NEWFOUNDLAND AND LABRADOR
HREB
HEALTH RESEARCH ETHICS BOARD

Research Proposal/Protocol: Guidance Document

***ALL* research applications are to be accompanied by a research proposal. The following will provide you with some information on what will need to be included in a research proposal.**

- **Introduction**: This is a clear and concise statement (1-2 paragraphs) of the problem you are going to investigate in your work. It is an overview of the steps you are going to undertake and some resolutions you suggest concerning your problem.

- **Literature Review**: Summarize the background of your problem, talk about the literature that already exists. Include titles and authors of the sources you use. (1-2 paragraphs).

- **Research Objectives**: Clearly state the objectives of your research project. When reviewing the information you propose to collect for your study, the HREB will need to understand why you need that information in order to satisfy your research objectives. This section of the proposal should give a clear sense of why you need to collect the data you will be describing in the following section ('Methodology').

- **Methodology**: Describe the ways in which you will gather your data and perform the analysis. This should be one of the biggest if not the biggest section in your proposal. Broadly speaking, your description of project methodology should unfold as follows:

    - **Basic description of the research design**: In particular, will you be undertaking primary data collection from live participants (i.e. survey research and interviews/focus groups) or will you be performing a secondary analysis of data that was or will be collected by someone other than your research team (i.e. retrospective audit of patient charts)?

    - **Identify the data sources/instruments**: From whom will you be getting your data? Will it come from patients, health providers, members of the general public, or some other kind of population? What selection criteria will you be using to determine whose data will be accepted for analysis?

    - **Describe the data collection instruments**: By what means will you obtain the data you will be analysing in your research? If your study involves primary data collection, will you be administering a questionnaire, or conducting focus groups or interviews? If so, you need to provide detail about the specific means and methods for collecting, storing, transferring, and ultimately disposing of those data. Will the questionnaires/interviews/focus groups be in-person or online? If the latter, please be sure to confirm that you will be using MUN's Qualtrics service for questionnaire

administration and MUN's Webex service for the interviews/focus groups. Will your interviews be recorded and/or transcribed and, if so, how and by whom?

If, on the other hand, your study involves secondary use of data that has been or will be collected regardless of whether or not your study proceeds you will need to provide details on who is the custodian of the data (i.e. NLHS)? What is the process by which the custodian will be transferring the data to you and how will you be accessing the data over the course of the study?

- **Data analysis**: What analytical techniques or methods will you be using to generate your study findings? Will these be quantitative or qualitative in nature? How will these techniques enable you to answer the research question you started with and satisfy your study objectives?

- **Ethical considerations (primary data collection**): If your study involves primary data collection, there are three primary ethical considerations you will need to document in your proposal:

  - **Recruitment**: What strategies will you use to recruit people into the study? Be sure to explain how you will make contact with prospective participants and obtain their contact information. Note that if you wish to recruit health care patients into your study, the HREB expects that the person making first contact will be in the patient's circle of care (see the yellow text box accompanying question 12.1 in the 'HREB – Application for General Use' for guidance).

  - **Consent**: This is arguably the single most important aspect of your ethics application. By what means will you obtain free and informed consent from your research participants? What will be the mode of consent: written, verbal, implied, or some combination of the three? Note that whichever mode you choose, and whatever your approach to data collection, you will need to submit with your application a consent document based on the 'General ICF Template – April 2023' accessible under the 'Attachments' tab in the Research Proposal application module. *Even if you are administering an anonymous online questionnaire, you still need to append a consent document as a introduction to your questionnaire.*

  - **Privacy**: What risks might your study pose to participants' privacy? How do you intend to manage or mitigate those risks?

- **Ethical considerations (secondary use):** If your study relies exclusively on data that has been or will be collected regardless of whether your study proceeds then you will need to clarify whether and how you will seek consent from those persons from whom the records

were originally collected. If you intend to request waiver of consent requirements, then you will need to indicate this in section 7.3 of the 'HREB – Secondary Use/Chart Audit' application module and reference the appropriate section of the TCPS2. Note, for secondary data requests that do *not* include direct identifiers, the relevant section is 3.7A (https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter3-chapitre3.html#b); for secondary data requests that *do* include direct identifiers, the relevant section is 5.5A (https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter5-chapitre5.html#d) – see the yellow text box accompanying question 7.3 in the application module for additional guidance.

- **Implications:** Very briefly describe the contribution you hope to make to your particular field of study.

- **Dissemination:** Very briefly describe how you plan to share your research findings. Who is the target audience and what is your method of sharing (i.e. To participants via a letter or to faculty of medicine via ground rounds)