBs must:

- a) adhere to the relevant UWO REB Guidelines (NMREB or HSREB) and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) ;
- b) provide the Office of Research Ethics with a list of the Sub-REB members annually and identify the person chairing or assuming the leadership role for the Sub-REB and responsibility for sign-off on approvals;
- c) have a sufficient volume of protocols to ensure an appropriate level of review experience:
 - i) Faculty/Department Sub-REBs: no less than 10 protocols per annum;
 - ii) Undergraduate Sub-REBs: no less than 3 protocols per annum,
- d) use the UWO NMREB or HSREB Protocol submission form or an alternate form that has been approved by the NMREB or HSREB;
- e) maintain records that clearly document who reviewed the protocol and the Sub-REB's decisions and dissents, and the reasons for them; (TCPS Article 1.8)
- f) use a standard approval notice that has been approved by the Office of Research Ethics;
- g) send a copy of the signed approval notice to the Office of Research Ethics at the time a project is approved;
- h) notify the Office of Research Ethics in a timely manner when a project is completed;

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- i) notify the Office of Research Ethics immediately in the event of a breach of an approved protocol by a investigator or staff;
- j) notify the Office of Research Ethics immediately if a research participant is harmed;
- k) institute a formal, annual surveillance routine for protocols that run for more than 12 months (TCPS Article 1.13 c);
- l) maintain records pertaining to the ethics approval for a study for 5 years after all the research data has been collected and contact with the research participants has ended.

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