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
  o Describe the study design
  o Give rationale for choosing the study design
• Study Subjects
  o Describe process of subject selection
  o Inclusion criteria—should be very specific and listed in numeric or bulleted form
  o Exclusion criteria—should be very specific and listed in numeric or bulleted form
• Describe process of control selection, if using controls

• Sample Size
  o Explain total number of subjects to be tested
  o 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)
  o If local subject numbers are insufficient, describe plan to address suboptimal sample size (partnership with other researchers, increased recruitment area, etc.)

• Data Collection
  o Define data points to be collected
  o Give rationale for any specific date ranges used to define data set
  o Describe which data points represent study outcome variables
  o Include any forms to be given directly to subjects exactly as will be used in the study
  o Include form to be used for investigator collection of data (see appendices)
  o If laboratory techniques are to be used, describe in detail

• Data Handling
  o Describe how data will be collected and stored
  o Explain steps taken to assure accurate and complete data collection
  o Describe steps taken to ensure security of any confidential information to be collected during study

• Data Analysis
  o Explain detailed plan for analysis of data
  o Describe statistics to be used
  o How will analyses performed test study hypotheses and specific aims?
  o Describe expected formats for presenting results

• Time Frame
  o Detailed and realistic time frame for subject recruitment and participation
  o Time frame for completion of entire study (including analysis)

• Strengths/Innovation
  o Describe the strengths of the study proposed
  o Describe specifically how this study will enhance the current body of knowledge

• Limitations
  o Describe potential problems that may arise and plans to address these problems
  o 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
  o 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