

SOP Title	200: REB Operations
Number Version	REB SOP 203 Activities Requiring REB Review
Version Date	July 27th, 2011
Approval Date	July 27th, 2011
Approved By	REB
Revised and Approved	September 21, 2016

1.0 PURPOSE

The purpose of this SOP is to describe specific research activities that require REB review and, conversely, those activities that do not require REB review.

2.0 GENERAL PROCEDURE STATEMENT

2.1 Statement of Institutional Authority

All research involving human participants (as defined below), carried out under the authority of UOIT, must be reviewed and approved in advance by UOIT's Research Ethics Board.

No intervention or interaction with human participants in research, including recruitment, may begin until then REB has reviewed and approved the research protocol, consent documents and recruitment materials.

The opinion of the REB should be sought whenever there is any doubt about the applicability of the *Tri-Council Policy Statement 2* and REB Policy to a particular research project. If individuals plan to conduct research projects that are believed not to be research and therefore not require review, they are advised to contact the Research Ethics Coordinator to discuss their project. Once a determination is rendered by the REB Chair, the applicant will be notified whether or not REB approval must first be sought prior to proceeding with the project.

3.0 SPECIFIC PROCEDURES

3.1 Activities that require REB Review

In accordance with the *TCPS2*, the review of the ethical conduct of research involving humans is limited to those activities defined in the *TCPS2* as "research" involving "human participants."

As per Article 2.1, *TPCS2*, the following requires ethics review and approval by an REB before the research commences:

- (a) research involving living human participants;
- (b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

3.2 Definitions

“Research” is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. A determination that research is the intended purpose of the undertaking is key for differentiating activities that require ethics review by an REB and those that do not.

“Human participants” (referred to as “participants”) are those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question.

“Human biological materials” include tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids. Materials related to human reproduction include embryos, fetuses, fetal tissues and human reproductive materials.

3.3 Secondary Use of Data or Information

REB review is also required for secondary use of data, as per the *TCPS2* Chapter 5, Section D, where secondary use of identifiable data refers to the use in research of information originally collected for a purpose other than the current research proposal.

3.4 Publicly Available Information

REB review is also required when utilizing publicly accessible digital sites where there is a reasonable expectation of privacy. For example: when accessing identifiable information in publicly accessible digital sites where the privacy expectation of contributors of these sites is much higher, such as Internet chat rooms and self-help groups with restricted membership. Also, where data linkage of different sources of publicly available information is involved, it could give rise to new forms of identifiable information that would raise issues of privacy and confidentiality when used in research, and would therefore require REB review (see Article 5.7).

4.0 Activities Not Subject to REB Review

In some cases, research may involve interaction with individuals who are not themselves the focus of the research in order to obtain information. Such individuals are not considered participants for the purposes of this SOP.

4.1 Publicly Available Information

As per Article 2.2, research that relies exclusively on publicly available information does not require REB review when:

- (a) the information is legally accessible to the public and appropriately protected by law; or
- (b) the information is publicly accessible and there is no reasonable expectation of privacy.

4.1.2 Naturalistic Observation

As per Article 2.3, REB review is not required for research involving the observation of people in public places where:

- (a) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups; and
- (b) individuals or groups targeted for observation have no reasonable expectation of privacy; and
- (c) any dissemination of research results does not allow identification of specific individuals.

4.1.3 Quality Assurance

As per Article 2.5, quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.

4.1.4 Re-purposing Quality Assurance Data

If data are collected for the purposes of staff performance reviews, or an evaluation in the course of academic or professional training but later proposed for research purposes, it would be considered secondary use of information not originally intended for research, and at that time may require REB review in accordance with this Policy.

However, as per Article 2.4 REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

4.1.5 Creative Practices

As per Article 2.6, creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

4.2 Failure to Submit Project for REB Review

The implications of engaging in activities that qualify as research that is subject to REB review without obtaining such review are significant (please refer to SOP 210 Non-Compliance). Results from such studies may not be published unless REB approval was obtained prior to collecting the data and cannot be used to satisfy degree completion requirements. In addition, conducting research without REB approval can constitute research misconduct in accordance with the provisions of UOIT's Integrity in Research in Scholarship and/or Academic Integrity Policies. If an investigator begins an activity that is not initially considered research that has changed in some fashion as to now require REB review, or if he or she may wish to publish the results, the investigator should submit a proposal to the REB for immediate review. Under normal circumstances, the UOIT REB will not review or grant approval for research that has been conducted without prior approval.