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Trillium Health Partners Research Ethics Board

Research Protocol Guidance Document

September 19, 2019

*This is a sample protocol document and not all content will be required for all types of research studies.*

*For questions related to the information contained in this document, contact* [*THPREB@thp.ca*](mailto:THPREB@thp.ca) *or 905-848-7580 ext. 1682*

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Study Title

Name of the principal investigator/student name (if it is a student study)

Name of Co-Investigators

Name of Supervisor (if it is a student study, otherwise, don’t need this)

Title of the principal investigator or supervisor (e.g. RPN, doctor)

Institution (e.g. THP, CVH)

Sponsor

Funder

Footer should include date, version number, page number and brief study title

Table of Abbreviations

Any abbreviations that you will be using in your protocol must be defined in this table in alphabetical order. If no abbreviations are being used, then this section does not need to be included

*ADH* – Antidiuretic Hormone

*DNA* – Deoxyribonucleic Acid

*LDH* – Lactate Dehydrogenase

*PRL* – Prolactin

*TSH* – Thyroid Stimulating Hormone

Include Table of Terms section below Table of Abbreviations

Introduction

The introduction is a quick and concise overview of the project (abstract) as to what your project is investigating and how it will be done.

Background and Literature Review

* What is already known or unknown (Knowledge gaps)
* Literature review
* What is the rationale of your study (i.e. significance and justification)?

Research Question/Objective(s)

Research Question/Hypothesis:

* What is the question you are trying to answer?

Primary objective and or Secondary objectives (if applicable):

* Outcome measures

Study Design

Population + Recruitment Strategies

* Population being studied
* Inclusion and exclusion criteria (including rationale and ethical justification)
* Sample size (justification and calculation)
* Describe consent process

Methodology

Within the methodology section, you must provide a detailed report about how you will conduct the study and how you will achieve your specific aims. It may contain, but is not limited to:

* Interventions – description of what is being tested (e.g. a drug, vaccine, a new procedure for treatment)
* Describe current standard of care, if applicable to the study
* Any training that may be required or information that needs to be given either to your research team or to the participants
* What the procedure will be in conducting this project. How will the data be collected? (E.g. testing and maintenance of independent, dependent and controlled variables; use of surveys and/or questionnaires)
* Project timeline
* Observations that will be made
* Laboratory investigations that may need to be done
* If the study is being conducted at multiple sites, how the methodology will be standardized across the sites

Follow-up

* How and when will you follow-up with the participants of the study?

Tools for Data Collection

* Research instrument/data collection tool (e.g. survey, questionnaires, Case Report Forms, checklists, records, experimental approach)? Must be reliable and valid.

Data Analysis

* What is your data analysis plan;
* Is there any software that you will be using to aid in analysis?

Anticipated Results

* What are the anticipated results?
* How will the results be used?
* Outcomes
* What criteria will you use to determine when the study should be stopped? (e.g. someone is harmed during testing, the target sample size has been tested, too many patients have withdrawn from the study?
* How will the results be used? (E.g. for publication, distribution)

Limitations

* Describe any study limitations

Ethical Considerations

* + *Plan for ethical review*
  + Persons who may be vulnerable in the context of the research (E.g. Are there safe guards put into place for participants from a these populations?)
  + Costs to participants, remuneration/compensation plan when applicable (with justification)

*Privacy & Confidentiality:*

* + Confidentiality issues (E.g. who will be collecting information from the participant? Who has access to this information? Is the patient information recorded by name, id number, participant number, etc.?)
  + Security issues (E.g. How will the data be protected? PHI, How and when will the data be destroyed?)

*Risks and Benefits:*

* + Safety Issues (E.g. Does the study harm the participant in any way? What measures will be taken to mitigate or prevent harm?)
  + If applicable, discuss potential for material incidental findings and the management plan

Dissemination plan

* Describe the dissemination plan
  + What information from this study will you disseminate?
  + To whom (e.g. participants, community, media)
  + Why will you be disseminating this information?
  + How will the information be released?

Appendices

Depending on the type of the research being done, the appendices may include:

* Glossary – if you feel a glossary will help with understanding the protocol
* Sample interview questions
* Sample Survey
* Diagrams – diagrams may be more relevant for a research paper, but if there are any diagrams that will help our understanding of the research being done, then please include them
  + Microscope images of the organism that is being treated or tested on
  + mind maps or flow charts explaining the methodology or the analysis method being used
* Any posters or pamphlets that will be released to the public
* Consent forms
* Data collection forms
* Study Budget
* Other applicable study tools and documents

References

MLA referencing format is ideal. Please refer to the following links for help on how to do MLA style formatting and referencing.

<https://owl.english.purdue.edu/owl/resource/747/01/>

<http://www.mla.org/>