2.1 Background & Rationale

In this section, you will describe the reasons for undertaking the project, the current state of knowledge, and how the project will address gaps in knowledge and improvements in public health. To describe the background and rationale, it might be helpful to think through the following:

- **Problem Statement**: To describe the problem or issue that this project will address, drawing on existing evidence to frame the problem/issue and provide context for the project.
  - What is the research problem you are seeking to address?
  - What is the state of the evidence (research and best practices) on the research problem?
  - Who is affected and to what degree? What is the impact of the problem (why does this matter?)

- **Rationale**: Building on the problem statement, to articulate why it is important to address this problem, what the current gaps in knowledge are, and how your project will fill the gap and help solve the problem.
  - What do we know now? Describe key existing evidence that addresses the research problem.
  - What are the gaps and limitations of the current evidence available in addressing the problem?
  - Are there clear gaps that you have identified in the existing evidence?
  - Based on the existing evidence on this problem, how is your proposed project a reasonable, appropriate, and logical next step?

- **Significance**: To explain the importance of the problem being addressed by your project, and clearly state the contribution your project will make to solving it. The review of literature should be incorporated throughout this section.
  - What is the significance of the evidence that has been identified, evaluated and summarized?
  - How will your study results contribute to the solution to the problem?
  - What specific gaps will be clarified by this project?
  - How will the public health system be enhanced if the proposed aims are achieved? How will the project improve knowledge, capacity, and/or public health practice?
  - What are the key outcomes/contributions that you anticipate will result from your project?
2.2 Research Questions(s) & Objectives(s)

In this section, you will state the project aim and define the research question(s) for the project. Some questions to consider include:

- Is the scope of your question(s) appropriate for this project? Is it feasible to answer this question(s)?
- Is your research question(s) specific enough? Are key elements included in your question?
  - Have you clearly indicated the context, setting, or environment for the research?
  - What is the population that this research is interested in?
  - If applicable, what is the service, program, intervention, or exposure being studied?
- Is it clear what the outcomes are that this research is interested in? If applicable, what kind of change is this research interested in?

2.3 Study Design

In this section, you will outline the proposed study method and include the rationale for choosing this approach. A complete methodology should cover off four major points: how, why, who, and when. To do this, you should:

- Identify what kind of research design is to be used and provide a justification for selection of this design.
- If applicable, define the study population and sample, identify sampling design, justify sample size, and describe mechanisms for recruitment.
- Describe the data that you plan to collect, and how you will collect it, including identifying items to be measured and describing tools you will use (for example, surveys or interview guides), so that other public health units may understand and replicate work.
- Detail who will do the data collection and what training will they receive.
- Describe your data entry, coding, analysis and interpretation plan (whether statistical or qualitative) and how they relate to the identified objectives.
- Some questions to ask yourself to complete this section:
  - Why is one approach or method used instead of another alternative? Why is it the best one to use?
  - Will you develop tools or use pre-existing ones? How will you demonstrate they are valid and reliable?
  - When will data be collected? Are there any special considerations to keep in mind for timing given your sample population?
  - Is your analysis plan appropriate to answer your research question(s)?
  - Will you use any analytic tools (SAS, NVivo, etc.)?
  - Will the project use a qualitative, quantitative or mixed design?
2.4 Ethics & Privacy Considerations
It is the responsibility of every member of the project team to ensure all required ethics and privacy approvals are received. The following considerations should be detailed in this section:

- How the anonymity of participants or informants, and the confidentiality of data during the conduct of research and dissemination of results will be stored, shared, protected and destroyed.
- The consent process, if data will collected.
- Considerations for research with vulnerable populations.
- Other privacy and confidentiality considerations.
- List of ethics approvals required and obtained.

2.5 Feasibility Considerations
In this section, you will elaborate on previous/preparatory work and resources that you will draw on to ensure project feasibility. Some questions to consider include:

- Has the team or any team members done previous work or pilot work that you will be drawing on?
- Are there other similar projects the team or team members have been involved in that were successful, and demonstrate the feasibility of your project?
- Are there specific resources or in-kind contributions to highlight?

2.6 Study Limitations
In this section, you will identify potential weaknesses in study design and methods, potential feasibility challenges, and how the team will minimize these limitations/avoid potential challenges. Some questions to consider include:

- What weakness might your design and methods impose? For example, what are the weaknesses of your analysis, instruments or sample?
- What are any potential sources of bias in your project?
- Are there challenges that might arise in terms of the feasibility of your project (dependencies, unknowns, tight timing, etc?)
- Are there any important limitations to their study, such as those that may result from the study design, sample size or population, analysis plan, or scope of the proposed research, and the strategies?
- For significant limitations, how will research project still be able to generate meaningful results and accomplish the desired objectives?
Additional Resources

- See chapter 5, ‘Writing the Needs or Problem Statement’ in Coley CM & Scheinberg CA. Proposal writing: Effective grantsmanship. This chapter describes how to write a problem statement.

- **Defining your Question: PICO and PS** (NCCMT). This tool helps researchers to define research questions for both quantitative and qualitative research.

- **Writing your Research Question.** This brief fact sheet provides guidance on how to get through the important first step in completing a research study.

- **Points to Consider about Recruitment and Retention while Preparing a Clinical Research Study** (National Institute of Mental Health). This document is helpful to promote thinking and discussion on participant recruitment. Although the resource was developed by NIHM for clinical research, many of the points are relevant to all types of health research.


- **CIHR’s Best Practices for Protecting Privacy in Health Research** is an excellent resource for researchers and reviewers to help identify and address privacy risks in research.

- **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)**. This TCPS 2 is a joint policy statement from the Canadian federal research agencies (CIHR, NSERC, and SSHRC). The first edition was published in 1998 to promote the ethical conduct of research involving humans.

- **The TCPS 2 Tutorial.** The Course on Research Ethics (CORE) is a self-paced course consisting of eight modules ranging from Core Principles to REB Review.

- Chasan-Taber L. Writing dissertation and grant proposals: epidemiology, preventive medicine and biostatistics. Boca Raton, FL: CRC Press; 2014. **Chapter 13: How to present limitations and alternatives**

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