

Research Study Proposal Form

Department of Clinical Research

STUDY TITLE:

DEPARTMENT/DIVISION:

FACULTY/FELLOW/RESIDENT/STUDENT NAME:

CLINICAL/RESEARCH MENTOR NAME:

STUDY PURPOSE

Clearly define the purpose of the study, the outcome(s) of interest, objectives to be accomplished, 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

Provide a summary of the literature, rationale for the study, and any preliminary findings.

- *Briefly sketch the background to the proposal listing key references, critically evaluate existing knowledge, clearly identify the knowledge gap to be addressed, and specifically identify the questions that the study is intended to answer.*
- *Why is it important that the specific questions/hypotheses be answered/tested?*
- *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

Describe the study design, population to be studied (e.g., subjects, inclusion/exclusion criteria), data source, 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 Department of Clinical Research.)*

- *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/DISCOMFORTS, BENEFITS, CONFIDENTIALITY

Describe all potential risk and discomforts the patient could experience. Detail all potential benefits to the patient and to society. Provide a complete description of how participant data will be protected. For retrospective studies using national-level data, please refer to the Data Use Agreement for the specific database to be used.

- *Complications of procedures, drug side effects and toxicities, psychosocial, non-medical, etc.*
- *Direct benefit to participant (if applicable); present and/or future benefit to society as a whole*
- *How will participant data be kept confidential?*
- *Remember: **No data** can be stored on personal laptops, hard drives, or flash drives*

REFERENCES

List all references provided in Background and Significance section.