Guidelines for PSRC Research Study Proposals

Please submit proposals to the Research Committee Chair (see contact information in footer). **Do not include any identifying information in your proposal.** Proposals will be reviewed in a blinded fashion. Please limit proposal to no more than two pages. Include Background and Methods sections. Your proposal should include, but are not limited to, the following information:

Background

1. Include relevant context and information necessary for the reviewer to understand your clinical question, stated objectives and methods; include data from preliminary studies as needed. Any references cited will not be included in the two-page limit.

2. State the clinical significance and relevance of your study proposal, the "gap in knowledge" that you wish to address. Why is your question important?

3. State your objectives as specific aims (typically between 1 to 3 aims) and, if applicable, the hypothesis that each aim will test.

Methods

1. State the study design.

2. Describe the study population (e.g. age, specific setting or provider type, specific sedative administered). State relevant inclusion and exclusion criteria.

3. State the desired time frame of data you wish to analyze.

4. Describe your data analysis plan. For example:
    a. State any planned descriptive statistics to examine the data collected in the study.

    b. State any planned comparative testing (e.g. t-test, chi square, ANOVA, Mann-Whitney)
        i. Define a priori your desired level of significance for any proposed hypothesis testing (e.g. $p < 0.05$).

    c. State any planned association/prediction analyses (e.g. correlation, regression)
        i. Describe how you will select your predictors/independent variables. e.g.potential association based on bivariable analysis, plausible clinical relationship with outcome.

    d. **Clearly define all outcomes, exposures, predictors (i.e. independent variables), potential confounders, and effect modifiers**. Explicitly state the components of any composite outcomes or variables (e.g. if your outcome is major adverse event, state all the outcomes that you are considering to be a major adverse event) or diagnostic criteria, if applicable.

5. Provide a list of all requested variables using the same exact wording and category labels as that used in the database itself.

*****IMPORTANT**: All manuscripts resulting from approved proposals must be submitted to the Research Committee for review **prior** to journal submission as part of standard procedure for research utilizing PSRC data and resources.

Research Progress Timeline

All approved studies will be assigned a Research Committee Liaison. The following milestones are in place to provide investigators with support and assistance when needed to achieve timely completion of the proposed research study:

Time 0	**Receipt of requested PSRC data** - If an iterative process is required to obtain the appropriate data for analysis, the date on which the final iteration of data is received will be Time 0.
6 months	**Investigators submit written progress report to Research Committee** - Recommended milestone for completion of data analysis
12 months	**Investigators submit written progress report to Research Committee** - Recommended milestone for initial manuscript submission - If milestone not achieved, your assigned Research Committee Liaison will provide assistance
18 months	**Investigators submit written progress report to Research Committee** - Research Committee Liaison to continue to assist if initial manuscript submission not yet made
24 months	**Investigators submit written progress report to Research Committee** - Recommended deadline for initial manuscript submission unless extenuating circumstances - Study continuation will be re-evaluated based on progress to date - If additional time is required, investigators will continue to work with Research Committee Liaison and provide written progress reports every 6 months to research committee until initial manuscript submission completed

There are no deadlines for abstract submissions. Decisions beyond the 24-month mark regarding study continuation in context of possible scenarios related to manuscript progress, submission attempts and acceptance will be made on a case-by-case basis by the Research Committee.

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