DIVISION OF CLINICAL RESEARCH & EVALUATIVE SCIENCES (CRES)
STUDY PROPOSAL

STUDY TITLE:

DEPARTMENT/DIVISION:

FACULTY/FELLOW/RESIDENT NAME:

MENTOR NAME:

STUDY PURPOSE: (1 Paragraph)

Clearly define the purpose of the study, the outcome(s) of interest, objectives to be accomplished, potential benefits to participants and/or society and specific questions/hypotheses to be answered/tested.

- *State concisely and realistically what the study described in this proposal is intended to accomplish.*
- *The purpose, objectives, questions/hypotheses should be clearly defined.*

BACKGROUND AND SIGNIFICANCE: (1-2 Paragraphs)

Provide a summary of the literature, rationale for the study, and any preliminary findings. Why is it important that the specific questions/hypotheses be answered/tested?

- *Briefly sketch the background to the proposal listing key references, critically evaluate existing knowledge, and specifically identify the questions that the study is intended to answer.*
- *State concisely the importance of the study described in this proposal by relating the specific purpose and objectives to the overall need in the community/environment of interest.*

DESIGN AND METHODS: (1-2 Paragraphs)

Describe the study design, population to be studied (e.g., subjects, inclusion/exclusion criteria), data source and recruitment methods (e.g., administrative claims data, survey data, registry/national/regional database, prospective study), intervention (if any), and specific measurements/instruments to be used (include reliability and validity information) in the data collection process.

- *Outline the research design and procedures that will be used to accomplish the specific study objectives.*
- *Procedures for obtaining informed consent (if applicable)*
- *Treatment assignment and randomization (if applicable)*
- *Data to be collected and when the data is to be collected*
- *Describe any special challenges or methodological approaches required for the study*

PROPOSED ANALYSIS/PLAN:

What quantitative and/or qualitative techniques will be used to answer/test each question/hypothesis? *(This section will probably need to be addressed and/or expanded after discussion with the Division.)*

- *Specific data variables being collected for the study (e.g., data collection sheets)*
- *Study endpoints*
- *Statistical methods*
- *Sample size considerations and power analysis (e.g., evaluable participants, etc.)*

RISKS AND DISCOMFORTS:

- Complications of surgical and non-surgical procedures, etc.
- Drug side effects and toxicities
- Device complications/malfunctions
- Psychosocial (non-medical)
- Radiation risks (see the Radiation Safety Committee)

REFERENCES: