

THE CONSENT FORM

This section provides common issues identified by the REB with the Consent Form.

1. **Missing or Incomplete Information:** All Researchers using consent forms must ensure that information contained within it is complete, accurate and clearly reflects what is within the proposed research proposal / protocol. Researchers are strongly encouraged to familiarize themselves with TCPS2 to ensure the submitted ICF contains all the minimal elements listed. You must ensure that the consent form complies with all federal and provincial regulations that govern research. An ICF template is available for download on the REB website.
2. **Who will Have Access to the Data?** The ICF should specify who will be accessing and/or viewing the participant's information. Specify what records will be used (i.e. medical records) and who will have access. Understand how PHIA impacts what you need to convey to the participant.
3. **Language Technical or Above Level of Understanding:** Strive to develop an ICF that is written at a level of language that is appropriate for the age of comprehension as to ensure all who require reading it, can.
4. **Poor Formatting and Flow:** Familiarize yourself with the REB formatting requirements to ensure compliance. The ICF should display the appropriate, current, University of Manitoba Logo. When using more than one type of consent, specify this in the title (i.e. healthy group consent).

DELAY IN APPROVAL = DELAY IN STUDY RESULTS

Researchers should apply the same diligent attention to the REB submission as to the design and conduct of their research project. To prevent unnecessary delays in the commencement of your project:

Ensure that your research proposal is clear, concise and with clear method and design that clearly answers the research question;

Ensure the submission form is accurate for the proposed research protocol and complete, answering all of the relevant fields and ensuring that the information provided is not in conflict with the protocol or the consent form. Clearly identify what data you are going to collect, how you are going to collect it, what tools you used in its collection and how you are going to analyze it.

Ensure the consent form contains language that is easily understood by the target population, is not too technical or contains too many acronyms or abbreviations. Ensure what is stated is sufficient and complies with regulations and REB formatting requirements.

Ensure supportive materials (ads, instruments, and data collection tools) are submitted and clearly explain how they will be used.

Ensure study advertisements make no unsubstantiated claims of benefit.

Bannatyne Campus Research Ethics Board

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Common REB Submission Pitfalls

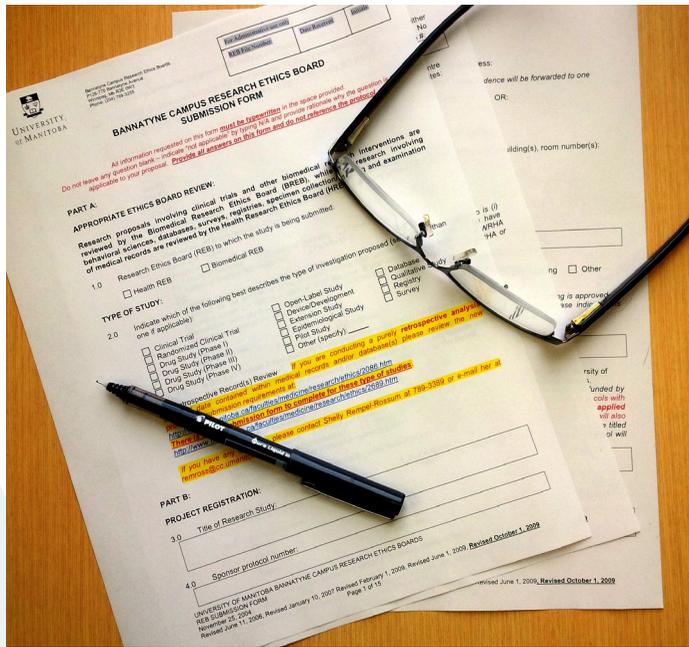
Tips for Making a Good REB Submission
& Avoiding Delays in Approval



Bannatyne Campus
Research Ethics Board



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THE STUDY PROPOSAL / PROTOCOL

This section discusses common findings identified by the REB with the submitted research study proposal / study protocol. These issues have resulted in a request for clarification or a content change in the proposal/protocol.

- 1. Poor Explanation – What’s the Goal of the Project?**
Clearly define within the proposal / protocol what question the research project is intending to answer; what hypothesis is being tested; or what the project is intending on achieving.
- 2. Lack of Details – Background and Rationale:** Ensure both the background and the rationale for conducting the study is clearly conveyed.
- 3. Poor Understanding of PHIA and Privacy Rules:** Familiarize yourself with PHIA (i.e. Section 24) and regulations and policies that pertain to privacy to adequately explain your procedures for safeguarding confidentiality and participant data.
- 4. Poor Explanation - Data Collection & Analysis:** Clearly identify what data is being collected, how it is being collected (i.e. identify the data collection tool, and describe when and how it will be used) and how data will be analyzed. Data collection should not be more comprehensive than what is outlined in the study objectives.
- 5. Poor Methodology or Study Design:** Methods outlined within the proposal/protocol should be clear and conform to generally accepted scientific principles and be scientifically sound, based on thorough knowledge of the scientific literature. The design should adequately answer the research question.
- 6. Excessive use of Technical Jargon & Abbreviations:** Limit the use of technical terminology; use layman’s terms; Limit acronyms and abbreviation use and clearly identify what acronyms mean when used.

THE STUDY PROPOSAL / PROTOCOL

Making a poor Research Ethics Board (REB) submission may result in denial of REB approval. Such denials delay the commencement of your project, potentially impacting your timely access to study funding, your study timeline, your contractual obligations, and your study budget. For these reasons, good submission practices to the REB are critical to ensure your project commences on time and completes within budget.

This brochure provides you with brief highlights of some of common pitfalls the REB has identified that result in submitted projects being delayed or approvals being denied outright. This information is intended to assist you in making good quality submissions to the REB, increasing the likelihood that your project will be approved on first pass (on initial submission).

Researchers are encouraged to further obtain a copy of the Bannatyne Campus REB - Investigator Training Manual which can be downloaded from the REB website or obtained in print from the REB Office.

THE REB SUBMISSION FORM

This section provides common errors or omissions identified by the REB with the REB Submission Form.

- Board Submitting to Not Identified:** Clearly indicate which board you are submitting to, BREB or HREB.
- Lack of and/or Missing Information:** Submission forms are to be complete with all the relevant fields containing responses that adequately answer the question. Researchers should ensure the application is submitted with appropriate contact information and signatures. Submission Checklist is available on the REB website and are required upon submission.
- Documents Identified as Being Used Not Submitted:** The REB is obligated to review all documents (such as the consent form, advertisements, instruments and data collection tools) listed in the research proposal/ protocol and REB submission form. Please submit these documents with the submission form.
- Inconsistent Responses between Submitted Items:** Ensure that the information provided on the REB Submission Form reflects what is stated within the proposal / protocol and what is stated within the consent. If an instrument has been identified in the proposal / protocol, it should be listed on the submission form and submitted.
- Poor Explanation - Consent Procedure (Q42 & 43):** if applicable, the consenting process should be clear and must include how participants will be recruited; the process of obtaining consent and who will obtain consent. Please Note: Clinicians are not permitted to obtain consent from their own patients.
- Poor Explanation - Confidentiality & Privacy:** Clearly articulate the procedures used to safeguard the privacy and confidentiality of study participants. Clearly identify what identifying data is being collected, how it will be stored and disseminated.