Research Protocol Template
Title:
Principal Investigator:
Other Investigators:
Institutional affiliations:

I. BACKGROUND AND SIGNIFICANCE

A. Background information on condition or problem to be studied**:** Include incidence, typical characterization of the condition, etc.

B. Previous studies looking at the same condition/problem: Include what has been looked at to this point, gaps in the literature, inconsistencies, and variations from what you will be proposing.

II. STUDY OBJECTIVE(S); INCLUDING SPECIFIC AIMS AND/OR HYPOTHESES

A. List the broad, long-term objectives and describe concisely and realistically what the research is intended to accomplish and the hypotheses to be tested.

III. METHODS

A. Study Design:
1. Definitions
2. Prospective/retrospective?,
3. # of centers, randomized?,
4. Blinded?, placebo?, etc.
5. Period of enrollment or chart review covers? Informed consent?
6. Study Drugs, Device, or Intervention
7. Randomization/Sampling (If appropriate)
8. Instruments: Standardized Surveys, etc. (provide a description of each)
9. Endpoints: the main thing that you are looking at

B. Study Population:
1. Who? Age, Sex, Race, Diagnoses if appropriate.
2. Inclusion/Exclusion criteria
3. Experimental group vs. Control group

C. Assessment of Resources
Indicate how investigator will ensure that the study:
1. Has sufficient access to the study population
2. Has sufficient time to conduct and complete the study
3. Has adequate qualified staff members to conduct the study

4. Facility is adequate to conduct the study
5. Staff has been adequately trained on the protocol and their specific research related duties

D. Study Procedures
Include a description of the study procedures (as they relate to the subject). Be sure to include (as applicable)
1. Plans for Recruitment
2. The number and estimated length of each study visit
3. Procedures and/or interventions that will be performed for each visit (a chart may be helpful)
4. If a drug study, include instructions for administering drugs, handling instructions, and storage and disposal instructions
5. For biological samples, explain how the samples will be collected, as well as storage, testing, and disposal methods
6. For behavioral studies, identify the instruments being used and who will be administering the instrument (including their qualifications
7. If a survey study, include who created the survey, whether survey has been standardized, how survey will be distributed and returned, and how confidentiality will be maintained
8. If chart review, indicate whether or not the materials will be obtained prospectively, or if the materials will come from previously existing specimens, records, or data. Explain what information will be used to identify potential human subjects for inclusion in research.

IV. DATA COLLECTION

A. How and what data will be collected (i.e. demographics, comorbidities; PSHx, Meds, Scores on standardized tools (APACHE, etc).

V. DATA ANALYSIS

A. Sample Size Considerations
1. Power analysis based on previous studies or exploratory study?
2. Justifying the sampling procedure

B. Statistical Methodology
1. Comparisons to be made and statistical tests to be used for the comparisons.

VI. DATA AND SAFETY MONITORING PLAN (if applicable)

A. Describe any provisions for monitoring the data for safety.

VII. STUDY LIMITATIONS

A. Potential Limitations of Procedures

VIII. ETHICAL CONSIDERATIONS

A. Informed Consent (Applies to studies using human subjects)
   1. Provide a description of the Informed Consent Process, including:
      a) Circumstances under which consent will be obtained
      b) How Consent will be documented
      c) Special Provisions for Vulnerable Populations
      d) Steps taken to minimize coercion
      e) Who will be involved in obtaining consent
      f) When will subject be approached
      g) Method used to ensure that subject fully understands study procedures

   2. If requesting waiver or alteration of consent, explain why it is needed to complete the study

B. Risks and Side Effects (Applies to studies using human subjects)
   1. Potential Risks (include medical, psychological, legal, financial, social)
      a) Assess for severity and likelihood
      b) Procedures for protecting against or minimizing risks
         i. Alternative treatment or procedures
      c) Unforeseen risks

   2. Adverse events (define)
      a) Provisions for medical and professional intervention
      b) Reporting adverse events

   3. Compensation for Injuries
      a) Where and from whom medical thereapy may be obtained
      b) Who will pay for the therapy
      c) Whom to contact in case of injury

C. Benefits to Subjects (Applies to studies using human subjects)
   1. Explain the expected benefits in relation to the subjects. If there are none, then state this. Explain the benefit to general science or others if applicable.

D. Costs to Subject (Applies to studies using human subjects)
   1. Clearly describe the financial costs that the subject may incur (if there are none, state as much).
      a) Justify any costs that the subject will incur as a result of participating in the study.

E. Compensation to Subject (Applies to studies using human subjects)
   1. Describe any compensation that is received by the subjects, whether monetary or otherwise. When determining compensation, keep in mind what is reasonable based on the time and effort required of the subject. The use of benefits to offset

the burden due to participation in the research should be incremental and not based on study completion.

a) Discuss schedule of payments based on their completion or partial completion

F. Provisions for vulnerable subjects (Applies to studies using human subjects)
   1. Indicate whether there will be vulnerable subjects in the study
   2. Describe additional protections provided to these subjects to protect their rights and welfare

G. Subject Privacy and Data Confidentiality (Applies to studies using human subjects)
   1. Privacy of Participants
      a) Describe appropriate provisions to protect the privacy of the subjects.

   2. Confidentiality of Data
      a) Provide a clear description of how the data will be disseminated. Outline the sharing of data with others outside of the institution, and include provisions for maintaining confidentiality. Additionally, describe how the results of the data will be used (i.e. presentations at professional organizations, submission to professional journals).
         i. Will data be identified?
         ii. How will Data be kept Secure (where will data be stored)
         iii. Who will have access to the data?

   3. Plan for Record Retention and disposal

   4. Limits to Confidentiality

IX. PLANS FOR DISSEMINATION OF FINDINGS

X. REFERENCES

XI. APPENDICES

A. Instruments, rating scales, consent forms, etc.