RRIC Requirement for a Written Research Proposal for Chart Reviews.docx for Chart Reviews 6/4/2010

<u>RRIC Requirement for a Written Research Proposal for Chart Reviews –</u> <u>Version 4.0</u>

Why does the CCMB RRIC require that a research proposal be submitted for chart reviews, when the University of Manitoba Research Ethics Board does not?

- A research proposal is essential for the proper conduct of any research study, even when the research only involves chart reviews.
- A good quality research proposal reflects proper understanding of the relevant literature and thorough consideration of major issues. That is the only way to help ensure that the study is well designed and that it is likely to accomplish its objectives.
- Poorly designed studies are a waste of resources.
- The ability to generate a clear, coherent and compelling proposal is an integral component in the training and education of student researchers. Circumventing this step is to their detriment.
- The CCMB RRIC's roles include educating staff and trainees about research as well as making sure that CCMB resources are used wisely

What are the essential components of a research proposal for chart reviews and cancer registry data studies?

The proposal should contain the following sections: Title – Abstract – Background/Introduction – Methods–Results – References.

Abstract.

- brief summary of approximately 400 words.
- should include the following:
 - o research question
 - rationale for the study
 - o hypothesis (if any)
 - o methodology
 - o predicted or expected results.

Background/Introduction

- should provide the necessary background or context for the research study
- the purpose and importance of the study should be clearly stated as well as its limitations
- a concise, thorough, well referenced review is recommended
- should end the introduction with a list of objectives of the study, the study hypothesis, and a list of research questions to be answered (in terms that are measurable)

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Methods

- should contain the facilities and resources that will be needed for the study
- provide information about the study population, sample size determination, data management and statistical analysis
 - Study population
 - Inclusion and exclusion criteria
 - How will potential participants be identified be specific
 - How will potential participants be recruited (if applicable) be specific
 - Sample size determination
 - Is the study adequately powered?
 - How is sample size determined?
 - o Data management
 - What data will be collected? Be specific, including a definition of what each data point means (e.g. what are you calling the date of diagnosis?)
 - Who will collect the data?
 - How will the data be obtained?
 - Are the data available in electronic charts?
 - Is there a need for the paper charts?
 - Are off-site paper charts needed?
 - Where will the data be recorded? Be specific. Append any data collection sheets to be used
 - How is data confidentiality and privacy maintained?
 - Who has access to data?
 - Is the data stored in secure media?
 - How long will the data be stored?
 - How will the data be destroyed after the study is completed?
 - o Statistical Analysis
 - What statistical tests will be used to analyze the data?
 - Who will do/assist with the statistical analysis
 - Study timeline may be provided
 - Start of data collection
 - Period of data analysis
 - Expected time of study completion
 - Expected presentation/publication venues and dates.

Results

- describe the expected results from the study
- provide any alternative interpretations if the results should turn out differently
- include specific goals about publication or presentation of the data

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References – suggested format

• Author(s) of the article, publication year, the title of the article, the title of the journal or magazine (in italics if possible), the volume number, and page numbers where the article can be found:

Budget (if applicable)

Appendices (if applicable)

The above recommendations are only meant as a blueprint and variations are allowed as long as the necessary information is provided. The study should be written in such a way that the study is reproducible by another individual.

Resources

http://www.mcmaster.ca/ors/guide/guide_proposal.htm