Preapproval Review Process

SOP Series	SOP 200 REB Operations
SOP Title	REB SOP 214: Preapproval Review Process
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PURPOSE

1. The purpose of these procedures is to describe the Research Ethics Board (REB) preapproval process. This process will allow Principal Investigators to seek approval for a standard research procedure that can be applied across similar studies. For illustrative purposes, this may include, but is not limited to, research programs that conduct several studies utilizing standard research procedures involving specialized equipment, recruitment of a unique population, and/or standard data collection procedures. The application process will require the completion of a preapproval application and a stand-alone document (e.g. Standard Operating Procedure or protocol) that will describe in detail the proposed standard research procedures. The REB will review the preapproval application according to the principles of the most recent version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), institutional policies & requirements, and applicable regulations. Once approved, the Principal Investigator (PI) can cite and append the preapproval process to subsequent REB applications. This will facilitate a harmonized review process and eliminate the need to answer the same questions about procedures and methods each time a new REB application is submitted.

DEFINITIONS

2. For the purposes of these Procedures the following definitions apply:

"Affiliated" means individuals who:

a. hold academic and/or clinical appointments at the University ,
b. are employed at the University, or
c. Retired University faculty.

"Delegate" is assigned responsibility by the REB Chair for decision-making to provide ethics review support to the University REB.

"Principal Investigator (PI)" is affiliated with the University and is the lead of the research team who has overall responsibility for the ethical conduct of the study/procedures and for the actions of any member(s) of the research team. The PI is responsible for communicating any changes to the study/procedures, material incidental findings, new information, and/or unanticipated events to their own REB as well as to local site researchers for multi-site studies, who must then inform their respective local REBs.

"REB Administration" includes the Research Ethics Officer and/or REB delegate who provides operational support to the University research ethics framework and REB.

"REB" refers to the Research Ethics Board authorized by the University.

"Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2)" is the joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada

(NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). This policy outlines ethical norms relevant to the conduct of research involving humans.

"University" refers to Ontario Tech University.

SCOPE AND AUTHORITY

3. These procedures apply to all preapproval applications involving human participants or human biological materials where a PI seeks approval for a standard research procedure that can be applied across similar studies.

4. The REB Chair (or delegate) and REB Administration are responsible for executing, overseeing the implementation, administration and interpretation of these procedures, as well as to ensure that the research ethics review related to the procedures are compliant with the applicable policies, regulations and guidelines.

PROCEDURES

5. Preapproval Submission Requirements

5.1. Principal Investigators shall complete the REB's Preapproval Application and **must append either** a Standard Operating Procedures (SOP) or protocol, whichever the PI deems appropriate for application, and supporting documentation if any, as part of the submission. The PI will decide if a SOP or protocol will be used for the submission.

5.2. The SOP/protocol must include an identification number assigned by the PI and a version date.

5.3. REB applications must include all individuals who are permitted to cite the preapproved SOP/protocol on REB submissions.

5.4. A recommended format of the SOPs may include the following elements:

a. Title,
b. SOP identifier and version date,
c. Purpose,
d. Definitions of terms, if applicable.
e. Scope and authority which defines whom or what the particular set of procedures applies and who defines the roles and responsibility for overseeing the implementation, administration and interpretation of the SOP.
f. Procedures which outline in a step-wise fashion the proposed standards, procedures and/or practices. The procedures shall define the roles responsibilities for executing the activities within the procedure.
g. References and related documents.

5.5. A recommended format of the protocol may include the following elements:

a. Title,
b. Protocol identifier and version date,
c. Rationale and background which outlines the reasons for the proposed preapproval,
d. Objectives,
e. Design,
f. Methodology,
g. Safety considerations,
h. Follow up,

i. Data management and statistical analysis,
j. Quality assurance,
k. Expected outcomes.

5.6. The PI shall submit completed preapproval applications, SOPs/protocols and supporting documentation through the IRIS Research Portal.

6. Review and Approval Process of Preapproval Submissions

6.1. The REB Administration shall promptly screen for completeness of new preapproval applications received through the IRIS Research Portal using the Pre-Submission REB checklist. Applications that are assessed as complete will be accepted for review. Incomplete applications will be returned to the PI for correction.

6.2. Accepted applications are assigned to the next available REB meeting and shall be reviewed according to the procedures outlined in REB SOP 205 (The Full Review Process).

6.3. REB determinations about the preapproval application are made according to procedures outlined in REB SOP 205 (The Full Review Process).

6.4. During the review process, the REB may require additional information or clarification from investigators. The REB shall send clarification and/or decision letters to the PIs via email.

6.5. Occasionally, the PI may be required to meet with reviewers to answer questions or explain the details of the preapproval application.

6.6. The PI is required to address each clarification separately, revise the preapproval application and supporting documentation to satisfactorily address the ethical concerns raised during the review. The PI must emphasize in the clarification response where the revisions were made in the application and provide clean and tracked copies of all revised documents. The PI shall resubmit the clarification response in the IRIS Research Portal.

6.7. Once all clarifications have been satisfactorily addressed, the REB shall email a decision letter to the PI.

6.8. In rare instances when a preapproval application does not receive ethics approval or conditional approval based on the ethical acceptability of the principles of the TCPS2, the PI is entitled to a reconsideration by the REB according to Article 6.18, TCPS2 2018 and the procedures outlined in REB SOP 212 (Process for Reconsideration or Appeal of Decisions of the REB). If the reconsideration does not resolve the disagreement, the PI may appeal the REB decision in accordance to these procedures according to Article 6.19, TCPS2 2018 and REB SOP 212 (Process for Reconsideration or Appeal of Decisions of the REB).

6.9. The PI is responsible for obtaining other institutional, multi-institutional and/or regulatory approvals/permission that are applicable to the preapproval process prior to implementing the preapproval SOP/protocol.

7. Ongoing Reviews of Preapprovals

7.1. All preapproved research procedures cited in REB applications are subject to continuing research ethics review under the Tri-Council Policy Statement 2 Articles 6.14, 6.15 , 6.16 and the procedures outlined in REB SOP 207 (Ongoing Review of Approved Research).

7.2. The PI shall submit an annual report (renewal) or end-of-procedures report (closure) to the REB through the IRIS Research Portal prior to pre-approval expiry.

7.3. The PI shall also submit to the REB reports of unanticipated issues, and requests for changes to approved procedures through the IRIS Research Portal. Proposed revisions to preapproved procedures must be reviewed and approved by the REB prior to implementation.

8. Preapproved procedures in new REB applications

8.1. When using preapproved procedures in new REB submissions, the REB file number, version date, number and title of the SOP/protocol must be cited in sections of the REB application where appropriate.

8.2. The approved SOP or protocol must be attached to the REB submission as an appendix.

MONITORING AND REVIEW

9. These Procedures will be reviewed as necessary and at least every three years (unless another timeframe is required for compliance purposes). The REB Chair (or delegate), REB Administration and/or REB delegate, or successor thereof, is responsible to monitor and review these Procedures.

RELATED POLICIES, PROCEDURES & DOCUMENTS

10. Pre-Submission REB checklist

REB SOP 205 (The Full Review Process)

REB SOP 207 (Ongoing Review of Approved Research)

REB SOP 212 (Process for Reconsideration or Appeal of Decisions of the REB)

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018)