POSNA
PEDIATRIC ORTHOPAEDIC SOCIETY OF NORTH AMERICA

REGISTRY RESEARCH PLAN AND SUPPORTING DATA

On continuation pages, give details in accordance with the outline below.

Formatting:

- Please use 12-point font Times New Roman, or 11-point font Arial, one-inch margins, and single spacing.
- The main body of the proposal (section A through E below) is **NOT TO EXCEED SIX (6) PAGES.**
- The supplementary section (F through G) should be in the same formatting and **NOT EXCEED FOUR (4) PAGES.**
- **If the proposal does not comply with these specifications, it will be returned to the applicant.**
- This page limit does not include cited references (section H). Figures can be incorporated into the grant proposal or may be submitted as supplementary material. If they are incorporated into the grant, they will not count towards the page limit (e.g. if a figure takes one half of a page, the grant could be up to six and half pages long).

A. **Scientific Aims** - provide a statement of objectives and specific aims.

B. **Significance** - explain why the results of the proposed work may be important.

C. **Background or Historical Review** – provide the context for the proposed work, and summarize the relevant literature to date on the subject of the proposed research.

D. **Previous work done on the project** - describe briefly any work you have done that is particularly pertinent to the aims of this project.

E. **Methods** - give details of your research plan, including how the results will be analyzed. For each specific aim mentioned in "A", show how your plan is expected to fulfill the aim. Include method of statistical analysis, if relevant. Power studies justifying sample sizes, and therefore cost of the grant, are strongly encouraged.

F. **Complete additional POSNA Registry Grant Application Questions**.

Registry Description and Goals

1. State the purpose of this registry and define the target population

2. Estimate number of patients to be included and describe enrollment scheme (consecutive, etc)
3. What is the length of observation and provide justification.
4. Define the registry end and plan for registry following 3rd year of POSNA funding.
5. Describe any prior registry data collected on this topic by these investigators/others.

Personnel

1. Identify the registry Leader (PI) and head research coordinator
2. Please describe the personnel structure needed to maintain and audit the registry at main center and other centers (data collectors, biostatistics, technological oversight, quality assurance)?
3. List prior registry participation and role by PI and other investigators.

Data Handling

1. Who will determine the core data points? When? Please submit if already designed.
2. What system will be used to collect the data?
3. How will missing data be dealt with?
4. At which points will the data be examined?

Registry Administration

1. Where will the registry be housed?
2. Describe the governance of the registry - Who will make decisions regarding data analysis, repercussions for poor performance, and changes in participating centers?
3. Who (or what team) decides about access to the data, publications, and authorship?
4. What plan exists should the leader or a participant relocate?
5. What is the planned meeting schedule of participating centers?

Funding

1. What funding is needed to start the registry?
2. What funding is needed annually to maintain the registry?
3. How is the research coordinator and other personnel funded?

G. **Timelines** – This is a very important part of registry grant. Provide a statement or flow diagram for the expected timelines for this project.

H. **Cited References** - list material referenced in application.

I. **Supplementary Information** (Pilot Study, Figures, and/or Appendices if necessary) – On projects where human subjects are placed at some risk, in some cases where animals

are used for experimentation, or where there is a laboratory methodology with which the applying institution has not had well documented experience, the investigator may submit a pilot study. In some cases, the applicant may want to provide a copy of a questionnaire or outcomes instrument as supplementary information for the grant reviewers, especially if the instrument is not readily available in the literature. Figures may be submitted in the supplementary material, rather than in the body of the grant. **Please be advised, however, that the reviewers will be primarily assessing the main body of the proposal (sections A through E). Material that is crucial for the assessment of the proposal should be included in the main body of the grant, not in the supplementary information.**

J. **Human IRB statement**, if applicable.

K. **Institutional Data Use Agreement**, if applicable- POSNA encourages transparency and equal access to registry data by all participating institutions. It is suggested that DUAs do not restrict participating institutions from access to deidentified data or from publishing on their individual institutional data. It is encouraged that DUAs reflect this philosophy.

L. **Role of the Orthopaedic Surgeon** - provide statement, clarifying role of orthopaedic surgeon, stating significant part taken in the planning and/or execution of the design and analysis of model. Simple technical roles such as obtaining tissue samples at surgery or providing patients for analysis are not generally considered to be substantial roles.

M. **Relevance of the project to the mission of the Pediatric Orthopaedic Society of North America-** Grants should emphasize the following:
1) Potential to have a profound effect on the quality and/or safety of the orthopaedic care of children.
2) Potential applicability on a global level.
3) Clear and measurable outcomes.
4) Ability to successfully complete the funding proposal as measured by past experience, preliminary data and pilot work.
5) Potential for expanded research, future publications and continued (extramural) grant funding.
6) Collaborative nature of the grant (number of investigators and institutions involved).