Research Project Proposal Format for Investigator-Initiated Research

Scientific Review Committee/Institutional Review Board
University of Tennessee College of Medicine Chattanooga & Erlanger Health System

General guidelines for proposal submission

- Number all pages
- Place title on all appendices
- First person language should not be used
- Proofread the proposal carefully—spelling and grammar check programs miss many errors
- All abbreviations and acronyms should be defined with first use in the document

Format of proposal submission

Title Page

- Title of Project
- Identify Principal Investigator, Institution, Department Affiliation
- Identify all Co-Investigators, Institutions, Department Affiliations

Abstract/Project Summary

- Should be ≤350 words
- Should contain most critical background and methodology information
- Bibliographic references should not be used in the abstract

Hypothesis

- State hypothesis/hypotheses to be tested

Specific Aims

- List specific aims in decreasing order of importance
- Specific aims can be subdivided into primary and secondary aims, if necessary

Background/Significance

- Should be thorough and clearly cover the current literature in the area to be studied
- References are required for all work cited and should be cited numerically in order used in the document
- Use the most recent reference sources that are relevant to the proposal
- This section should end with a description of how the proposed study will add to the current body of knowledge

Preliminary Work

- Any preliminary work done by the current investigators relevant to this study should be included here
- Many investigators will leave this section blank for a new area of study

Methods

- Study Design
    - Describe the study design
    - Give rationale for choosing the study design
- Study Subjects
    - Describe process of subject selection
    - Inclusion criteria—should be very specific and listed in numeric or bulleted form
    - Exclusion criteria— should be very specific and listed in numeric or bulleted form

    - Describe process of control selection, if using controls
- Sample Size
    - Explain total number of subjects to be tested
    - Justify number of subjects to be treated
        - Describe statistical methods used to determine adequate sample size
        - Show effect size, alpha (standard is 0.05), and beta (standard is 0.8)
    - If local subject numbers are insufficient, describe plan to address suboptimal sample size (partnership with other researchers, increased recruitment area, etc.)
- Data Collection
    - Define data points to be collected
    - Give rationale for any specific date ranges used to define data set
    - Describe which data points represent study outcome variables
    - Include any forms to be given directly to subjects exactly as will be used in the study
    - Include form to be used for investigator collection of data (see appendices)
    - If laboratory techniques are to be used, describe in detail
- Data Handling
    - Describe how data will be collected and stored
    - Explain steps taken to assure accurate and complete data collection
    - Describe steps taken to ensure security of any confidential information to be collected during study
- Data Analysis
    - Explain detailed plan for analysis of data
    - Describe statistics to be used
    - How will analyses performed test study hypotheses and specific aims?
    - Describe expected formats for presenting results
- Time Frame
    - Detailed and realistic time frame for subject recruitment and participation
    - Time frame for completion of entire study (including analysis)
- Strengths/Innovation
    - Describe the strengths of the study proposed
    - Describe specifically how this study will enhance the current body of knowledge
- Limitations
    - Describe potential problems that may arise and plans to address these problems
    - Describe potential confounding variables in the study and plans to account for the confounders

Risks and Benefits to Human Subjects, Animal Care, Hazardous Materials

- Risks to Study Subjects
    - All studies collecting patient data have the risk of accidental disclosure of protected health information
- Direct Benefits to Study Subjects
- Benefits to Society
- If animals to be used, provide detailed plans describing number of animals, plans for the care and disposal of the animals
- If hazardous materials to be used, describe detailed plans for safe use, storage, and disposal of materials
- Discuss ethical concerns involved in conduct of the proposed study

Budget/Research Environment (facilities, clinical space, etc.)

- List total cost to be incurred to complete study
- Identify source of funding for study conduct
- If multiple areas of cost to study, itemize budget as appropriate

References Cited

- List relevant literature to the proposed study
- Make every attempt to cite the most recent and relevant literature in the area to be studied

Appendices

- Data Collection Form that will be used to collect actual study data, most often in one of the following formats
    - May be Excel spreadsheet or similar file if collecting data electronically
    - May be Word document or similar file if using paper for data collection
- Any survey or measurement tool to be given directly to the subjects
- Previous publications of preliminary work, if any