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.

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