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| SOP Title | 200: REB Operations |
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1.0 PURPOSE

This standard operating procedure outlines the required documents and supporting information required from investigators for REB submission and review.

2.0 GENERAL PROCEDURE STATEMENT

REB members often rely solely on the documentation submitted by investigators, or other parties, for initial and continuing review. Therefore, this material must provide REB members with enough information about a study to assess if it adequately meets the REB's criteria for approval. A submitted protocol will be scheduled for REB review only when the REB Administration determines that the information and materials submitted present an adequate description of the proposed research.

3.0 RESPONSIBILITY AND AUTHORITY

The Chair, Vice-Chair and the REB Administration are responsible for executing this SOP.

The President, through the UOIT Research Ethics Board has authorized the UOIT REB to review research involving human participants conducted by faculty, staff, and students under the auspices of the University of Ontario Institute of Technology.

4.1 SPECIFIC PROCEDURES

4.2 The Application Process

The UOIT REB requires that applications for initial and continuing review of research involving human participants be submitted to the REB Administration

4.2.1. Submission Requirements for Initial Review

Submission requirements for initial review are outlined on the REB Application form and the accompanying REB Application and Website (www.uoit.ca/reb). All sections of the application form, including all required accompanying documentation, must be completed or the application will not be reviewed. The principal investigator and all co-investigators must submit a certificate showing completion of the latest TCPS 2 tutorial. Student investigators and research assistants require understanding of the TCPS requirements and are strongly encouraged to complete all TCPS 2 education and training modules.

It is strongly encouraged that PIs with questions or concerns set up an appointment to discuss these concerns with the Research Ethics Officer in advance of submission. The Officer will require a minimum of one week to examine any new applications.

4.1.2 Submission Requirements for Continuing Review

During the term of the approval, investigators must inform the REB about any changes to the study. Investigators must send a *Change Request Form* and any revised documents to the REB Administration. All revisions should be highlighted. Revisions cannot be implemented until the REB has granted approval.

4.1.3 Submission Requirements for Clarification Letters

During the review process, reviewers may require additional information or clarification from investigators. Requests will be sent to investigators (the PIs), via email, in the form of clarification letters. Investigators are required to address each clarification separately within the clarification letter, revise any documentation affected by the clarification, and return all documents to the REB Administration. All responses and revisions should be highlighted. In very rare cases, investigators may be required to meet with reviewers to answer questions or explain the details of the study.

4.1.4 Reporting Unanticipated Problems or Events

Investigators must report all serious and unexpected study-related events to the Chair of the REB and the REB Administration as soon as is reasonably possible but no longer than **two (2) business days after the problem**. The obligation to report extends to the discovery of any new information that might adversely affect the safety or well-being of participants. Reports must include a completed *Adverse/Unanticipated Events Notification* (available on IRIS) and any relevant documentation. Investigators may be required to meet with a member of the REB to discuss the event and/or changes required to minimize risks.

4.1.5 Annual Renewals

Prior to the relevant REB approval expiration date, investigators requesting renewal of an approved research project must submit either a completed *Renewal Request* (if the study is ongoing; available on IRIS) or a *Project Completion Notification* (if the study has ended; available on IRIS). If a renewal request is not submitted by the expiration date, the study will be suspended.

4.1.6 Submission Deadlines

REB applications can be submitted at any time. However, in order for an application to be sent to the next full board meeting for review, it must have been received by the REB Administration ten (10) business days before the meeting date.