OUTLINE FOR RESEARCH PROPOSALS

Use of this format is required for protocols that have not already undergone scientific review and are being sent to the Research Review Committee. For protocols that have undergone scientific review and are being submitted for IRB review only, investigators may choose to submit their grant narrative instead of this document, but should ensure that all information requested here is addressed by the protocol sent to the IRB.

YOUR PROPOSAL SHOULD INCLUDE ALL OF THE INFORMATION THAT FOLLOWS.

Instructional text is offered in blue and should be removed from the final document. Please retain the headings shown in black, noting "not applicable" where necessary.

Project Title
Principal Investigator

1. ABSTRACT:

A half-page abstract should be prepared that contains information on the background, methods, expected results and implications for the field.

2. OBJECTIVE OF THE STUDY:

- *State the research questions and/or hypotheses where applicable to be addressed by the proposed research.*

3. SIGNIFICANCE OF THE STUDY:

- *This section is a justification for undertaking the study.*
    - *Briefly (in a half-page or less) explain the magnitude of the problem and why time and effort should be spent on this research.*
    - *Describe the practical or theoretical importance of the research by presenting an argument as to what the study is expected to contribute to a better understanding of the problem or to a certain body of knowledge.*

4. REVIEW OF THE LITERATURE:

Present only the most pertinent research studies supporting your argument and discuss only the highlights of the cited studies.

- *Outline the information in a logical sequence (e.g., chronologically) to provide context for the proposed research.*
- *Detail how previous research has not answered your specific research question nor tested your stated hypothesis.*
    - *Point out any technical flaws detected in previous research.*
    - *To the extent that your proposed research overlaps with previous research, show how your prospective study will differ from these studies and how it will complement them.*
    - *If little or no previous work can be found in the area of the proposed study, cite those studies most closely related to the proposed research.*

5. PRELIMINARY DATA

Provide data collected by the investigators or their collaborators to support the proposed research questions, hypotheses, and/or design of the project. If no preliminary data are available, state "Not applicable".

6. METHODOLOGY:

A. Study overview and design

In a few sentences outline the design and activities of the study, identifying the study groups, evaluations and time points, and any interventions. (For example:

Example 1: "This study will assess participant responses to two forms of electrical stimulation to inform future study protocols."

Example 2: "This study will use a randomized, double-blind, placebo-controlled study design to test the effectiveness of the intervention relative to control"

Example 3: "This study will use a 2x2 mixed, repeated- and between- subjects design. The between subjects factor will be Group (individuals with TBI vs. Controls); the within-subjects factor will be Time (time 1 vs. time 2)"

Example 4: "This longitudinal observational study will assess pain prevalence at 3 months, 6 months, and 12 months post-injury to characterize resolution or persistence of pain over time.")

Specify whether the study involves only one performance site, or if multiple sites are involved. If multiple sites are involved, name the sites.

B. Participants

- *General Description*
  - *Give a brief description of the participants (sex, age, physical or mental status, and ethnicity), method of selection (random, stratified, convenience sample, etc.) and numbers of participants to be recruited in all groups.*

- *Inclusion/Exclusion Criteria*
  - *Indicate the criteria for the selection of study participants.*
  - *If populations at special risk (children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons) are to be studied, provide the reason(s) for their inclusion.*
  - *Specify population groups to be excluded (e.g., pregnant women).*

- *Sample Size*
  - *Provide details on how the overall and group sample sizes were determined. Base this on estimates of experimental effects drawn from your pilot data or literature. Critically evaluate the relevance of effects cited in terms of factors including participant groups, experimental design, and treatment exposures.*

C. Research procedures

- *Proposed Procedures*
  - *Concisely describe how the study will be conducted by explaining the variables involved, measuring instruments or equipment, and techniques and conditions.*
  - *Describe how data will be collected.*
  - *If the study will include an intervention, describe the intervention.*
  - *If the study is to be conducted according to a detailed protocol of a pharmaceutical company or other outside agency, include a summary in this section and attach the full protocol as an appendix.*
- *Measures*

  If the study involves the use of a novel scale, questionnaire, or structured interview, attach the text of such instruments as appendices. Validated measures in common usage do not need to be included in the initial submission but may be requested by reviewers at a later time.
- *Drugs or Devices*
  - *Drugs: As applicable, provide specific information on proposed dosage levels and schedules. Include both the generic and commercial name of each drug and summarize available information on efficacy and side effects. State FDA approval status of the drug as planned for use in the study.*
  - *Devices: Describe the characteristics of the device, its interface with the user (implanted, external, etc.) State FDA approval status of the device as planned for use in the study. Provide images.*
  - *If no drugs or devices are being used, simply indicate "Not applicable."*
- *Blood sampling*
  - *State the volume to be drawn on each occasion and the frequency of sampling from the same participant. If none is to be drawn, enter this statement: "No blood will be drawn."*
- *Data management*
  - *Describe where hard copy documents and data will be stored and who will have access. If no hard copy documents will be stored, indicate so.*
  - *Describe where electronic documents and data will be stored and who will have access. The preferred platform for storage of electronic data is REDCap when possible, or a server that is backed up regularly and has controlled access. We recommend against storage of data in electronic files on a local computer, even if password protected and encrypted as there is still risk for data loss. Please consider any special requirements of the sponsor or funding source (if applicable) when composing this section.*
  - *If the project involves multiple sites, describe how data will be shared among sites.*
  - *If this is a trainee project, discuss where data will be stored after the trainee completes their program and who will have responsibility for managing the data post-program completion.*
  - *If data will be shared for use in future research, please indicate where data will be housed and what actions will be taken to de-identify the data.*
  - *Ensure that your methods for data management and sharing (where applicable) comply with any requirements of the study sponsor.*

D. Analysis

Briefly give the procedures for analyzing and synthesizing the data.

For each hypothesis or research question, concisely describe how the data collected in the proposal will be analyzed and how the results of the analysis will address the hypotheses or research questions of the study.
Specify independent and dependent variables for each analysis.

The statistical tests to be performed should be described, such as, "a two-tailed, paired t-test at the 5 percent level of significance".

7. HUMAN RESEARCH CONSIDERATIONS

A. Recruitment and Informed Consent

Describe how participants will be recruited for this study. Include description of the site(s) from which participants will be recruited and how potential candidates will be informed of the study. If a paid recruitment service will be used, identify the service and their proposed activities. Provide copies of any advertisements to be used for recruitment.

If screening is required, specify which aspects of screening, if any, will take place before consent is obtained, and which aspects of screening will take place after consent. Specify the methods that will be used for screening (chart review, telephone interview, etc.). If health information will be obtained before informed consent, please provide a Request for Waiver of HIPAA Authorization in your application packet.

State whether informed consent will be obtained from all participants. If informed consent will be obtained, use the Consent Form Template as the model. If it is not planned to do so, provide a thorough justification for a request to waive the requirement for informed consent. (Note: Federal regulations provide that written informed consent be obtained from each participant of a research activity, but this requirement may be waived by the IRB under specific circumstances; contact IRB for additional guidance.) Describe who will obtain informed consent, when consent will be sought, the setting in which it will be obtained (inpatient unit, telephone call, in-person interaction at research center, etc.) and what actions will be taken to protect the privacy of participants, provide adequate time to consider study participation, and protect against undue influence to enroll.

B. Management of Anticipated Risks

- *Risks*

  State, in adequate detail, any anticipated physical, mental, emotional, or financial risk to the participants and the degree of likelihood that such risk may occur.

- *Adequacy of protection against risks*

  State the measures taken to protect participants against the risks listed, including w*hat measures will be taken to protect the confidentiality of the data to be obtained and the participants' rights to privacy.*

C. Participant Compensation

- *Indicate and justify the type and/or amount of payment to research participants.*

D. Multi-Site IRB Review

- *If this study does not involve multiple sites, simply indicate "Not applicable".*
- *If the study does involve multiple sites describe the following:*
  - *The names of the participating sites (or refer to Study Design section)*
  - *The role of each site, particularly whether it will be enrolling participants or collecting data*
  - *Please indicate which IRB will serve as IRB of record. Please consult with the IRB if you have questions pertaining to IRB review of collaborative research.*

8. WORK SCHEDULE:

This section pertains to the administrative planning for the project.

- *Give a brief estimate of the time requirements for each phase of the study. This information may be presented in a Gantt Chart.*
- *Particular attention should be paid to the expected rate at which subjects will enter the study.*

9. REFERENCES:

References cited should be listed in alphabetical order in standard medical reference format (Index Medicus). If the journal to which the investigator intends to submit the article requires references in another format this may be used instead.