Title:	
Version:	
Date:	
Name and Address of Sponsor / Funder:	
Principal Investigator and Affiliation:	{name, designations} {institutional affiliation(s)} {address} {telephone number / email}
Other Investigators and Affiliations:	{name, designations} {institutional affiliation(s)} {address} {telephone number / email}

Background and Rationale

Provide the background and rationale for the study. For example: What is the current gap in knowledge? Why is it important to fill this gap? How will the results of this project contribute?

Hypothesis / Key Question

What is the hypothesis being evaluated or the key questions being asked in the research?

Selection of Patients

Inclusion Criteria:

Exclusion Criteria:

Procedure

Retrospective Chart Review *(Retrospective means the data is already in existence when the project is submitted to the REB for initial review.)*
OR
Prospective Chart Review *(Prospective means the data is not in existence when the project is submitted to the REB for initial review)*

Date range of the chart review **(***mm/dd/yyyy to mm/dd/yyyy)*

Source (location) of records to be reviewed.

How the charts to be reviewed will be identified.

Who will identify charts to be reviewed? Who will review the charts?

Confidentiality of data

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

Specify who will have access to collected patient data.

Clarify how long collected patient data will be stored and how it will be destroyed when no longer needed (Please see the HSNRI Stewardship of Research Records Policy to guide this section: e.g. It is recommended to store research records for ten years).

Consent

Describe how consent to be obtained and attach a copy of the informed consent.
OR
A waiver of consent can be requested. The REB may approve research that involves an alteration to the requirements for consent set out in TCPS 2 Articles 3.1 to 3.7 if the REB is satisfied, and documents, that all of the following apply:

a. *the research involves no more than minimal risk to the participants;*
b. *the alteration to consent requirements is unlikely to adversely affect the welfare of participants;*
c. *it is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;*
d. *in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and*
e. *the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with TCPS 2 Article 3.7B.*

To request a waiver of consent provide a rationale that addresses the above requirements.

Risks and Benefits:

Risks: *(outline the risks associated with the study e.g. A privacy breach is a risk, as with any study dealing with personal health information.)*

Benefits: *outline the benefits associated with this study e.g. The participants whose charts are reviewed are not likely to receive any benefit from the proposed research; however, society and investigators may benefit from the knowledge gained (indicate the anticipated future benefits of your research).*

Statistical Considerations

Specify how data will be analyzed and by whom.

Appendices:

The Data Collection Form must be attached to the protocol (This form should list the data elements that will be collected from the medical record. It should not contain any direct or indirect identifiers except for a unique subject code.)

References

Include a list of the references cited in this protocol.