Title:	
Version:	
Date:	
Name and Address of Sponsor / Funder:	
Principal Investigator and Affiliation:	
Other Investigators and Affiliations:	

Background and Rationale

Provide an overview of the current state of knowledge/care and describe why there is need for change/improvement/research, and why the knowledge which will be gained is of interest to clinicians, patients, or administration.

Hypothesis & Objectives

Provide a clear statement of the hypotheses, or research question and objectives. The objective(s) should be listed as short statements of the scientific goals of the study.

An effective research question or hypothesis outlines what the research is proposed to achieve, and helps define exactly what data is required to answer the research question.

Study Design and Methodology

Study design: *Describe your study design in the context of how you will gain evidence which will be used to draw your conclusions. (e.g. are you completing a retrospective chart review, a prospective observational study, questionnaire, meta-analysis, a descriptive, cohort, cross-sectional, or case-control study etc.).*

Study Population*: Define the criteria for inclusion, recruitment and any exclusion criteria for each group. Include the estimated sample size.*

Study Procedures: *Describe, in chronological order where possible, the procedures you will follow and that each participant will undergo, which are solely for research purposes. Include a schedule and approximate time for each activity.*

Data Collection and Management*: Describe how data be collected, stored, secured, and destroyed.*

Timeline*:* *Provide a timeline for the project, (estimated start date and end date).*

Statistical Analysis

Specify how data will be analyzed and by whom.

Informed Consent Process

Describe how participants will be screen and how and by whom consent to be obtained.

Attached a copy of the informed consent form, if a waiver will be requested please provide rationale

Confidentiality of data

Describe how data (both paper and electronic) will be stored to safe-guard confidentiality (e.g. in a locked cabinet, password protected computer).

Specify who will have access to collected patient data.

Clarify long collected patient data will be stored and how it will be destroyed when no longer needed.

Refer to Chapter 5 – Privacy and Confidentiality in the TCPS_2 for more detailed instructions surrounding confidentiality and de-identified or anonymized information.(http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/)

Risks to Participants

Identify any potential or real risks involved while conducting the study. The TCPS_2 defines minimal risk as that which poses no greater potential for harm than the participant would expect in their everyday life, as it relates to the research

Benefits to Participants

Include any benefits to the participant or to the overall research field.

Budget

Attach if applicable (if this is a funded project)

References

Include a list of the references cited in this protocol.

Acknowledgements

Include information on anyone who made a substantial contribution to the creation of the protocol.