**Research Protocol**

Adapted from and expanded upon The Royal College of Physicians and Surgeons of Canada Chapter 17 (Tagalackis, 2011)

Submit this document with the Research Involving Human Subjects Application. Applications that do not include a protocol will not be reviewed.

1. Project title
2. Protocol synopsis (table with key information for quick reference)
3. Project summary/abstract (no more than 250 words)
4. Research proposal (4-6 pages)
   1. Background:
      1. Should tell a story/present an argument about why the study needs to be done
      2. Should establish the importance of the topic (e.g. the problem is prevalent, severe, getting worse, time-sensitive, etc.)
      3. Should establish the gap in the literature that the proposed study will fill
      4. Should present a succinct and curated set of facts, not an annotated bibliography
      5. Normally, each sentence should be referenced
   2. Primary research question and aims
      1. Research question- specify the purpose of the study using the SPIDER framework (Sample, Phenomenon of Interest, Design, Evaluation, Research type, <https://www.nccmt.ca/knowledge-repositories/search/191>)
      2. What is the ultimate aim (i.e., goal) of the research?
      3. Are there any secondary research questions that will be answered?
   3. Study design and methods
      1. Approach
         1. Qualitative, quantitative, or mixed methods?
         2. If mixed methods, what is the emphasis: mainly qualitative, mainly quantitative, or equal
         3. If mixed methods, is it exploratory sequential, explanatory sequential, convergent parallel, or embedded ([Mixed Methods Research Guide With Examples (dovetail.com))](https://dovetail.com/research/mixed-methods-research/)
      2. Design
         1. Is the study observational or interventional? Prospective or retrospective? Cross-sectional or longitudinal?
         2. What specific design is being used (e.g. cohort study, experimental design, longitudinal survey study, phenomenological investigation, etc.)
      3. Study population
         1. What is the target population?
         2. How will people from the target population be identified, selected, and approached (prospective), or how will they be identified and selected (retrospective)
         3. What inclusion and exclusion criteria will determine whether a person qualifies for the study
         4. If people will be allocated to groups, how will this happen (e.g., purposeful assignment, matching, randomization, minimization). Include the exact procedure that will be used
      4. Operational definition of all variables
      5. Methods of data collection
         1. How will you measure your outcomes and other variables?
         2. What steps will you take to ensure that the data is collected accurately, precisely, and consistently (over time and across data collectors)?
      6. Procedures
         1. Explain the nature, frequency, and number of contacts that you will have with research participants. What will happen at each meeting?
         2. If running an intervention study, how will you track participant compliance with the intervention?
      7. Data management plan
         1. How will you deal with missing data and outliers?
         2. Where will the data be stored, and for how long?
         3. Who will have access to the data?
      8. Statistical or other analysis to be performed
         1. What statistical test or analytical procedure will be used to answer your primary research question?
         2. What tests or analytical procedures will be used to answer your secondary questions (if applicable)?
         3. If doing an intervention study, how will you analyse data from a sample with imperfect compliance? (intention to treat analysis, per protocol, etc., [Common pitfalls in statistical analysis: Intention-to-treat versus per-protocol analysis - PMC (nih.gov)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4936074/))
      9. Sample size justification. How do you know that your sample size will be large enough? Report a power calculation, if applicable. G-power is a free software tool for power analysis ([Universität Düsseldorf: G\*Power (hhu.de)](https://www.psychologie.hhu.de/arbeitsgruppen/allgemeine-psychologie-und-arbeitspsychologie/gpower)
5. Study timeline (50-100 words)
6. Study timeline (50-100 words)
7. Strengths and limitations (250-300 words)
8. Anticipated results
9. References
10. Roles and expertise of team members (use table)

Roles and Expertise of Team Members

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Roles, responsibilities, and contributions for each team member and qualifications related to role | If the project involves community participants such as knowledge users, please explain the specific support(s) provided by the participant, and the applicant’s ties with said communities | Relative proportion (in percentage) of each member’s contribution to proposed project |
|  |  |  |  |