University of British Columbia – Children's & Women's Research Ethics Board

UBC C&W Research Ethics Board
Room A2-141A
950 West 28th Avenue
Vancouver, B.C. V5Z 4H4
Tel: (604) 875-3103
Email: cwreb@bcchr.ubc.ca
Website: www.phsa.ca/researchethics
RISe: https://rise.ubc.ca

GUIDELINES FOR WRITING A RESEARCH PROTOCOL

All of UBC's REBs mandate that a research protocol MUST be submitted for all research applications regardless of the type of study. These must be submitted as separate documents attached to box 9.1 of the RISe application form. *The C&W REB does not allow proposals submitted to granting agencies to be used to meet this requirement.* Protocols must include the following components:

1. A background literature review (with accompanying references) that includes an explanation of the need/justification for the study.
2. The study purpose
3. Hypotheses
4. Objectives
5. Specification of endpoints/outcomes (if applicable)
6. Research design including statistical analysis plan (if applicable) and
7. Detailed research procedures

This outline provides the investigator with a general approach to a study protocol when preparing for a protocol for submission to the UBC C&W Research Ethics Board for review and approval. Although not all sections may be applicable to all studies submitted, the basic framework outlined below is expected from all successful applicants.

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1. COVER SHEET / INTRODUCTION PAGE

- Must include:
  - Protocol title
  - Protocol identifying number
  - Version date
  - Amendments – must be numbered and dated
  - Include the name and address of both the sponsor and the medical monitor (if someone other than the sponsor)
  - Display the name and title of the investigator responsible for conducting the research
  - Address and telephone number(s) of the research site(s)

2. BACKGROUND AND JUSTIFICATION

- Should address two key messages:
  A. *Statement of the problem*
  B. *Justification of the study*
- Provide a review of the relevant literature in the area (with citations in the text) to provide the rationale for the clinical query. Identify gaps in the literature that demonstrate the need to conduct the study.

3. STUDY PURPOSE

- This is a concise statement that follows from the well-established study background to answer the research question of interest.
- Should convey to the reader that the underlying hypothesis/purpose is of importance and there is a relationship to the current literature.

4. OVERVIEW

- Should answer the study questions. Objectives can vary (either descriptive or quantitative) and a study may have both primary and secondary objectives, where the primary objective is the one the investigator is most interested in addressing. The primary objectives dictate design and methods. Examples of study objectives are as follows:

A. Disease Specific

i. To determine the prevalence of a symptom
ii. To determine the prevalence of a disease
iii. To determine the clinical signs and symptoms of a disease
iv. To determine the immunologic response to vaccination

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B. Diagnostic tests/health measurement specific
   i. To determine the accuracy or predictive value of a diagnostic test
   ii. To develop or validate a psychometric/health measurement tool

C. Intervention specific (clinical trial)
   i. To determine the difference between an intervention and placebo, or other inactive control
   ii. To determine the difference between two or more interventions

D. Pilot Study
   i. To obtain data (pertaining to recruitment rates, standard deviation in the study sample, data management problems, etc.)
   ii. To help establish feasibility and design of subsequent clinical trial

E. Qualitative Studies
   i. To investigate participants perceptions regarding a disease, clinical care, educational or other experience

5. HYPOTHESIS

- Translation of the objectives in terms that allow statistical testing

6. RESEARCH DESIGN

- The research design should cohere with the objectives of the study.
- The study methodology should be constructed in a manner that demonstrates the study will be able to achieve the outcome(s). This section should address the basic questions of:
   A. What will be done?
   B. How will it be done?
   C. Will the methods allow the study to answer the study question?
   D. Have the investigators considered a *priori* any limitations of their study design?
- Outline the following in the section of Research Design:
   A. ***Study Design*****:** comparative trial, cohort, case control, cross-sectional, etc. with a brief justification of why this design is chosen.
   B. ***Study Sample*****:** define which population the study is sampling from, inclusion/exclusion criteria, mechanisms of recruitment and address issues of follow-up.
   C. ***Sampling Design*****:** define the sampling frame (district, household, persons, etc.), sampling method (random, cluster, stratified), and randomization procedures (block, random number generation, etc.).

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D. ***Sample Size*:** provide the power calculation based on principal objective(s) and discuss any feasibility issues identified *a priori* in attaining this sample.

7. METHODS AND PROCEDURES

- Summarize the research design and sequentially identify all procedures to be used to accomplish the specific aims of the project. Clearly identify and distinguish procedures that are considered experimental, procedures that are performed exclusively for research purposes (including "extra" routine tests), and procedures that would occur regardless of the research (i.e., standard of care). Point out any procedures, situations, or materials that be hazardous, and the precautions to be exercised to maintain participant safety.
- **Data Analysis and Data Monitoring**: Describe the statistical or analytical methods to be used. For all studies involving greater than minimal risk, describe how the data will be monitored to ensure the safety of the participants. For research involving intervention that entails potential serious risk to participants, compares blinded treatments over a long time period, or which may call for "stopping rules" for certain endpoints, a data monitoring committee may be required to protect the safety or welfare of participants. A detailed description of its operation (e.g., membership, function, frequency of review, stopping rules) should be included.
- **Data Storage and Confidentiality:** Describe where the research data will be stored during and after the study and how it will be secured. The investigator must take necessary steps to maintain confidentiality of data. This includes coding data and choosing an appropriate and secure data storage mechanism preventing unauthorized access to data. State who will have access to the data and how the data will be used. If data with participant identifiers will be released, specify the person(s) or agency to whom the information will be released and the purpose of the release (e.g., routine verification of case report forms).
- **Transition from Research Participation:** If applicable, describe how participants terminating their participation in the research will be returned to their usual care (e.g., taper study medication and resume usual medication, return to primary care provider).

8. RISK/BENEFIT ASSESSMENT

(A determination as to the risks and benefits of the research to participants is the responsibility of the REB; however, the following information is still required in the submited protocol):

- **Risk Category:** State the risk that the research presents as one of the following: Minimal, or Greater than Minimal.

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- **Minimal Risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. A risk is a potential harm associated with the research that a reasonable person would likely consider injurious.

- **Potential Risk:** Describe the potential risks associated with the study. Risks are not only physical, but can be psychological, sociological, economic, or legal. Risks include any specific toxicities noted in the investigator's brochure. If possible, estimate the probability that a given harm may occur and state its potential reversibility.
- **Protection Against Risks:** Describe how the study design will prevent or minimize any potential risks or discomfort. Potential risks and discomforts must be minimized to the greatest extent possible, such as by monitoring, appropriate withdrawal criteria and follow-up.
- **Potential Benefits to the Participants:** Describe potential medical benefit(s), if any, for those participating in the research. If there are no anticipated benefits, this should be stated.
- **Alternatives to Participation:** This section should include a description of alternative therapies or courses of action which are available should the participant elect not to participate in the study.

9. PARTICIPANT IDENTIFICATION, RECRUITMENT AND CONSENT/ASSENT

- **Method of Identification and Recruitment:** Describe how prospective participants will be identified and recruited. The identification and recruitment of participants must protect privacy and be free of undue influence. Recruitment of an investigator's own students, employees and patients is considered coercive in most circumstances. The steps taken to minimize undue influence must be included if these individuals are to be enrolled as participants.
- **Process of Consent:** Describe or list everyone who is authorized to obtain consent and how the process of informed consent will be structured to be conducive to rational and thoughtful decision making by the participant (or participants legally authorized representative) without any element of coercion or undue influence. If used, 'Auditor/Witness' roles would be described in this section.
- **Capacity:** If not, all participants will have the capacity to give informed consent, describe how capacity will be assessed and by whom. Describe the anticipated degree of impairment relative to their ability to consent to participate in research. Research with persons who have diminished capacity is allowed only for minimal risk or direct benefit studies.

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- **Participant/Representative Comprehension:** All investigators have a legal and ethical obligation to ensure that prospective participants or participants' representatives have sufficient knowledge and comprehension of the information represented by the elements of informed consent to enable them to make an informed and enlightened decision whether or not to participate or allow participation in research. In this section, describe how it will be determined that the participants or authorized representative understood the information presented. This section should clearly document that the investigator has an adequate plan in place to assure an acceptable level of comprehension before consent is obtained. If children or decisionally impaired adults will be participants, this section should also include a specific plan to assess comprehension during assent (the participant's agreement).
- **Debriefing Procedures:** In psychological studies where any information will be purposely withheld from the participant, state the information to be withheld, justify this non-disclosure, and describe the post-study debriefing of the participant.
- **Consent Forms:** Consult UBC C&W REB consent form guidelines for specific sections required for consent documents (http://www.phsa.ca/researcher/ethics-approvals/research-ethics-approval/ubc-childrens-womens-research-ethics-board#Guidance--&--documents)
- **Documentation of Consent:** The PI is responsible for ensuring that valid consent is obtained and documented for all participants. If not already addressed above (see Process of Consent section), specifically describe how consent will be documented and how and where documentation will be stored.
- **Costs to the Participant:** Describe and justify any costs that the participant will incur as a result of participating in the study. This section should clarify who (e.g., sponsor, grant, participant) will pay for procedures associated with the study or necessary follow-up. Normally, participants should not have to pay for research procedures that do not provide direct benefit. No charge may be made for costs covered by another entity. Participants may not be charged for investigational drugs without the written permission of the FDA.

10. REFERENCES

- Please include a reference section at the end of the protocol. Relevant literature should be cited in the text. Please provide any additional relevant citations and add a section at the end to provide details of the articles cited, as is usually expected for a research protocol.