

Bannatyne Campus Research Ethics Board **RESEARCHER TRAINING MANUAL**

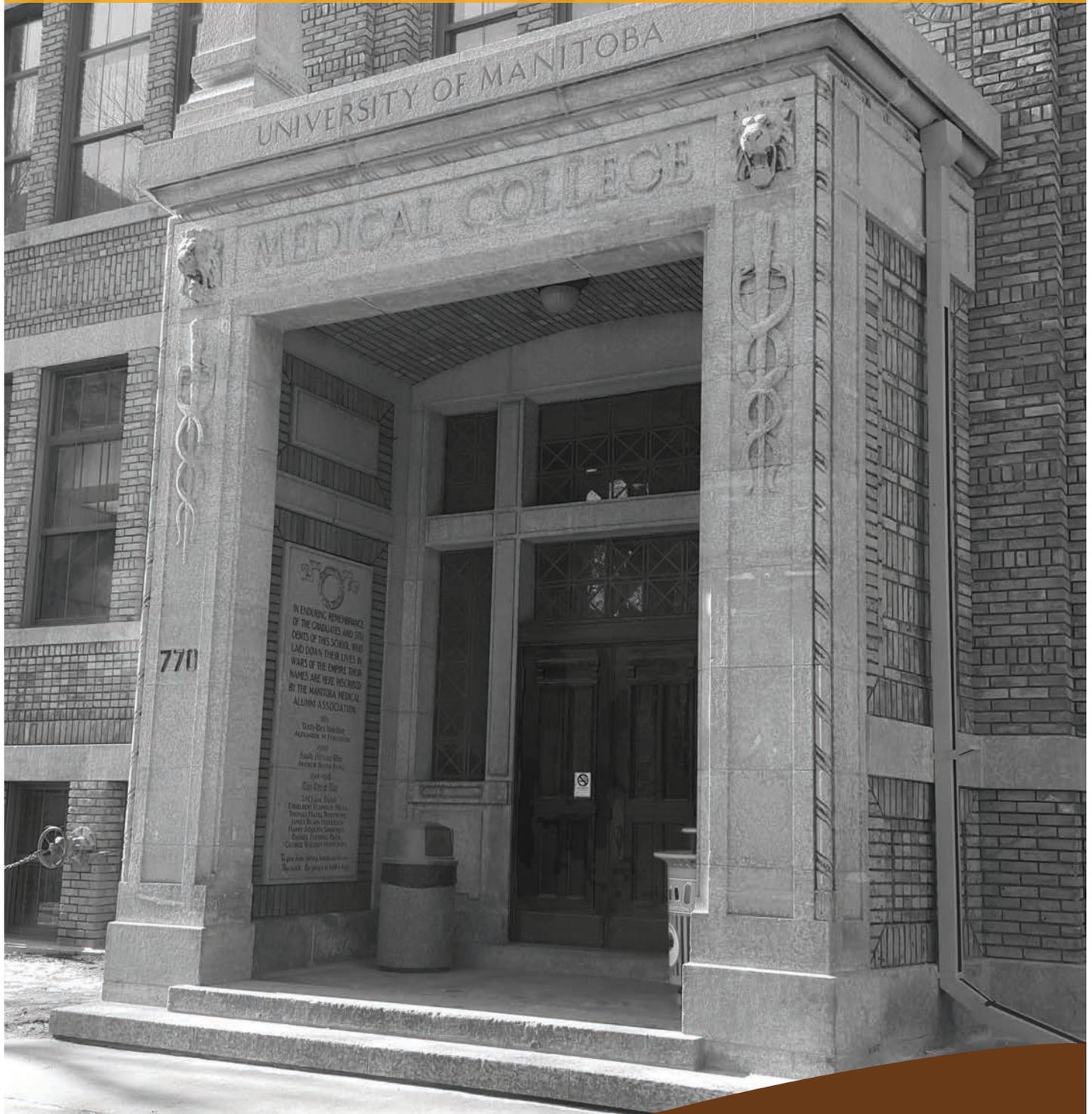




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1. INTRODUCTION

The University of Manitoba is committed to protecting the rights and welfare of human research volunteers participating in research studies. All research projects involving humans conducted at, or under the auspices of the University of Manitoba, require ethical review and approval prior to conduct. Of the five (5) Research Ethics Boards at the University of Manitoba, the Bannatyne Campus has two (2) research ethics boards, the **Biomedical Research Ethics Board (BREB)** and the **Health Research Ethics Board (HREB)**. The Biomedical Research Ethics Board (BREB) reviews research projects that involve human participants that are to participate in clinical trials involving drugs or devices or other biomedical research interventions. The Health Research Ethics Board (HREB) reviews research projects that involve projects related to behavioral sciences, observational research, database research, surveys, registries, specimen collection/banking and/or the examination of medical records. Both Boards are located on the Bannatyne Campus in the Pathology Building and serve researchers on and off campus.

Both BREB and HREB are committed to the ethical conduct of research involving human in accordance to the Tri-Council Policy Statement (TCPS 2), Health Canada and FDA regulations, ICH-GCP and in accordance with the University of Manitoba's policies.

2. SUBMITTING TO THE REB

2.1 When REB Review is Required

In accordance with the University of Manitoba policies, any undertaking in which a university affiliated faculty, staff or student investigates and/or collects data on human participants for research purposes must be approved by a University of Manitoba Research Ethics Board (REB) prior to implementation whether the research is carried out on University premises or elsewhere.

Researchers that do not hold a rank or title with the University of Manitoba but are affiliated with the Winnipeg Regional Health Authority (WRHA) through (i) employment with the WRHA or have a written contract for service with the WRHA; or (ii) privileges under the WRHA's Medical Staff By-Laws and are conducting research at facilities, owned by or operated by the WRHA or under the direction of the WRHA, are entitled to submit to the Bannatyne Campus Research Ethics Board. In some cases, the Researcher may be required by the WRHA to submit the proposed research to a University of Manitoba Research Ethics Board for review and approval prior to implementation.

2.2 How Research is Defined

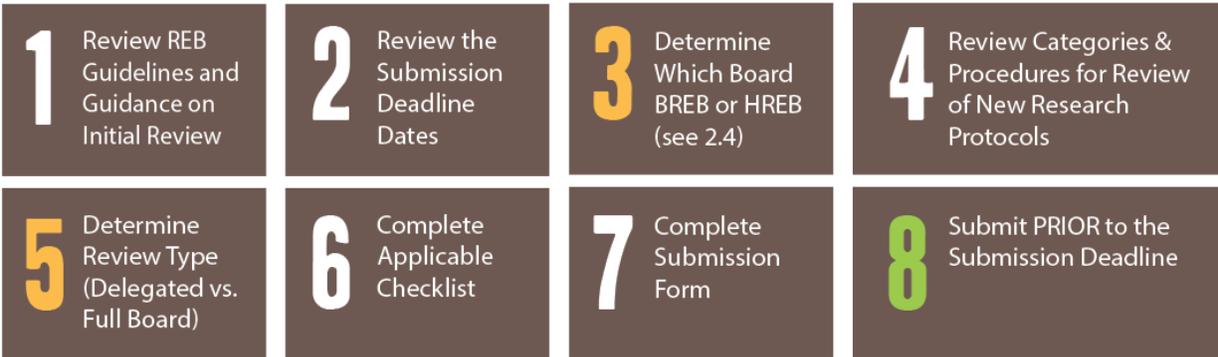
The definition as per University of Manitoba Policy "The Ethics of Research Involving Humans" used in determining if an activity needs prior REB approval is as follows:

Human Research 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. survey, 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)."ⁱ For more information, or a complete listing of types of projects regarded as research, please visit the Bannatyne Campus Research Ethics Board web-page "Research Requiring Review".

Tri-Council Policy Statement 2 defines a clinical trial as any "investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes".ⁱⁱ These interventions include, but are not limited to, pharmaceutical products, cells and other biological products, surgical procedures, radiological procedures, devices, process-of-care changes, and preventative care.

2.3 The Submission Process

▼ START



▼ END

2.4 Which Board to Submit To

There are two (2) Research Ethics Boards located at the Bannatyne Campus, the **Biomedical** Research Ethics Board and the **Health** Research Ethics Board. Members from the Colleges of Medicine, Dentistry, Pharmacy, and Rehabilitation Sciences, the affiliated teaching hospitals, and their associated research foundations can submit their research projects/protocols to the appropriate REB.

A. Biomedical Research Ethics Board: This Ethics Board is responsible for reviewing research proposals involving clinical trials with a biomedical research intervention. This would include interventions involving pharmaceutical products, biologics, devices and natural health products, surgical procedures and standard of care changes (e.g. additional biopsy over and above the standard of care) of a medical/clinical nature.

B. Health Research Ethics Board: This Ethics Board is responsible for reviewing research proposals that include both clinical and non-clinical trials involving behavioral sciences and interventions, surveys (including online surveys), focus groups, questionnaires, quality of life research, prospective and retrospective examinations of medical records and other personal records (e.g. student records, records held in administrative databases etc.), genetic and non-genetic collection, analysis and banking of biological specimens, registries, etc.

2.5 Categories of Procedures for Review of New Research Protocols (Appendix A)

In accordance with the Tri-Council Policy Statement 2 (TCPS 2), ICH Good Clinical Practice Guidelines (ICH-GCP), 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 **Categories of Procedures for Review of New Research Protocols** is intended to assist the researcher/Principal Investigator (PI) in determining:

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

Researchers are strongly encouraged to review the Categories and Procedures for Review of New Research Protocol attached in **Appendix A**.

2.6 Type of Review - Delegated vs. Departmental vs. Full Board Review

In accordance with the Tri-Council Policy Statement 2 (TCPS 2), ICH Good Clinical Practice Guidelines (ICH-GCP), 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 the study participants involved in the research. The three types of review are:

- A. Delegated Review:** Studies determined to be of negligible or minimal risk may be eligible for delegated review. This means that the proposed research project would be reviewed by either the Board Chair, an appointed delegate by the Chair, or a subset of the full Board. Investigations of an epidemiological nature, where data is anonymous, retrospective chart reviews, surveys or questionnaires that are non-intrusive, sensitive or are limited in the collection of potentially identifying information may qualify for delegated review.
- B. Departmental Review:** Undergraduate students conducting research may only require ethical review of their proposed research projects via departmental review. To be eligible for this review process, the project must pose no more than minimal risk; meet criteria set out by the Chair of the applicable REB; not involve deception, sensitive topics that would cause more distress than would normally be encountered, or direct contact with potentially vulnerable populations such as children, prisoners, those with a cognitive impairment or psychiatry illness and is closely supervised by a University of Manitoba Faculty member who is the instructor for the course.
- C. Full Board Review:** All research submitted for review to the REB that does not qualify for delegated or departmental review will be reviewed via full board.

For more information on what may constitute studies eligible for review, please refer to the Bannatyne Campus REB Website or contact the REB Coordinator.

2.7 Requesting REB Review - The Submission Process & Requirements

Depending on the process of review (Delegated, Departmental or Full Board Review) submission to the REB requires the completion and submission of an application form and submission of supporting documents (research proposal/protocol, consent forms, patient materials, data collection materials and proposed study advertisements, study budget).

Submission Checklists: The Submission Checklist document is available for download off the Bannatyne Campus REB website. The document is intended to provide you with guidance on the submission requirements, including what is required to be submitted, and how many of each document. **A completed checklist must accompany ALL submissions to the Bannatyne Campus REB.**

There is a specific submission checklist for the following submissions:

- Checklist for Full Board Review of New Studies
- Checklist for Delegated Review of New Studies
- Checklist for Retrospective Chart or Records Review
- Checklist for Single Case Reports

Failure to provide appropriate documentation as listed on the checklist and submission forms will result in application being returned to the submitter.

All research submitted for initial review **will require full board review** unless it is specifically outlined as a study qualifying for delegated or departmental review in the “**Categories and Procedures for Review of New Research Protocol**” guidelines. The following completed and signed application forms will be required at the time of submission to the REB:

- **Full Board Review:** For all research proposals/studies being submitted to full board (i.e. studies not listed in the delegated or departmental review category) please complete and include in your submission the University of Manitoba Bannatyne Campus Research Ethics Board “**Checklist for Full Board review of New Studies**” (Appendix B) with the required documents collated (gathered and assembled together in order) as outlined within checklist.
- **Delegated Review:** Complete the University of Manitoba Bannatyne Campus Research Ethics Board “**Checklist for Delegated Review of News Studies**” (Appendix C). All supportive documents must be collated (gathered and assembled together in order) and submitted as outlined in the checklist
- **Retrospective Chart Reviews:** For exclusively retrospective review of records or databases, please complete the University of Manitoba Bannatyne Campus Research Ethics Board “**Submission Form for Retrospective Chart Review**” (Appendix D).
- **Single Case Report Review:** Applications to the Bannatyne Campus REB that are for single case reports, please complete and submit the “**Checklist for Single Case Report**” along with your supportive materials as specified within the checklist.
- **Departmental Review:** Applications to the Course based Research Review Committee (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.

All documents should be hand delivered or couriered to the REB office by no later than the submission deadline posted on the website. Late submission will be deferred to the next month for review.

2.8 The Submission Form

All submissions to the Bannatyne Campus Research Ethics Board must be accompanied by a completed and signed Bannatyne Campus Research Ethics Board Submission Form. Researchers are to complete and submit either the “**REB Submission Form**” (for interventional studies, RCTs, database, qualitative, registry or survey studies) or the “**Retrospective Chart or Records Review Form**” for retrospective chart or records review studies. If you are proposing using radiation in your research project, you also must complete a Radiation Proposal Summary Form.

All applicable fields in the submission form are to be completed. Submission forms received that are incomplete, missing information, or do not sufficiently address the question may be returned to the submitter.

Submission forms **MUST** contain the most current contact information for the primary researcher (i.e. Principal Investigator/Researcher) and, if applicable, the study coordinator or primary contact for the study. Specifically, submitters are to ensure that the mailing address, phone number(s) and email address(es) are complete and accurate. Mailing addresses should include a specific room # or mailstop # rather than just a department, building, ward, or floor unless those who will be in receipt of the mailed communications will be able to direct your mail to you with ease.

2.9 The Consent Form - Required Format

According to Tri-Council Policy Statement 2, Researchers "shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project."ⁱⁱⁱ All consent forms must comply with the following formatting:

- Full protocol title is to appear on each page as either a header or footer;
- Page number and total number of pages to appear on each page (i.e. 1 of 5 pages) as part of the header or footer;
- A space should be available for the participant's initials on the header or footer of each page (e.g. "Participant Initials: ____");
- Use official letterhead of the local investigator for the first page of the Participant Information and Consent Form (photocopy is acceptable);
- Use at least a size 12 font in all parts of the text;
- All sections of The Participant Information and Consent Form, except for the Statement of Consent, should be written in the 3rd or 2nd person perspective. The Statement of Consent should be written in the 1st person perspective;
- All sections outlined as headings should appear in the consent. For studies with minimal risk to participants, some flexibility will be allowed;
- Each page of the Participant Information and Consent Form must have a version date in the footer. If the Participant Information and Consent Form is amended, the version date should be updated as well and the new version must be submitted to The University of Manitoba Biomedical Research Ethics Board for approval prior to use.

2.10 Advertising for Study Participants

All advertising material, including those proposed for social media (e.g. Facebook and Twitter), must be reviewed and approved by the REB prior to implementation. Advertisements may be reviewed through delegated review procedures. The REB will review the information contained in the advertisement and the mode of its communication to ensure that the procedure for recruiting participants is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

When advertisements are to be taped for broadcast, the REB may either review the final audio/video tape, or alternatively, the REB may review the wording of the advertisement prior to taping to preclude re-taping because of inappropriate content.

A. Content of the Advertisements

No claims should be made, either explicitly or implicitly, that a drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device. Such representation would be misleading to participants and would involve promotion of investigational drugs and/or investigational devices.

Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as "new treatment", "new medication" or "new drug" without explaining that the test article is investigational. A phrase such as "receive new treatments" implies that all study participants will be receiving newly marketed products of proven worth. Advertisements should not promise "free medical treatment" or "free medication" when the intent is only to say participants will not be charged for taking part in the investigation. Advertisements may state that the participants will be paid, but should not emphasize the payment or the amount to be paid.

3. MAKING A GOOD REB SUBMISSION

Prior to submitting to the REB, researchers are strongly encouraged to familiarize themselves with the **Bannatyne Campus Research Ethics Board's Guidelines and Guidance on Initial Review**. Researchers should also review the REB submission deadlines and meeting dates to time their submission accordingly.

To ensure a good submission in all cases, always ensure the submission checklist has been reviewed and completed.

3.1 Common Pitfalls - Resulting in unnecessary delays and denial of REB approval

Poor submissions to the REB may result in your application being rejected or denied REB approval. Such denials can delay the commencement of your project and the study timeline and may prove to be costly. As such, good submission practices to the REB are critical to ensure your project commences on time and on budget. Below are common pitfalls that may result in submitted projects being delayed or approvals being denied.

3.1.1 The Study Proposal/Protocol

This section discusses common issues identified by the REB with submitted research study proposals/ protocols. These identified issues resulted in required clarifications, requested changes to the proposal/ protocol, and delays in approval until the clarifications / changes were addressed.

A. Lack of understanding of PHIA, FIPPA and privacy issues.

It is strongly recommended that Researchers familiarize themselves with privacy legislation, such as PHIA and FIPPA, and local regulations and policies surrounding the handling, storage and dissemination of data that may contain personal health information to ensure the study proposal/protocol is compliant.

B. Poor explanations of what the goal of the project is, or what hypothesis is being tested.

Researchers should clearly define what question the project is intending to answer or what the goal of the project is that they are intending on achieving.

C. Poorly described background or rationale for the research.

Researchers should ensure that the background and rationale for the research project is clearly conveyed in lay terms to allow a person without professional or specialized knowledge in the area to be able to understand the project description and terms being used.

D. Poor explanation of what data is being collected, and how it is to be used.

The study proposal/protocol should clearly identify what is being collected, how it is being collected, and how data derived will be used. Researchers should avoid generalizing terms or going on "fishing expeditions". Data collection should not be more comprehensive than what is outlined in the study objectives. For example, Researchers should say they are collecting blood pressure, heart rate, and respiration rate rather than simply saying "vital signs".

E. Poor explanation of the research methods.

The REB is obligated to consider the study design and quality of the Researcher's submission to adequately evaluate the risk-benefit ratio to study participants.

- Researchers should ensure that the research methods are clear and conform to generally accepted scientific principles, are scientifically sound, and are based on a thorough knowledge of scientific literature.
- Researchers should ensure that the research design adequately answers the research question.

Researchers should consider the methods proposed for participant selection, treatment assignment, and the collection of sensitive data.

F. Study Proposal/Protocol too technical - above level of understanding of the REB.

Researchers are to keep in mind that those reviewing the submitted research proposal/protocol may not all have training in your specialty or area of study interest. As such, the research proposal/protocol should not be too technical, (i.e. using technical jargon, medical terminology that is uncommonly recognized or understood). Researchers should avoid using too many acronyms, and where acronyms are used, they should be spelled out or defined at minimum the first time they are used in each document.

3.1.2 The REB Submission Form

This section discusses common issues identified by the REB with submitted Bannatyne Campus Research Ethic's Board Submission Forms. These identified issues resulted in required clarifications, requested changes/edits, delays in approval, and in some cases, denial of approval or rejection of the submission.

A. Research Ethics Board the Researcher is submitting to is not identified (checked) properly in the submission form. (Question 1.0)

Researchers are to ensure that either the Health **OR** Biomedical is checked. If Researchers are not sure which board to submit to, they are to contact the REB Office PRIOR to the submission deadline.

B. Missing or incomplete information. (Entire Submission Form)

Researchers risk unnecessary delays to the commencement of their project when they fail to submit a completed REB submission application form. Researchers must ensure that all relevant fields are complete and contain responses that adequately answer the question posed.

Submission forms received that are incomplete, missing information, or do not sufficiently address the question may be returned to the submitter.

Researchers are to ensure the application is submitted with the appropriate signatures and accompanying documentation requiring review (i.e. protocol, consent forms, advertisements, instruments etc.). The REB has created submission checklists which are required with each submission. Failure to submit without the checklist may result in the submission being denied.

C. Documents identified as being used, but not submitted (i.e. ads)

Researchers are to ensure that all documentation identified on the submission form are submitted to the REB.

D. Responses inconsistent between the study proposal/protocol and the submission form. (Entire Submission Form)

Researchers are to ensure that information provided in the submission form reflects the information contained in the study proposal/protocol and that responses are consistent throughout the form.

E. Inadequate contact information provided

Researchers **MUST** provide contact information which includes their mailing address, phone # and email address. If the Researcher has a study coordinator or alternate contact, this person should be clearly identified by name, along with the mailing address, phone # and email address. Researchers should refrain from using "departments", Wards, and/or "floors" as their primary mailing contacts. Contact information should be specific to the Institution, Building or Department and Room # or Mailstop.

F. Instruments not identified in the submission form

Instruments that are being used in the study for the collection of data (i.e. surveys, questionnaires, assessment tools) should be clearly identified and explained how they will be used.

G. Consent procedure poorly explained and who is obtaining consent not clearly identified (Questions 42 and 43)

If applicable, the consenting process must be clear and must include/begin with how study participants will be recruited (i.e. through public advertising). Information pertaining to process or procedure of providing the study information and consent form to the study participant should also be included.

The person who has been assigned by the Researcher to obtain consent from the research participant should be clearly identified and understood (i.e. research assistant).

Note: Clinicians are not permitted to obtain consent from their own patients.

H. Handling, Use and Storage and Privacy and Confidential Information not clear, incomplete or poorly explained (Questions 48 through 53)

Researchers are to clearly articulate the procedures used to safeguard the privacy and confidentiality of their study participants including the protection of their personal data and/or personal health information, not only during the research project, but after the project has been completed (i.e. publishing the findings).

Researchers are to clearly identify what identifying information (i.e. name, address, date of birth, initials, PHIN, medical records number etc.) they are intending to collect, how this is being documented, stored and who will have access to the information (i.e. study monitor, colleague at another institution). Researchers are to clearly articulate what information/data will be disseminated or leave the site and must provide an adequate rationale why these identifiers are required on records that leave the study site.

Researchers are to clearly specify how long they intend on retaining the data collected and the procedures for securing and storing the data. When the data is to be destroyed, Researchers need to clearly articulate the destruction methods (i.e. confidential shredding).

All persons who will have access to confidential and potentially identifiable data need to be clearly identified in the submission form (Question 52). Researchers are to identify all the agencies (i.e. Health Canada, FDA, sponsors, CROs) and individuals (i.e. research personnel) who may have access to the confidential data collected for the study and the information in the medical records, now or in the future.

I. Misunderstanding the difference between identifiable, de-identified, anonymized and anonymous information.

Researchers should familiarize themselves with the following terms and use them appropriately in the submission form:

Identifiable information: information or data that could potentially allow a person to identify a specific individual.

De-identified Information (aka coded information): information or data about specific individuals that has been "coded" as to prevent an individual from being identified by those reviewing the collected data who are not authorized to know the identity of the individual. Direct identifiers are removed from the individual's data, but each record containing the data has an assigned code which can be linked to identifiable information by the Researcher or his/her study team. (i.e. assignment of a participant number and all initials and identifiers removed).

Anonymized Information: information where direct identifiers and/or identifying codes have been irrevocably stripped or deleted from the collected data so the data can no longer be traced or linked back to the individual.

Anonymous Information: information gathered that has never been and can never be linked to specific individuals.

3.1.3 The Participant Information and Consent Form (if applicable)

This section discusses common issues identified by the REB with Participant Information and Consent Form. These identified issues result in required clarifications, requested changes/edits, delays in approval, and in some cases, denial of approval or rejection of the submission.

Researchers are strongly encouraged to familiarize themselves with the **Informed Consent Guidelines (Appendix E)** located on the Bannatyne Campus Research Ethics Board Website.

A. Missing or Incomplete Information with the Consent Form

Researchers risk unnecessary delays to the commencement of their projects when they fail to submit a consent form that is complete. Informed consent templates are available on the Bannatyne Campus REB website as reference.

Researchers must ensure that the consent form contains, at minimum, the essential elements as defined with TCPS 2.

Consent Forms should clearly explain the purpose of the research study.

The consent form should, at minimum, contain the following statements/information:

- Expected duration of the Participants participation;
- Description of the procedures, including tests, drugs, questionnaires, assessments, that will be used;
- Clearly identifying what is “experimental” and what is not; whether a placebo control is being used; and what is beyond the standard of care procedure.
- Clearly identify what interventions are being administered, when, and by whom.
- Describe any appropriate alternative treatment options or procedures. A statement should be made advising the participant that they may elect to receive standard treatment instead of participating in research.
- Describe any risks that are known about the procedure, treatments, or risks of participating. Researchers are also to provide a statement advising that the particular treatment may involve risks to the participant which are currently unforeseeable.
- Researchers should clearly identify any benefit, or lack thereof, that the Participant or others may experience.
- Researchers **MUST** include a statement that advises the participant that if any significant new information becomes available during the research, which may be related to the participant’s willingness to participate, will be provided to them.
- If applicable, Researchers are to disclose that they are getting paid by the Sponsor in the introduction of the consent.
- Researchers are to provide a statement saying that participation is a) voluntary; b) that the participant may refuse to participate; and c) that participation can be terminated by the participant at any time without prejudice.
- Researchers are to provide a statement that participation in the study could be halted or terminated by the Investigator or Sponsor without the Participant’s consent.

Researcher **MUST** provide his/her contact information on the consent form.

B. Understanding the Impact of PHIA on a Consent Form

Consent forms must specify who will be accessing and/or copying records containing personal health information (PHI) and which records (e.g. Medical Records, if so at which site; Research Study Records; Physician's office records, etc.). Per PHIA, disclosure of PHI may be made without the consent of the individual only if the committee has determined that:

- the research is of sufficient importance to outweigh the intrusion of privacy that would result from the disclosure of PHI,
- the research purpose cannot reasonably be accomplished unless identifying PHI is provided in a form that identifies or may identify individuals,
- it is unreasonable or impractical for the person proposing the research to obtain consent from the individuals the PHI is about, and;
- the research project contains:
 - reasonable safeguards to protect the confidentiality and security of the personal health information, and;
 - procedures to destroy the information or remove all identifying information at the earliest opportunity consistent with the purpose of the project.

C. Language Use is Too Technical / Above Acceptable Reading Standards / Levels

Researchers should strive to develop a consent which is written at a level of language that is appropriate to the age of comprehension of the participant population. It is generally accepted that consent forms be written at a grade 6 - 8 reading level.

Researchers should refrain from:

- Legalistic phrases or technical jargon;
- Overuse of abbreviations and acronyms, and;
- Volumes, weights and measures that are not expressed in meaningful scales (i.e. blood draws could be described in numbers of teaspoons).

D. No Separate Consent for Storage of Biological Materials

Biological Materials are defined as human tissue (e.g. bone, muscle, skin, connective tissue, organ tissue), hair, blood body fluids, feces and DNA/RNA. The collection, storage, and use of human biological materials for research must be undertaken with the free and informed consent of the competent donors.

The collection, storage, and use of human biological materials for research must be undertaken with the free and informed consent of competent donors. In the case of incompetent donors, free and informed consent must be obtained from an authorized third party. In the case of deceased donors, free and informed consent must have been expressed in a prior directive or free and informed consent must be obtained from an authorized third party (TCPS 2, Article 12.1).

Informed consent is required when the biological material to be used in research whether acquired incidentally or purposefully per TCPS 2, 12.1. "Acquired incidentally" refers to material left over from clinical samples or extra samples acquired at the same time as clinical samples. **The consent form for research use of human biological samples should be separate from the consent form for clinical procedures.**

E. General Principles of a Consent for Collection, Use and Storage of Biological Materials Consent Missing

The general principles (TCPS 2 Chapter 12) for informed consent, **as outlined in the consent form templates for the Bannatyne Campus**, should be applied in addition to the following issues specific to the collection of biological material:

1. The purpose of the research for which biological samples are being collected;
2. The type and amount of the biological sample to be taken; the manner in which sample will be taken; and the safety and invasiveness of acquisition;
3. The potential uses for the sample, including any commercial uses Use for genetic research must be specified.
Note: Generalized descriptions of the potential uses are only acceptable if the samples are anonymized.
4. Potential benefits and harms from the research (including, where appropriate, benefits and harms to families, groups, or communities).
5. Specify how long the samples will be. Note: Storage for an indefinite period of time is only acceptable if the samples are anonymized.
6. Specify where the tissue will be stored; and, if applicable, who will be responsible for distributing the tissue for future research.
7. The consent form may be designed with yes/no check-boxes giving participants the opportunity to consent to or refuse certain categories of research. Examples include:
 - Future use of identifiable samples for any study relating to the condition for which the sample was originally collected;
 - Future use of anonymized samples for any study relating to the condition for which the sample was originally collected;
 - Future use of anonymized samples for studies that are unrelated to the condition for which the sample was originally collected;
 - Use of samples for one particular study;
 - Future contact permitted to ask for permission to do further studies; etc.
8. Describe the safeguards to protect the individual's privacy and confidentiality;
9. Describe any identifying information attached to specific samples, links to personal information, and potential for traceability.
10. When the consent is obtained in a clinical setting, it should be clear that refusal to consent to the research use of biological materials will in no way affect the quality of the patients' clinical care;
11. The participants should be told whether they will be provided with the results of the tests. In the case of anonymized samples, where appropriate, participants may be given the overall results of the study. The results should be disclosed when they signify a clinical problem and methods to ameliorate or treat the condition are available. If the results will not be disclosed, reasons for this should be provided.
12. Where the samples are identifiable, the participants should be able to request that his/her sample be destroyed. The exercise of the right to withdrawal is not possible in the case of anonymized samples and the participants should be informed of this in the consent form;
13. Where appropriate, the researcher should inform the participants at the time of consent that the subject is not entitled to any financial or commercial benefits arising from the research;

14. If the biological samples or data derived from the research are to be sent to other researchers or institutions, the participants should be informed at the time of consent to participation and given the opportunity to decline (e.g. using a yes/no check box). The recipient researcher's/institution's policies governing storage and access to stored samples should be forwarded to the REB along with the request for approval.

F. No Separate Consent Form for Genetic Research

The consent form for research use of human biological sample, including for genetic research, should be separate from the consent form for clinical procedures (TCPS 2 Article 12.1).

In addition to the guidelines for research involving stored biological material, the following must be considered for genetic research:

- The researcher must ensure that the results of genetic testing and genetic counseling records are protected from access by third parties (e.g. insurers, employers), unless free and informed consent to do so is given by the participants (TCPS 2, Article 13). For example, for some studies the REB may request that there be no mention of the study in the participant/s medical charts.
- Family information in databanks must be coded so as to remove the possibility of identification of participants within the bank (TCPS 2, Article 13.5).
- Children may be at particular risk for stigmatization both within and beyond the family because of knowledge gained through genetic studies. Genetic research involving children [regarding specific diseases] should not be done unless an effective intervention is available and the information to be gained outweighs the risk of harm. (e.g. it may be appropriate to offer testing to children in a family for an early onset condition such as polyposis coli, for which the knowledge affects treatment options, but inappropriate to test children for an adult onset condition such as Huntington Disease for which no effective prevention yet exists (TCPS 2, Article 13.5).
- Where appropriate, researchers and the REB shall ensure that the research protocol makes provision for access to genetic counseling for the participants (TCPS 2, Article 13.4).
- Gene alteration (including "gene therapy") that involves human germline cells or human embryos is not ethically acceptable. Gene alteration for therapeutic purposes and involving human somatic cells may be considered for approval.

G. Considerations when Preparing Assent Forms

When preparing assent forms for children, it is especially important to convey information that is sensitive to their perspective on the procedures, risks, discomforts, and inconveniences using terms that are developmentally and cognitively appropriate. The Assent Form should be brief, no longer than 2 pages, plus one for signatures.

H. Consent Poorly Formatted or Not in an Acceptable Format

Researchers are to ensure that submitted consent forms comply with the formatting requirements. Consent forms should display the appropriate, current, University of Manitoba logo. When a research study uses more than one consent form they must be appropriately labeled as to their purpose (e.g. focus group consent form, genetic consent form) or study populations (e.g. health controls consent form).

I. Inadequate Contact Information Provided

Researchers **MUST** provide local contact information which include their mailing address and phone # (email address is optional). If the Researcher has a study coordinator or alternate contact, this person should be clearly identified in the consent with the contact phone #.

3.1.4 Other Materials

Researchers should apply the same diligent attention for other supportive materials that will be used during the conduct of the study as to prevent unnecessary delays for the project.

A. Advertising: Making Unsubstantiated Claims of Benefit

Researchers should be cognizant of the language within their proposed advertisements to ensure that the advertisements used to recruit study participants **makes no unsubstantiated claim of benefit**, either explicitly or implicitly (i.e. that a drug, biologic or device is safe, effective or that the test article is known to be equivalent or superior to any other).

B. Advertising: Payment/Honorarium Amount Displayed

Advertisements may state that the participants will be paid (i.e. stipend / honorarium), but should not emphasize the payment **or the amount to be paid**.

C. Advertising: Missing Information

Study advertisements should convey, at minimum, the nature of the study, the study population sought, and where to contact to get more information.

D. Submitting Multiple Ads for Review with no Explanations

Researchers should conform to good documentation principles by way of identifying each advertisement submitted, with version numbers or dates within the footer of the document. (i.e. Poster Advertisement #1, Version 1.0).
Researchers should not submit multiple versions of study ads without clearly identifying the ad and its purpose.

E. Data Collection Tool: Collecting Data Not Identified in the Protocol

Researchers are only allowed to collect data that is outlined and specified within the research proposal/protocol. Data that is being collected that is part of a validated survey, questionnaire or assessment tool is acceptable if the tool has been identified in the protocol, otherwise, each data item should be identified using terminology that is commonly understood.

F. Amended Materials Not Submitted in Track Changes

Amended materials (i.e. protocol, consent forms, study ads) are to be submitted to the REB in tracked changes (i.e. colored or ~~strikeout~~) as to allow for clear identification of what was changed.

3.2 Good Documentation Practice

Researchers should consider conforming to good documentation principles when submitting to the REB such as:

- Clearly written documentation contains titles and subject headings;
- Page numbers using or following the standard of XZ of Y (i.e. Page 4 of 10);
- Clear versioning of each amendment, iteration, or release which displays the version and date within the footer of the document (i.e. version 1.1, 2015-Sept-15);
- Use of consistent date formats across all documents (i.e. year, month, day).

4. RESEARCHER RESPONSIBILITIES

A Researcher is ultimately responsible for the research project he/she is conducting throughout that project's lifecycle (i.e. from conception to publication). Researchers conducting research have an obligation to adhere to good research practices and reporting requirements as mandated by regulations governing research conduct, whether they are affiliated with the University of Manitoba or not. Researchers are strongly encouraged to familiarize themselves with federal, provincial and local legislations, regulations and guidances and institutional policies that govern research to ensure ongoing compliance. Below are regulations, that at minimum, the researcher should familiarize themselves with.

4.1 Regulations and Guidelines Governing Research

A. Personal Health Information Act of Manitoba (PHIA)

Is a piece of Manitoba legislation that establishes rules governing the collection, use, disclosure, retention and destruction of personal health information (PHI). From a research context, it is an Act that recognizes an individual's right to privacy with regards to their PHI, while balancing the researchers need to collect and use a research participant's PHI. Researchers are strongly encouraged to familiarize themselves with PHIA, in particular, **section 24** (Appendix F), which pertains specifically to health research.

The REB must be provided with explicit information as to how participants are going to be recruited and approached (e.g. through review of medical charts, direct contact with participants, etc.) to ensure that the importance of the research outweighs the intrusion into privacy. The REB must be assured that safeguards are in place to protect the confidentiality of PHI. The approval to access PHI (i.e. logs, etc.) and to approach individuals about a research study will be incorporated into the REB review process.

Researchers affiliated with the University of Manitoba and Winnipeg Regional Health Authority (WRHA) must sign a PHIA agreement whereby the Researcher agrees to the following:

- Not to publish PHI in any form that could reasonably identify the individuals concerned.
- To use the PHI solely for the purposes of the approved research project. If researchers will be approaching individuals participating in a study about future studies, the consent to participate in the original study should include consent to this approach.

B. Tri-Council Policy Statement (TCPS 2):

Is a policy that was conceived, drafted, and implemented by three federal research agencies, the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities research Council of Canada (SSHRC). The policy focuses on ethical conduct of research based on the core principles of respect for persons, concern for welfare, and justice.

To be eligible to receive and administer research funds from the above three agencies, Institutions must therefore ensure that research conducted under their auspices adhere to this Policy - as such, **"Researchers are expected, as a condition of funding, to adhere to the TCPS"**, and Institutions are to support the Researcher's efforts in doing so. Researchers should familiarize themselves with TCPS 2 to ensure compliance with this policy.

TCPS Official Website: www.pre.ethics.gc.ca

As of September 2011, all Students, Researchers and Faculty submitting to Bannatyne Campus Research Ethics Board for protocol or project review and approval will require completion of the TCPS 2 Tutorial: Course on Research Ethics (CORE). **CORE** is a self-paced, online, modular tutorial related to the conduct of safe and ethical conduct of research on humans. Course completers can print and submit to the REB their certificate of completion.

Course on Research Ethics (CORE): <http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>

Please note: The National Institutes of Health Online Tutorial - Human Participants Protection for Research Teams (<https://phrp.nihtraining.com/users/login.php>) must be completed for any key personnel listed on the grant/contract for USA federally funded studies (e.g. NIH, Centers for Disease Control, US Army etc.).

C. ICH-GCP {E6}

Is an “international quality standard” which was devised by the International Conference on Harmonization (ICH), an international body that defines standards, which governments can transpose into regulations for clinical trials involving human participants. These standards provide the technical requirements for pharmaceuticals for human use and serves as a basis for much of the regulatory content in Health Canada regulations and FDA Regulations. If research involves the use of a pharmaceutical, device, or natural health product, researchers are strongly encouraged to familiarize themselves with this standard.

ICH Official Website: www.ich.org

D. Health Canada Regulations:

Researchers should ensure that they are familiar with Health Canada Regulations if their research involves a pharmaceutical drug (whether investigational or post-market), medical device, or natural health product to ensure compliance with same.

- **Food and Drug Regulations (FDR) - Part C - Division 5:** If the research protocol involves the use of a drug, Researchers are strongly encouraged to familiarize themselves with the regulations under this part and division to ensure compliance with the regulations. The regulations define what constitutes a Qualified Investigator and lays out the responsibilities of the investigator.
- **Medical Devices and Natural Health Products Regulations:** If the research protocol involves the use of a medical device or natural health product, Researchers should visit the Health Canada website and familiarize themselves with these regulations to ensure compliance with same.

E. Food and Drug Administration (FDA)

If the research involves a drug or medical device under and FDA IND (Investigational New Drug) or Medical Device, Researchers should familiarize themselves with the Code of Federal Regulations.

- **Code of Federal Regulations, Title 21, Part 312 (21 CFR 312):** Pertains to investigational drug regulations for clinical trials, of which Subpart D pertain to the responsibilities of the investigator.
- **Code of Federal Regulations, Title 21, Part 812 (21 CFR 812):** Pertains to investigational medical device regulations for Investigational Device Exemptions and covers the procedures for the conduct of clinical studies with medical devices including application, responsibilities, labeling and records management.

4.2 Clinical Trial Registration

Per Article 11.3 of TCPS 2, “All clinical trials shall be registered before the recruitment of the first participant in a recognized and easily accessible public registry.” The International Committee of Medical Journal Editors (ICMJE) also requires registration of clinical trials in a public trials registry “at or before the time of first patient enrollment as a consideration for publication.”^{iv} If your research meets the definition of a clinical trial, as defined by TCPS 2, Researchers are to register their clinical trials on a public registry that is recognized and accepted by the University of Manitoba REB. Researchers are to refer to the Bannatyne Campus Research Ethics Board Guidelines for Registering in a Clinical Trials Registry (Appendix G).

4.3 Conflicts of Interest

It is the Researchers responsibility to report any conflict of interest, perceived or real, of financial or personal interest, that may compromise the integrity of or have the appearance of compromising the Researcher's independence or objectivity in the performance of the research. Researchers are to disclose this in sections 58.0 - 60.0 of the initial submission form. Researchers are obligated to report on any potential conflicts of interest to the REB throughout the research project's lifecycle. Researchers are encouraged to familiar themselves with University of Manitoba Conflict of Interest Policy.

4.4 Adverse Event / Unanticipated Problems Reporting

Adverse Event or Unanticipated Problems collection and reporting are required for all research studies regardless of whether it is a clinical or non-clinical trial, sponsor or investigator initiated. Adverse Event collection should document unfavorable changes in current health status of the research participant or any incident, experience or outcome that suggests that the research may place participants or others at a greater risk of harm (including physical, psychological, economic or social harm). The investigator must ensure the protocol outlines how adverse events will be defined, documented and monitored at the site and subsequently reported to the sponsor(s), Health Canada, applicable regulatory authorities (e.g. FDA, US Department of Health and Human Services) and the Research Ethics Board (REB). The investigator should review the Health Canada website for guidance on reporting requirements to regulatory agencies.

Researchers are strongly encouraged to familiarize themselves with the "Local Adverse Event Reporting and REB Review" SOPs located on the REB website.

4.5 Annual Approval (Compliance)

All research studies, databases/registries or specimen repositories, etc. that received initial approval from a Bannatyne Campus Research Ethics Board (REB) must be resubmitted for annual approval to the appropriate REB **no later than 4 weeks prior to the expiry date** noted on the initial certificate of final approval if the Research intends to continue the research past the expiration date. This includes all research studies, databases or specimen repositories, etc. that may be 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. Local research databases/registries or specimen repositories should submit an application for annual approval up until the point the data or specimens are destroyed.

Researchers MUST report the statuses of their research studies to the applicable REB (BREB or HREB).

Researchers are to familiarize themselves with the Annual Approval /Continuing Review Guidelines to ensure compliance with same (Appendix H).

In 2015, the Bannatyne Campus REB initiated an Annual Approval Expiry Notification System, whereby Researchers will be notified, by email, of their pending approval expirations. Researchers will receive notification of their approval expirations 60, 30 and 14 days prior to expiration. On the day that approval expires, Researchers will be requested to cease all study related activities and if no response is received from the Researcher 30 days past expiration, the REB will close the file and the Researcher will be required to re-submit.

Notification and Compliance Process for Annual Approval Expiries (HIGH LEVEL)



As a courtesy, the Bannatyne Campus REB office should be notified of closure via the Bannatyne Campus Research Ethics Board Final Study Status Report of any study previously submitted for ethical review regardless of whether the study received final approval or not.

A. Tips when requesting Annual Approval:

- All requests for annual approval, including research approved by the HREB and BREB, must be submitted using the Bannatyne Campus Research Ethics Office "**Annual Study Status Report**".
- Submit the request for annual approval 4-6 weeks prior to the expiry date noted on the initial certificate of approval or last annual approval certificate to ensure there is no lapse in approval.
- If recruitment is ongoing, include one copy of the consent form presently in use for review and approval.
- It is the Researchers responsibility to report any conflict of interest, perceived or real, of financial or personal

4.6 Protocol Deviations

As per ICH GCP 4.5.2 "The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial participants, or when the change(s) involves only logistical or administrative aspects of the trial (e.g. change in monitor(s), change of telephone number(s))."^v

This guideline outlines the requirements for submitting information concerning a protocol deviation that had not received prior approval by a Bannatyne Campus Research Ethics Board, as required under ICH GCP 4.5.2, because the deviation was necessary in order to ensure the participants safety, was of an inadvertent nature, or was administrative in nature.

4.7 Submission of Amendments and Amended Documents

Researchers are obligated to follow the procedures outlined in the proposal/protocol approved by the Research Ethics Board (REB). If the Researcher or study Sponsor recognizes the need for modification to the proposal/protocol, the Researcher is obliged to file a **protocol amendment** with the REB.

Researchers need to evaluate whether or not the consent form (if applicable) also requires being amended to coincide with the changes to the protocol.

Examples of amendments that require REB review include, but are not limited to, changes in: key personnel (e.g. principal investigators, co-investigators, study physicians); research protocol objectives; advertising materials (flyers, radio spots, etc.); research procedures; participant populations (e.g., age range); location where research will be conducted; consent/assent form; recruitment procedures; date for completion of study; procedures for monitoring safety data etc.

A Certificate of Approval from the REB must be granted prior to implementing the change.

A. Tips when submitting Amendments/Changes to a protocol:

- Complete and review the Bannatyne Campus REB "Submission Requirement Checklists for Amendments, Additions or Changes to Approved Studies Delegated Review or Full Board Review".
- All changes must be submitted on the Bannatyne Campus Research Ethics Board "Request for Amendment/Changes to a Previously Approved Study" form.
- Additions to amended documents must be underlined or in bold text and any deletions indicated by ~~strikethrough~~.
- Remember to revise the version date in footer of each page of amended consent forms and the title page on all supporting documents.

5. RESEARCH QUALITY MANAGEMENT

Reporting to the Vice-President Research and International Office, the Research Quality Management (RQM) unit is part of the Office of Research Ethics and Compliance (OREC) team. RQM assists the Research Ethics Boards (REBs) with post-approval oversight activities through consultation, site visit (audits) and meetings with researchers (Faculty members and students). RQM also provides support through facilitation of educational events. Through collaboration with members of the research community, RQM helps support best practices in the conduct of research with humans.

A. Education

Educational activities promote safe and ethical conduct of research involving humans across all academic disciplines.

Educational site visits (audits) involve a review of researcher practice at the research site. This may include a review of researcher responsibilities and obligations as determined by federal regulations and international guidelines that govern the conduct of research involving humans.

B. Collaboration

RQM will meet with the Principal Investigator and members of the research team to better understand the site-specific activities involved in the conduct of a study and whether institutional policies, international research guidelines and federal regulations are being met. Site visit (audit) findings are translated into positive learning opportunities.

C. Evaluation

Ongoing review and evaluation of the RQM program is sought through regular reporting to the VPRI, consultation with the research community, and formal review by university audit services.

Research Quality Management Website: <http://umanitoba.ca/research/orec/736.html>

6. ABBREVIATIONS AND DEFINITIONS

6.1 Abbreviations

AE: Adverse Event

BREB: Biomedical Research Ethics Board (Bannatyne Campus)

CFR: Code of Federal Regulations

CTA: Clinical Trial Application

CTA-A: Clinical Trial Application - Amendment

FDA: Food and Drug Administration (USA)

GCP: Good Clinical Practice

HREB: Health Research Ethics Board (Bannatyne Campus)

NOL: No Objection Letter

QIU: Qualified Investigator Undertaking

REB: Research Ethics Board

TCPS 2: Tri-Council Policy Statement 2, December 2014

TPD: Therapeutic Products Directorate

6.2 Definitions

Adverse Event: Per Health Canada an adverse event is... “Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.”^{vi}

Clinical Trial: Per Health Canada a Clinical Trial is... “an investigation in respect of a drug for use in humans that involves human participants and that is intended to discover or verify the clinical, pharmacological or pharmaco-dynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug.”^{vii}

Human Research: Human Research 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. survey, 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).

Research: Involves diligent systematic investigation of a subject matter aimed to discover, interpret facts, theories or knowledge or to address a specific hypothesis. It involves the collection of data about a particular study participant or volunteer.

7. RESOURCES

Personal Health Information Act of Manitoba (PHIA)

- <http://www.gov.mb.ca/health/phia/index.html>

Application of Personal Health Information Act (PHIA) in a Research Ethics Context:

- http://umanitoba.ca/faculties/health_sciences/medicine/ethics/phia.html

PHIA Requirements for Databases

- http://umanitoba.ca/faculties/health_sciences/medicine/ethics/guidelines.html

Tri-Council Policy Statement (TCPS) 2

- <http://www.pre.ethics.gc.ca/>

Tri-Council Policy Statement (TCPS) 2: Course on Research Ethics (CORE)

- <http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>

Research Integrity - University of Manitoba, Research International

- <http://umanitoba.ca/researchintegrity/>

Responsible Conduct of Research - University of Manitoba, Research International

- http://umanitoba.ca/research/media/Responsible_Conduct_of_Research.pdf

Office of Research Ethics & Compliance

- <http://umanitoba.ca/research/orec/735.html>

Health Canada/Good Clinical Practice

- <http://umanitoba.ca/research/orec/ethics/gcp.html>

Research Quality Management - University of Manitoba

- <http://umanitoba.ca/research/orec/736.html>

8. REFERENCES

ⁱ "The Ethics of Research Involving Humans", University of Manitoba, Policy Revised July 2nd, 2013

ⁱⁱ Ethical Conduct for Research Involving Humans, Tri-Council Policy Statement 2, Dec. 2014, p. 202

ⁱⁱⁱ Ethical Conduct for Research Involving Humans, Tri-Council Policy Statement 2, Dec. 2014, p. 28

^{iv} International Committee of Medical Journal Editors, www.icmje.org

^v International Conference on Harmonization, Good Clinical Practice, E6 (R1), May 1996

^{vi} Health Canada Guidance of Industry:

<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demanded/guide-ld/ich/efficac/e2a-eng.php>

^{vii} Health Canada Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications:

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demanded/guide-ld/clini/ctdcta_ctddec-eng.php#a21

Personal Health Information Act (PHIA):

APPENDICIES

A: Categories of Procedures for Review of New Research Protocols:

- http://umanitoba.ca/faculties/health_sciences/medicine/ethics/media/Catorgies_for_review_of_new_procedures.pdf

B: Checklist for Full Board Review of New Studies:

- [http://umanitoba.ca/faculties/health_sciences/medicine/ethics/media/Checklist_NEW_STUDIES_\(Full_Board\).docx](http://umanitoba.ca/faculties/health_sciences/medicine/ethics/media/Checklist_NEW_STUDIES_(Full_Board).docx)

C: Checklist for Delegated Review of New Studies:

- [http://umanitoba.ca/faculties/health_sciences/medicine/ethics/media/Checklist_NEW_STUDIES_\(Delegated\).docx](http://umanitoba.ca/faculties/health_sciences/medicine/ethics/media/Checklist_NEW_STUDIES_(Delegated).docx)

D: Submission Form for Retrospective Chart Review:

- http://umanitoba.ca/faculties/health_sciences/medicine/ethics/media/Retrospective_Charts_or_Records_Review_Submision_Form.doc

E: University of Manitoba Bannatyne Campus Research Ethics Board - Informed Consent Guidelines

- http://umanitoba.ca/faculties/health_sciences/medicine/ethics/consent_guidelines.htm

F: Personal Health Information Act (PHIA), Section 24:

- <http://web2.gov.mb.ca/laws/statutes/ccsm/p033-5e.php>

G: Guidelines for Clinical Trials Registration:

- http://umanitoba.ca/faculties/health_sciences/medicine/ethics/media/Clinical_Trial_Registration_July_2012.doc

H: Annual Approval /Continuing Review Guidelines:

- http://umanitoba.ca/faculties/health_sciences/medicine/ethics/media/AnnualReviewProcedures-RevisedJun2015.pdf