UNIVERSITY OF MANITOBA

Bannatyne Campus Research Ethics Boards
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Annual Review/Continuing Review

1.0 Introduction

In accordance with the Tri-Council Policy Statement 2 (TCPS2), ICH Good Clinical Practice Guidelines, Health Canada regulations and University of Manitoba policies, continuing review of an ongoing project should occur at intervals appropriate to the degree of risk to human participants and should consist of at least the submission of a succinct annual status report to the Research Ethics Board (REB).

The following guideline is intended to:

- assist the researcher understand his/her responsibilities for ensuring appropriate annual review/approval is obtained
- outline submission requirements for annual review
- outline procedures used by the Bannatyne Campus REB for continuing review/annual approval
- outline actions that will be taken by the Bannatyne Campus REB for non-compliance of ensuring appropriate review/approval.

2.0 Annual Approval

All research studies that received initial approval from a Bannatyne Campus REB must be resubmitted to the appropriate REB **prior to** the **expiry date** noted on the initial certificate of approval. This includes studies for which the study is closed to accrual/enrolment and/or where there is ongoing follow-up of study participants (e.g. continued collection of mortality/morbidity information related to the initial study, research databases/registries, etc.).

Studies that do not involve participant participation, for example, secondary use of data, must be submitted for renewal up until the point that the data acquisition is completed.

3.0 Expiry Date of Studies

The initial REB approval for a research study is for a maximum **one- year term.** In the case of a study approved by an expedited review process or prior to 2004, the approval expires on the one year anniversary of the original approval date. For studies undergoing full board review after 2004, the expiry date is one year from the date of the full board meeting in which the study was granted conditional approval. The expiry date (anniversary date) will be clearly listed on the certificate of approval for all studies approved after 2004. Subsequent renewals also expire on the one year anniversary date of the approval for renewal. This date may change over time when your study requires annual full board review.

The REB may at any time grant approval/renewal for a period of less than one year. This will be clearly indicated on the approval certificate.

Amendment approval after the initial approval/renewal date also expires at the same time as the initial approval or renewal of the study.

Annual/Continuing approval implies that the most recent version of the protocol, Investigators Brochures, advertisements, letters of initial contacts or questionnaires and recruitment methods are approved. If the study remains open to accrual the most recent version(s) of the applicable informed consent forms (ICF) will be reviewed and listed on the certificate of approval.

4.0 Determining whether expedited or full board review is required

4.1 Expedited Review

Most requests for annual review, other than those outlined below that require full board review; can be submitted for expedited review. Requests are screened initially by the REB coordinator and then reviewed and approved by the Chair on behalf of the full board.

The Chair can at any time put a request for annual/continuing renewal forward to the full board.

Timelines

Protocols for expedited review are usually reviewed on a weekly basis by the Chair. The time of submission of a request for annual/continuing approval to review will vary according to the volume of submitted applications to the REB office.

Decisions

Certificates of annual/continuing approval 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.

When 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 request for annual/continuing approval is not approved, the Chair will specify the conditions required to grant continuing 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.

4.2 Full Board Review

Sponsors that require Full Board Review

Some sponsors require full board review for renewal of certain studies. Studies funded by the United States Department of Health and Human Services (DHHS)(i.e. NIH, Center for Disease Control) or studies sponsored by other United States Federal Agencies ***usually*** require full board review. The researcher must familiarize themselves with the requirements of the sponsor to ensure the appropriate review is received.

These agencies require full board review when:

- research is open to enrollment of new participants and/or
- research participants are involved in research related interventions

Other Studies that should be considered for Full Board Review

For a study that has been **ongoing for more than five years** and is not merely confined to data analysis or long term follow-up of participants, consultation with the Chair of the appropriate REB should be made as to whether the study should be reviewed at a full board meeting.

If it is determined by the Chair that full board review is required, the researcher will be requested to provide an annual study status report which provides an overview of the study procedures, recruitment methods, risk/benefit profile and the provisions in place to protect confidentially.

Timelines

The certificates of approval or the recommendations of the board for continuing approval will usually be mailed within 5-7 business days of the full board meeting.

5.0 Submission Process/Required Documents

The PI is responsible for submitting the request for annual/continuing approval to the Bannatyne Campus REB Office in a timely manner to ensure annual approval/continuing is appropriately secured by the expiry date should he/she need to respond to any concerns raised by the REB during the review. Ideally, the Bannatyne campus should receive the request for annual approval **no later than 6 weeks before the expiry date** of the most recent certificate of initial approval or annual approval.

Delegated Review

Please complete the "University of Manitoba Bannatyne Campus Research Ethics Board Submission Requirement Checklist – **Annual Review for Delegated Review"** with the required documents collated as outlined on the checklist.

If the Chair defers the protocol to full board review, the PI will be contacted to provide additional copies of relevant documents.

Full Board Review

Please complete the "University of Manitoba Bannatyne Campus Research Ethics Board Submission Requirement Checklist – **Annual Review for Full Board Review"** with the required documents collated as outlined on the checklist.

All documents submitted for full board annual review MUST be hand delivered or couriered to the REB Office by the submission deadline date. Late submissions will be deferred to the next month meeting for review.

6.0 Failure to Submit an Annual Study Status Report by the Expiry Date

The responsibility lies with the Principal Investigator (PI) to ensure that he/she has applied for annual/continuing approval **before the expiry date** noted on the last certificate of approval. At 60, 30 and 14 days prior to REB approval expiration, the REB office staff will send reminder notices via email to the PI and identified study contact advising that the study's approval is about to expire. Any PI desiring to continue study related activities beyond the expiry date listed on the last certification of approval must submit to the REB a completed Annual Study Status Report. Failure to submit this report and apply for annual/continuing approval renewal before the study approval expires; failure to respond to the REB after expiry notifications have been sent to the PI; and failure to provide the REB with a Final Study Status Report indicating study closure, may result in the following actions being taken:

- **Date of Approval Expiration:** The PI will be contacted by the REB in writing (via email) and by phone advising him/her of the expired approval and further requesting the PI to immediately cease all study related activities, including advertising for, screening, recruiting and enrolling of new participants, conducting the consent process, the collection of data and/or identifiable private information from existing participants, and the analysis of existing data and/or identifiable private information, including the collection of specimens.

- **Date of Approval Expiration**: If applicable, notification will also be sent to the Institutional Review Committee Chair of the institution where the study is being conducted advising of the study approval expiry and the failure to comply with requesting continuing approval. The Chair will also be advised that the PI has been requested to cease all study related activities by the REB. If the applicant is a student, his/her supervisor will be notified.

- **30 Days after expiry notification has been sent to the PI**: If the PI has not made contact with the REB office to address the non-compliance of requesting continuing approval within 30 days following the delivery of the expiry notification, formal termination of the study file with the REB office will occur. If the PI desires to reactive the study following the study file being terminated with the REB, then PI will be required to submit a completed new application to the **full board** along with a cover letter addressed to the Chair explaining the reasons why an annual/continuing approval renewal request was not submitted. If applicable, the Chair of Institutional Research Review Committee where the study is being conducted will also be advised of the study file termination. Notice of the study file termination will also be sent to the University of Manitoba Research Quality Manager.

Participants already enrolled in the study may continue to receive the study intervention **while the renewal application is processed,** even if the initial approval/subsequent renewal has expired. The REB will have the discretion to allow the PI to continue with his/her study related activities should the study approval expire if the Annual Study Status Report has be received in the REB office and is being processed (reviewed by Chair or Board).

The REB may further elect to restrict all future new submissions of any PI who repeatedly fails to comply with these continuing review request submission guidelines.

Enrolling new participants after the expiry date has lapsed can only begin once the Annual Study Status Report has been approved and a Certificate of Annual Approval is issued to the PI unless otherwise agreed to in writing from the REB, such as temporary conditional approval until the certificate is issued.

Please note: **Retroactive approval will not be granted.**

7.0 Quality Assurance Monitoring

Representatives of the REB or University may schedule periodic quality assurance audits of research protocols involving human participants. The procedure for quality assurance monitoring is currently under review. In addition to the REB, representatives of the National Council on Ethics in Human Research (NCEHR) as well as the Senate Committee on Research Involving Human Subjects may schedule periodic assessments or audits.

The REB should be informed as soon as the site is made aware of upcoming site audits conducted by sponsoring companies or regulatory authorities. The REB may participate or be witness to such audits. The audit report should be submitted to the REB for review.