UNIVERSITY OF MANITOBA

Bannatyne Campus Research Ethics Boards
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# Categories and Procedures for Review of New Research Protocols

## 1.0 Introduction

In accordance with the Tri-Council Policy Statement 2, ICH Good Clinical Practice Guidelines, Health Canada regulations and University of Manitoba policies, submissions to the Bannatyne Campus REBs will receive proportionate review, based on the degree of risk. That is, the depth and extent of the ethics review will be proportional to the anticipated degree of risk to study participants.

Studies determined to be of negligible or low risk may undergo *delegated or departmental review*, while protocols that involve greater than minimal risk must undergo full REB review.

The following guideline will assist the researcher/Principal Investigator (PI) determine:

- whether a new protocol qualifies for delegated/departmental review; and
- outlines the submission requirements for full board and expedited review of new protocols

## 3.0 Definitions

**3.1 Human research** is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation involving participants. It refers to any project that involves the collection of specimens, data or information from persons, through intervention or otherwise. Included are procedures that have a low degree of invasiveness (e.g. surveys, interviews, naturalistic observations, exercise or psychometric testing, examination of patient records), as well as more invasive procedures (e.g. blood sampling, insertion of a cannula, administration of a substance).

**3.2** A **research participant** in human research is a person, who by virtue of his/her involvement in a data-gathering situation or activity is a source of primary data or information.

**3.3 "Minimal risk" research** is defined as research in which the probability and magnitude of possible harms implied by participation in the research is not greater than those encountered by participant in those aspects of their everyday life that relate to research.

**3.4 REB** – Research Ethics Board

**3.5 TCPS** - Tri-Council Policy Statement

**3.6 CRRC** - Course Base Research Review Committee

**3.7 HERC-** Human Ethics Resource Committee

## 4.0 Research Activities that require REB Review

- Any undertaking in which an university faculty (including G.G.T academic staff and affiliated staff), staff, or student investigates and / or collects data on human participants

for research purposes must be approved by a University of Manitoba REB prior to implementation. This includes research carried out on University premises or conducted elsewhere.

- University of Manitoba REBs have the authority to review protocols submitted by the Winnipeg Regional Health Authority (WRHA) researchers. To qualify as a WRHA researcher you must be a researcher who is (i) employed by the WRHA or have a written contract for services with the WRHA; of (ii) have privileges under the WRHA's Medical Staff By-Law. If you are requesting review as a WRHA Researcher, your study must be carried out at facilities owned by or operated by the WRHA or under the direction of WRHA.

## 4.0 Research Exempt from Ethics Review

Prior ethics review and approval from an REB will normally **not be required** for the following projects.

- A limited type of research most often found within the humanities, fine arts, and in some historical research relying exclusively on publicly available information, which involves:
  - information which is legally accessible to the public and appropriately protected by law, such as a public database where aggregated data that cannot be associated with any individual are obtained;
  - information already in the public domain (e.g. autobiographies, biographies or public archives) where there is no reasonable expectation of privacy; and/or
  - research involving a living individual in the public domain, or an artist, based exclusively on publicly available information, and as long as the subject is not approached directly for interviews or access to private papers. Nevertheless, it is the responsibility of the researcher to ascertain that any information used from these sources is presented in an accurate fashion. There are exceptions; research involving publicly accessible digital sites (such as Internet chat rooms or self-help groups with restricted membership) should undergo REB review.
- Archival analysis of records by University departments normally engaged in the collection, maintenance, and analysis of such records. Nevertheless, it is incumbent on such units to ensure that the anonymity of individuals and confidentiality of their records are maintained.
- Class research projects which involve humans and which are conducted by students on other members of the class as exercises to learn how to conduct research.
- Research involving the observation of people in public places where intervention by or interaction with the researcher is not involved, there is no reasonable expectation of privacy, and the research results will not allow identification of specific individuals.
- Creative practice activities, unless employed in the context of research to obtain responses from participants used to analyze a research question.
- Quality Assurance or Quality Improvement studies, program evaluation, performance reviews or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes. **NOTE: Some journals may require ethics approval for such projects.** Such projects can be submitted for ethical review with consultation of the REB. The REB is **unable to provide retrospective approval** if the study is already completed.

## 5.0 Determine the Levels of Review required for initial review:

### 5.1 Full Board Review Criteria

All research submitted for initial review that is not outlined below as qualifying for delegated review will require **full board review.**

### 5.2 Delegated Review Criteria

Research deemed to be minimal risk and falling in this category may be reviewed via a delegated process:

- Investigations primarily epidemiological in nature and where data is anonymous or anonymized (i.e. not linked to personal identifying information such as name address, initials, date of birth, etc.) involving retrospective or prospective study of existing data, documents or records. **Review TCPS 2 for definitions on anonymous data.**
- Research involving a mail returned survey(s) or questionnaire(s) provided the questions are not unduly alarming, intrusive, sensitive or embarrassing and there is limited collection of potentially identifying information (i.e. names, address, e-mail address or identifiers such as SIN, PHIN are not collected).
- Secondary analysis of anonymized or de-identified data collected from a previously approved research project by a Bannatyne Campus REB at the discretion of the chair.
- Retrospective chart or records review study where data is anonymous, anonymized or de-identified.
- Research protocols from the National Research Council which qualify as per SOP REB 24 “National Research Council and Bannatyne Campus REB Coordination”.
- Request to establish an electronic or paper database of individuals who agree to be contacted for consideration in future research studies. The data collected is limited to information required to contact individuals and to establish eligibility criteria for future studies. (NOTE: Research databases/registries designed to monitor or evaluate clinical care shall usually undergo full board review.)
- New investigators/sites for protocols that have already received approval from the BREB/HREB at a full board meeting within the past year.
- Expanded access/compassionate use protocols (for pharmaceutical studies) may be considered for delegated review with prior consultation of the REB coordinator.
- Research involving analysis of anonymous, anonymized or de-identified biological samples in the custody of well-established tumor/tissue banks supported by an Advisory Committee (e.g. Manitoba Breast Tumor Bank) for which participants have previously consented to use of their biological samples for research.
- In consultation with the Chair, graduate course based projects may be considered for delegated review provided they have undergone ethics review as per the departmental review process outline in SOP REB 07 Departmental Review. Consultation with REB may be required to organize Departmental Review committee.
- In consultation with the Chair, minimal risk studies not included in the above list may be considered for delegated review that **do not involve direct contact** with potentially vulnerable populations (e.g. children or adolescents(under 18 years), mentally incompetent, prisoners, etc.).

**NOTE:** generally all research projects/studies involving genetic analysis are **not eligible** for the delegated review processes.

### 5.3 Departmental Review

The ethical review of research that is to be carried out by undergraduate students as part of their course work may be appropriate for the departmental level process.

To be eligible for review and approval by a Course Base Research Review Committee (CRRC) the research must be:

- ❑ pose no more than minimal risk
- ❑ meet specific study type criteria set by Chair of applicable REB (consult REB Office when organizing the CRRC)
- ❑ not involve significant deception
- ❑ not involve research on sensitive topics that could cause more distress than would normally be encountered by research participants on a daily basis
- ❑ not involve direct contact with potentially vulnerable populations (e.g. children, individuals with cognitive impairment, prisoners, institutionalized individuals, individuals living with psychiatric illness)
- ❑ is closely supervised by a University of Manitoba faculty member who is an instructor in the course.

Departmental level review should not be used for research in which a student is carrying out research that is part of a faculty member's own research program. The REB should review such research.

For projects conducted by an entire class or group of students, the instructor should submit the protocol to be followed on behalf of the entire class, or groups of students, to the Departmental Course-based Research Review Committee (CRRC). Approval is given to the instructor who takes responsibility for the ethical conduct of the data collection exercise. Under these conditions, the instructor takes on added responsibility to ensure that all students understand and follow principles of ethical conduct.

In cases where the instructor or student's supervisor is uncertain whether a course exercise constitutes research, whether it is necessary to submit a single protocol on behalf of the class or individual protocols, or whether ethics approval is required at all, the written opinion of the REB or CRRC Chair must be sought by the instructor or student's supervisor before undertaking the class exercise.

## 6.0 Submission Requirements

Applicants should indicate the level of review on their cover letter they are requesting based on the criteria of studies listed in these guidelines that qualify for delegated review and **not** based on the ***speed*** *w*ith which they would like to receive approval.

The REB Chair will make the final decision as to whether a delegated or full review is required.

### 6.1 Uncertain whether Ethics Review is Required

If a PI is uncertain whether REB review is required, he/she must outline the main intent of the project in a one page summary addressed to the appropriate Chair or e-mail summary to the REB coordinator and specifically request whether REB approval is required. This must be submitted to the REB coordinator at least **4 weeks prior to the submission deadline for full board review** to provide sufficient time to advise whether ethics review is required.

### 6.2 Relevant Ethics Board at Bannatyne Campus

The researcher/PI should submit to a Bannatyne Campus Research Ethics Board when their primary appointment with the University of Manitoba is with the Colleges of Medicine, Pharmacy, Dentistry and Medical Rehabilitation. WRHA researchers who do not hold an appointment with the University of Manitoba should submit to the University of Manitoba REB which covers their discipline (e.g. WRHA nurses to the Nursing/Education REB on Fort Gary Campus).

There are two Research Ethics Boards (REBs) at the Bannatyne Campus: the Biomedical Research Ethics Board (BREB) and the Health Research Ethics Board (HREB).

- The **BREB** reviews all research ethics protocols involving clinical trials and other biomedical research interventions.
- The **HREB** reviews research from the Bannatyne campus involving the behavioral sciences, surveys, and registries, specimen collection/banking examinations of medical records and protocols of generally lesser risk.

If you are in doubt as to which would be the more appropriate board to review your new study, please contact either the Bannatyne Campus Office at **789-3255** or the Fort Gary Office at **474- 7122**.

### 6.2 Delegated Review

If your study falls in the category of studies outlined in Section 5.2, please complete the "University of Manitoba Bannatyne Campus Research Ethics Board Submission Requirement Checklist- ***NEW STUDIES for DELEGATED REVIEW***" with the required documents collated as outlined on the checklist.

For exclusively retrospective review of records or databases (as per section 5.2) please complete the "University of Manitoba Bannatyne Campus Research Ethics Board ***Submission Form for Retrospective Chart Records Review***. The submission requirements are listed on the second page of this submission form.

These requirements and forms are posted on the Submission Requirements link on the website.

All documents should be hand delivered or couriered to the REB office by the submission deadline date. **Late submissions will be deferred to the next month for review.**

If the Chair defers the protocol to full board review the researcher will be contacted to provide additional copies of all documents.

### 6.3 Departmental Review

Applications to CRRC must be submitted by the instructor (or student and instructor) on the REB submission form. The instructor must contact the appropriate department for specific submission requirements related to that department.

### 6.4 Full Board Review

**For all studies <u>not listed</u> in the delegated review category** please complete the "University of Manitoba Bannatyne Campus Research Ethics Board Submission Requirement Checklist- ***NEW STUDIES for FULL BOARD REVIEW***" with the required documents collated as outlined on this checklist. These requirements and forms are also posted on the Submission Requirements link on the website.

All documents should be hand delivered or couriered to the REB office by the submission deadline date. Late submissions will be deferred to the next month for review.

### 7.1 Delegated Review

#### Timelines

Protocols for delegated review are usually reviewed on a monthly basis by the Chair at the time the protocols are reviewed for the full board meeting. The time of submission of a protocol to review will vary according to the volume of submitted new applications to the REB office. Typically they will be reviewed within 10 - 21 days of the full REB submission deadline date.

#### Decisions

Certificates of approval for new studies are mailed usually within one business day from the decision of the Chair. This certificate is forwarded either to the Principal Investigator (PI) or the individual requesting the information on the submission.

If minor changes are requested the REB coordinator will contact the PI/study coordinator by e-mail or phone. When major changes are requested or the study is not approved, the Chair will specify the conditions required to grant approval in writing to the PI. If these conditions are not met by the PI, the study will be submitted to the full board as the Chair is not authorized to issue final non-approval of a study.

### 7.2 Departmental Review

#### REB notification

The CRRC is required to maintain a log of protocols received and decisions reached, to report these twice annually (December 15 and April 15) to the REB, and deposit all documentation with the Bannatyne Campus Research Ethics Office for archival purposes.

### 7.3 Full Board Review

#### Timelines

The decisions from the full board review are communicated in writing to the local PI within 5- 7 business days of the meeting date.

#### Decision Making

At the end of each meeting the protocols are categorized as follows:

1. **Approved as submitted-** The certificate of approval is issued for a term of one year and expires on the one-year anniversary date of the full board meeting at which the study was granted approval. The certificate of approval will list the items that were reviewed and approved (i.e. protocol, informed consent, recruitment appendix, questionnaire appendix, etc.).

2. **Approved with suggestions for minor changes** - This type of approval is used when there are suggestions for minor changes to the proposal that must be addressed by the Principal Investigator before final approval is given. The REB authorizes the Chair to grant final approval when the suggestions have been responded to satisfactorily by the Principal Investigator. The Chair signs the certificate of approval which is issued for a term of one year and expires on the one-year anniversary date of the full board meeting at which the study was granted conditional approval. The certificate of approval will list the items that were reviewed and approved (i.e. protocol, informed consent, recruitment appendix, questionnaire appendix, etc.).

3. **Approved with conditions-** This type of approval is used when there are questions or requested changes to the proposal that must be addressed by the Principal Investigator before final approval is given. A letter must be submitted to the REB by the Principal Investigator, which lists the issues identified by the board and includes the responses to each. The REB authorizes the Chair to grant approval when the concerns have been responded to satisfactorily by the Principal Investigator. When these conditions are met, the certificate of approval is issued for a term of one year and expires on the one-year anniversary date of the full board meeting at which the study was granted conditional approval. The certificate of approval will list the items that were reviewed and approved (i.e. protocol, informed consent, recruitment appendix, questionnaire appendix, etc.).

4. **Deferred (tabled)** –This decision is rendered pending receipt of additional information or major revisions to the protocol submission and requires review by the full REB at one of the scheduled meetings. A letter must be submitted to the REB by the Principal Investigator, which lists the issues identified by the board and includes the responses to each. The Principal Investigator may be invited to the next meeting to provide an opportunity to reply to the review before the REB makes a final decision

5. **Not approved** – This decision is rendered when the REB has significant concerns with respect to the scientific and/or ethical integrity of the protocol and has concluded that the research cannot be conducted as outlined in the submission. A statement of the reasons for "not approving" the protocol submission will be communicated in writing to the Principal Investigator and if appropriate suggestions provided as to how the protocol may be revised to address the committee's concerns. Principal Investigators have the right to appeal REB decisions as per SOP REB 15 Appeals of REB Decisions. Alternatively, protocol submissions can be re-submitted for a new review provided significant changes as requested by the REB have been made. These requests must be submitted to the full board.

**Note: Research activity, including screening and recruitment, must <u>not</u> begin until the certificate of final approval is issued to the Principal Investigator.**

## 8.0 APPEALS OF REB DECISIONS

### APPEAL PROCESS

Appeals of REB decisions may be made to the Human Ethics Resource Committee (HERC) by researchers who feel they have not received a fair and just review by one of the REBs. Appeals will be heard by HERC only if they are based on procedural grounds that the original REB had not given the protocol a fair and just review. Appeals will not be heard on substantive grounds, i.e. on the contents of the proposal that the REB did not approve. More information regarding the appeal process can be found in U of M Policy: The Ethics of Research Involving Humans.

**Appeal Contact Office**

Appeals to the HERC should be submitted via the Human Ethics Coordinator at Fort Gary Campus. For an up-to-date address please call **474-7122.**