Procedure for Policy on The Ethical Conduct of Research and Other Studies Involving Human Participants	Manual: Reference Number: *103-1*
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See related policies: The Ethical Conduct of Research and Other Studies Involving Human Participants
Conflict of Interest
Scholarly Integrity
Intellectual Property
Operational Approval for Research
Externally Funded and/or Sponsored Research

See related procedures: Procedure for Policy on Conflict of Interest
Procedure for Policy on Scholarly Integrity
Procedure for Policy on Intellectual Property
Procedure for Policy on Operational Approval for Research
Procedure for Policy on Externally Funded and/or Sponsored Research

Procedure

1.0 General Instructions

1.1 Applications that *require full board review* (above minimal risk studies) must be received at least 10 business days prior to a scheduled meeting in order to be reviewed at the upcoming meeting; however, there are instances when applications are required earlier (e.g., due to planned office closures). The Research Ethics Board (REB) typically meets at 12:00 pm on the second Monday of every month at Wascana Rehabilitation Centre.

1.2 Applications must be complete (including all required signatures) in order to qualify for review at the next meeting of the Research Ethics Board. An Investigator may have their application for full board review screened by a member of Research and Performance Support prior to their submission to the REB by contacting ResearchEthics@rqhealth.ca with a request for screening no later than 2 business days prior to the submission deadline.

1.3 Applications that *do not require full board review* (i.e., minimal risk studies that meet the criteria for delegated review, as outlined in the guidance notes linked in the ethics application form) may be submitted at any time and will be reviewed on an ongoing basis.

2.0 How to Submit an Application

2.1 All applications for ethical approval of research proposals (i.e., those requiring full board review and those qualifying for delegated review) are made by submitting ONE electronic copy of the completed application form and all attachments in PDF format. The electronic copy of an application and all related files should be sent to ResearchEthics@rqhealth.ca. Hard copies of the application and associated documents are not required, however hard copies of the Principal Investigator and Department Head signature pages are required for above minimal risk studies.

3.0 What to Include

a) Application for research ethics review (with guidance notes removed);
b) All applicable recruitment materials, consent forms, data collection tools, master lists, investigator brochures, etc.;
c) Supporting documentation (e.g., Health Canada No Objection Letter, approvals from other REBs);
d) Required ethics tutorial certificates of completion
    i. McMaster Chart Audit Tutorial (http://ethics.mcmaster.ca/chart/): Required for study personnel performing retrospective chart reviews;
    ii. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition (TCPS 2) tutorial (http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/): Required for all study personnel conducting prospective studies involving patients;

iii. Good Clinical Practice (GCP) training (https://www.citiprogram.org/):
Required for all study personnel conducting clinical trials; and

iv. "Health Canada Division 5 – Drugs for Clinical Trials Involving Human Subjects" (https://www.citiprogram.org/):
Required for all study personnel conducting clinical trials; and

e) CV for Principal Investigator (for prospective biomedical studies).

4.0 Submitting to Two or More Separate Research Ethics Boards

4.1 There are occasions when a researcher is required to apply to more than one Research Ethics Board (REB) for approval. If his/her project requires research ethics review from more than one REB, that study would fall under the provincial process for reviewing multi-jurisdictional applications. The Regina Qu'Appelle Health Region, University of Regina, and University of Saskatchewan are parties to a provincial research ethics harmonization process. This means that if an application requires review by two or more of these REBs, an investigator should email his/her application to the relevant REBs simultaneously. Upon receipt of the application by the relevant REBs, one REB will be assigned as the initial review site. All applicable REBs will still be involved in the review of the project, however an investigator will only receive ONE set of feedback ("Notice of Ethical Review") representing the requirements of all applicable REBs. An investigator must wait until he/she has received full approval from all relevant REBs before proceeding with his/her research. This will include a Certificate of Approval from the initial review site (the main REB assigned to your project) as well as a letter of reciprocity from the receiving REB(s). In rare instances in which a harmonized review cannot be conducted, the investigator will receive separate Certificates of Approval from each site.

4.2 Investigators must submit all continuing ethical review documentation (e.g., annual renewals, applications for amendments) to all REBs who have issued a Certificate of Approval. Copies do not need to be sent to REBs who have issued a letter of acceptance instead.

5.0 REB Review Process

5.1 The application is recorded and forwarded to the Chair of the Board. Following review by the Committee, the Chair will communicate the decision regarding suitability to the applicant in writing.

5.2 The outcome of the first review of the application through either a Full Board or a Delegated Review will be one of the following four decisions:

- **a) Approval**: The Certificate of Approval will be issued for a term of one year.
- **b) Provisional Approval**: The REB endorses the study with some changes and authorizes the Chair to grant approval when the concerns addressed to the researchers in the Notice of Ethical Review (i.e. the provisions) have been satisfactorily addressed.
- **c) Deferral:** Based on the documentation provided, the REB is unable to make a final decision. The decision is deferred for full board review at such time as the researchers submit the supplementary information or documentation as specified by the REB in the Notice of Ethical Review.
- **d) Not Approved**: The REB does not authorize the conduct of the research in the RQHR.

This decision will be forwarded to the applicant with an outline of the requested changes, if any. Research projects must not be initiated until full approval is granted.

6.0 REB Review Fee

6.1 The fee for ethical review of industry-sponsored studies is **$3,500.00** (industry sponsors include for-profit organizations such as pharmaceutical or medical device companies, or agents thereof). The fee covers the submission of the initial request for ethical review, subsequent amendment and renewal applications, as well as the review of submissions for Unanticipated Problems Reporting.

6.2 A Certificate of Approval will not be issued until payment of the required fee is received.

6.3 **Waiver Criteria**

The ethical review fee for industry-sponsored research may be waived for studies receiving a grant-in-aid (normally an investigator-initiated study

with partial funding – e.g., supply of drugs or devices or a very limited amount of funding from an industry sponsor); waiver of the review fee must be approved by the Chair of the Research Ethics Board.

6.4 **Payment of Ethical Review Fee**

6.4.1 Cheques and requests for invoices sent to the REB office AFTER the submission of the initial application must include a memo with the exact title of the research study and the Principal Investigator's name.

6.4.2 Cheques should be addressed to "Regina Qu'Appelle Health Region" and sent to*:*

Regina Qu'Appelle Health Region Research Ethics Board
Research and Health Information Services
2180 - 23rd Avenue. Room M-704
Regina, SK S4S 0A5

6.5 **Requirements for Fee Refund**

The ethical review fee applied to industry-sponsored research will be refunded in full, provided that the associated research study is withdrawn prior to review by the Research Ethics Board. If the research study is withdrawn or terminated after a review by the Research Ethics Board has taken place, $1,750.00 of the fee will be retained and $1,750.00 will be refunded.