# PEDIATRIC ORTHOPAEDIC SOCIETY OF NORTH AMERICA 9400 West Higgins Road, Suite 500, Rosemont, IL 60018 (847) 698-1692• FAX (847) 268-9694

## ADMINISTRATIVE POLICIES AND PROCEDURES FOR POSNA RESEARCH GRANTS

### 1. OBJECTIVE:

The purpose of this grant is to provide funding for high quality clinical registries (multicenter preferred) for pediatric orthopaedic conditions.

#### Grants should emphasize the following:

- Potential to have a profound effect on the orthopaedic care of children.
- Ability to successfully complete the funding proposal as measured by past experience, preliminary data and pilot work.
- Potential for expanded research, future publications and extramural grant funding.
- Collaborative nature of the grant (number of investigators and institutions involved).
- 2. Eligibility: See Section I. A.
- 3. **Deadline for Application: December 3**
- 4. Period of Grant: 1 to 2 Years (Start-Up Grants are 1 year)
- 5. Amount: Up to \$30,000 (Start-Up Grants are up to \$10,000, Directed Research up to \$50,000)
- 6. Application: Must be submitted through ProposalCENTRAL website: Log in as an applicant here: <u>https://proposalcentral.altum.com</u>

If you have trouble with the adobe pdf file, you can email <u>raymond@aaos.org</u> for an application is Word format.

# CHECK OFF AND RETURN WITH APPLICATION:

#### ADMINISTRATIVE

- $\hfill\square$  Cover Sheet
- □ Key personnel Page
- □ Budget Page
- □ Budget Justification Page
- D POSNA/NIH BioSketch for key personnel
- □ Facilities

#### RESEARCH SPLAN AND SUPPORTING DATA

- □ Lay Summary and Project Summary
- □ Specific Aims
- □ Research Strategy
- $\Box$  References
- $\Box$  Role of Orthopaedic Surgeon
- □ Animal IACUC or Human IRB Statement if applicable
- □ Supplemental material if applicable
- $\Box$  Response to Reviewers if resubmission

#### Additional Information

Animal IRB, if applicable

- □ Approved
- □ Pending

Human IRB, if applicable

- □ Approved
- □ Pending

A member of POSNA serves as the principal or co-principal investigator.

In the case of the Awards, the PI must be the POSNA member.

- □ Yes
- $\Box$  No

I currently am a PI on a POSNA research grant

- $\Box$  Yes
- 🗆 No

# **Reviewer Criteria Used in Scoring of Grant Applications**

(This is information that the reviewers will be looking for when reviewing your application)

# A. Relevance (to POSNA)/Significance/Potential for Future Funding

- i. Is the project relevant to the mission of POSNA?
- ii. Do the aims of the proposed project address an important question?
- iii. What is the likely impact of the project to the field if successfully completed?
- iv. Are the results of this project likely to enhance the potential for further peer reviewed research funding related to the issue being studied?

# B. Originality; Novel; Innovative

- i. Is the proposed study original? (Or has this been done previously but poorly?) OR
- ii. Will the results of the project result in new information? (Have the potential to provide new information)
- iii. Is the project innovative? (Uses or will result in novel concepts, approaches or technologies)

# C. Methods: (Quality and clarity of the study design, methods and analysis)

- i. Is the study design valid/appropriate for the question/s and aims of the project?
- ii. Is the study design the strongest feasible design to address the question/s and aims of the project?
- iii. Are the methods clearly described for each of the specific aims?
- iv. Is the analysis clearly articulated?

# D. Investigator/s / Track record

- i. Do the members of the investigative team have the requisite content experience/expertise to conduct the project?
- ii. Do the members of the investigative team have the requisite methodologic experience/expertise to conduct the research?
- iii. Do the investigators have a track record of successful completion of research?
- iv. (Recognize that some POSNA grant awards are aimed at supporting new or less experienced investigators)

# E. Feasibility: Research Setting, Timelines & Budget

- i. Is the research setting / environment conducive to the successful completion of the project?
- Are the specified timelines reasonable to accomplish the aims of the project? (including IRB approval; lab set up or participant recruitment; follow-up until final outcomes etc)
- iii. Is the budget reasonable and appropriate to accomplish the aims of the project?

# I. POSNA RESEARCH GRANTS - PROGRAM INFORMATION

# A. <u>Eligibility</u>:

1. <u>For POSNA Research Grants</u>: A member of POSNA must serve as the principal or co-principal investigator. Ph.D.'s or D.V.M.'s may serve as the principal or co-principal investigator, as long as they are working in an orthopaedic department with a member of POSNA as the co-principal investigator. There are no age requirements for applicants of the POSNA research grants.

2. <u>For POSNA Directed Research Grants</u>: A member of POSNA must serve as the Principal Investigator.

3. <u>For the POSNA Awards</u>: The PI must be a member and they do have specific age and practice year requirements.

#### See individual grant and award descriptions on our website for specific details.

- B. <u>Application Procedure</u>:
  - 1. Applicant will indicate on the application whether this is a New Submission or a Re-submission.
  - 2. See "Research Plan and Supporting Data" (next page)
- C. <u>Notification of Award</u>

A written notification, to winners, will be sent out in February. Announcement to the membership will take place at the POSNA Annual Meeting. Grant begins on June 1 in the year of the award. Directed Research grants will run for up to three years.

# **RESEARCH PLAN AND SUPPORTING DATA**

# Grants should emphasize the following:

a) Potential to have a profound effect on the quality and/or safety of the orthopaedic care of children.

- b). Potential applicability on a global level.
- c) Clear and measurable outcomes.

d) Ability to successfully complete the funding proposal as measured by past experience, preliminary data and pilot work.

e) Potential for expanded research, future publications and continued (extramural) grant funding.

f) Collaborative nature of the grant (number of investigators and institutions involved.

IMPORTANT: Please take note that some of the POSNA grant format has changed. This is to align with the standards of the NIH RO3 and R21 granting mechanisms to facilitate applicants to apply for federal funding without restructuring their grants.

If the proposal does not comply with the following specifications, it will be returned to the applicant.

## 2)Required Documents:

- a) Lay Summary
- b) Project Summary
- c) Specific Aims
- d) Research Strategy
- e) References
- f) Role of Orthopaedic Surgeon
- g) Animal IACUC or Human IRB Statement if applicable
- h) Supplemental material if applicable

# 2) Document Descriptions:

a) Lay Summary:

Lay summary is a brief summary of a research project or a research proposal that has been written for members of the public, rather than researchers or professionals. It should be written in plain English, avoid the use of jargon and explain any technical terms that have to be included. These summaries are essential to communicate to the public the focus of POSNA research.

## b) Project Summary

Include the project's broad, long-term objectives and specific aims. Include a description of the research design and methods for achieving the stated goals. Write in plain language, so even a non-scientist can understand the importance of the project. *This summary most contain a statement of relevance of the project to the mission of the Pediatric* 

*Orthopaedic Society of North America.* This is a condensed version of the specific aims. These summaries are essential to communicate to the scientific community the focus of POSNA research.

#### c) Specific Aims

Briefly state: Significance, Hypothesis, Innovation and Impact if hypothesis is proven true and delineate the specific aims for the project with brief description of methods. This is the 'blue-print' of the proposed project. It serves as an overview for reviewers of your grant and allows others who were not assigned to read your grant gain a quick overview of your proposal so that they can participate in discussion of your grant.

### d) Research Strategy

Background:

<u>Significance</u>: Explain the epidemiology, morbidity, mortality and cost of the clinical problem. Provide the context of the proposed work and summarize the relevant literature regarding historical and current treatments and why they are limited.

<u>Hypothesis</u>: Clearly state a hypothesis and provide rationale for the hypothesis. Innovation: Explain how the hypothesis is innovative.

Immediate and Long Term Impact: Explain what part of clinical significance would change if your hypothesis is proven true both a) from the work proposed witching and b) from future work stemming off of the broader theory of your work.

<u>Approach</u>: 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.

Sample Size: *Power studies justifying sample sizes, and therefore cost of the grant, are required.* If not applicable, an explanation as to being exempt is required.

Timeline: Delineate a plan as to when the research will be completed. Be sure that the plan is not overly ambitious.

#### e) References

Not counted against research strategy listed immediately after research strategy

## f) Role of 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.

g) Animal IACUC or Human IRB

#### h) Supplemental Material:

(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.

#### i) Response to reviewers

If this is a resubmission, please provide a one-page explanation as to how the research group addressed the concerns raised by the previous cycle's reviewers. Although unlikely that the grant will be reviewed by the same reviewers, the POSNA research committee will be sure to consider how the investigators were able to overcome the previous cycles reviews. Failure to provide an adequate response will reflect poorly on the resubmission.

## 3) Page Limits:

- 1) Lay Summary: 15 lines of text or less
- 2) Project Summary: 35 lines of text or less
- 3) Specific Aims: 1 Page
- 4) Research Strategy: 6 Pages including figures and media
- 5) References: 2 pages
- 6) Role of Orthopaedic Surgeon: 15 lines of text
- 7) Animal IACUC or IRB: Unlimited
- 8) Supplemental Material: Unlimited however, this section may not include material essential for grant review, i.e. methodology etc.

# 4) Paper Size and Margins

Use paper size no larger than standard letter paper size (8 ½" x 11"). Provide at least <u>one-half inch margins</u> (top, bottom, left, and right) for all pages. No applicant-supplied information can appear in the margins.

# 5) Font (size, color, type density) and Line Spacing

Adherence to font size, type density, line spacing and text color requirements is necessary to ensure readability and fairness. Although font requirements apply to all attachments, they are most important and most heavily scrutinized in attachments with page limits.

Text in your attachments must follow these minimum requirements:

- Font size: Must be 11 points or larger. Smaller text in figures, graphs, diagrams and charts is acceptable, as long as it is legible when the page is viewed at 100%.
- Some PDF conversion software reduces font size. It is important to confirm that the final PDF document complies with the font requirements.
- Type density: Must be no more than 15 characters per linear inch (including characters and spaces).
- Line spacing: Must be no more than six lines per vertical inch.

• Text color: No restriction. Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.

We recommended the following fonts, although other fonts (both serif and non-serif) are acceptable if they meet the above requirements.

- Arial
- Georgia
- Helvetica
- Palatino Linotype

Legibility is of paramount importance. Applications that include PDF attachments that do not conform to the minimum requirements listed above may be withdrawn from consideration.

## II. INSTRUCTIONS FOR COMPLETING RESEARCH GRANT APPLICATION

#### A. <u>See Application at ProposalCENTRAL</u>

#### B. <u>Budget and Justification:</u>

1. Enter budgets for year funds are requested. At bottom of page provide justification. Use an additional page (see application) if necessary.

2. Salaries and Wages: Enter the name, percent of time on project and salary requested, as well as normal fringe benefits, i.e., pay for vacation, sick days, and holidays charged to the grant. On budget justification page state what each person will be doing. <u>No</u> salary can be requested for principal investigator or co-principal investigator.

3. Permanent equipment: Any major piece of equipment or apparatus costing more than \$500.00 should be itemized, and justifications made.

4. Consumable supplies: Glassware, chemicals, supplies and all expendable materials obtained from the stockroom of the institution may be grouped in this category under appropriate subheading.

5. All other expenses:

a. Retirement plan and Federal Insurance Compensation Act employer contributions may be charged to grants, when such contributions are the normal practice of the institution. The percentage of such costs charged on behalf of a given individual must be calculated based on the percentage of that individual's salary charged to the grant. These expenditures must be shown in this category for approval.

b. Up to 200 reprints, without covers, of any paper carrying the credit line "Aided by a Grant from the Pediatric Orthopaedic Society of North America" may be charged against the grant if the principal investigator so desires.

- c. No travel funds can be charged against the grant.
- d. No overhead or indirect costs can be charged against the grant.
- C. <u>Bio Sketches</u>: Use format/template on ProposalCENTRAL website.

Biographical sketches must be submitted for all investigators. <u>They should not exceed five</u> <u>pages for each person using the current NIH Format</u>. Be sure to (1) List research funding relevant to this project for the past five years – include current funding. (2) List funding received for other research projects the last five years, including your own institution – include current funding. (3) List current funding with potential overlap with this proposal. And (4) List pending grants with potential overlap with this project (grants you have applied for, but have not yet received notification).

E. Facilities:

(1) List facilities available at your institution. (2) List research funding relevant to this

project for the past five years – include current funding. (3) List funding received for other research projects the last five years, including your own institution – include current funding. (4) List current funding with potential overlap with this proposal. and (5) List pending grants with potential overlap with this project (grants you have applied for, but have not yet received notification).

F. Lay and Project Summary:

Provide <u>15 line lay summary</u> and 35-line project summary (See POSNA Research Application Research Plan and Supporting Data instruction for more detail).

G. <u>Research Plan and Supporting Data</u>:

1. Detailed instructions are provided in the document: "POSNA Research Application Research Plan and Supporting Data". Page limits should be strictly followed.

2. Relevance of the Project to the Mission Statement of the Pediatric Orthopaedic Society of North America.

"The objective of this Society shall be the advancement of pediatric orthopaedic surgery. This Society is devoted to the enhancement of care for children with musculoskeletal problems. Therefore, the purposes of this Society are exclusively to foster, promote, support, augment, develop and encourage investigative knowledge of pediatric orthopaedic surgery; to develop and encourage methods of prevention of disorders of the musculoskeletal system..."

3. POSNA encourages transparency and equal access to registry data by all participating institutions. It is suggested that Data Use Agreements 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.

#### III. GUIDELINES

#### A. Fiscal Procedures and Policies:

1. Facilities to be provided by Grantee Institution:

a. Grantee institution is expected to provide all necessary, basic facilities and services. These include the facilities and services that normally could be expected to exist in any institution qualified to undertake orthopaedic research.

b. In particular, it is expected that the grantee institution will provide, whether from its own funds or from grant funds other than those of POSNA, the following, unless otherwise specifically agreed upon:

(1) Laboratory space

(2) Maintenance service, including maintenance, supplies and service contracts

(3) Telephone services

(4) Library service, including subscriptions to periodicals and the purchase of books

(5) Laboratory furniture

(6) Salary of principal investigator, co-principal investigator and of secretarial personnel

(7) All travel expenses of personnel working under the grant

(8) Worker's compensation, public liability or other hazard and special insurance

(9) Office equipment

(10) Employee group life, disability, medical expense or hospitalization insurance Lantern slides, color plates, etc. Hospital bed expense, nursing or related services even though used for research studies. Indirect Costs Tuition expenses of personnel on grant.

(11) L1antern slides, color plates, etc.

(12) Hospital bed expense, nursing or related services, even though used for research studies.

(13) Tuition expenses of personnel on grant.

2. As a matter of policy, POSNA funds may not be used for remodeling or building construction costs.

3. Ownership of the Equipment:

Equipment purchased under POSNA grants becomes the property of the institution, unless otherwise specified by the POSNA before termination of the grant or its extensions.

## B. <u>Budget Policies and Reports</u>:

1. Reports of expenditures must be prepared and be signed by the responsible financial officer, and submitted to POSNA for approval with accompanying documents. The approved financial report is returned to the financial officer with the grant payment. Expenses must be submitted by category, i.e., Salary and Wages, Equipment, Supplies, Animals, Other.

2. A Final budget report, twelve (12) months, for all Research Grants, of one year duration, shall accompany the grant final report outlining the findings and achievements, no later than three (3) months after the grant period has terminated (September 1st).

2. For Research Grants of two-year duration, a twelve (12) month financial expense progress report and a twelve (12) progress report on the research, must be submitted no later than three (3) months after the first year (by September 1).

4. At expiration of grant, any unexpended balance of \$100.00 or more must be refunded to POSNA within sixty (60) days together with the report of expenditures and accompanying documentation, properly submitted.

5. Separate accounts must be maintained for each grant. These accounts, with substantiating invoices and payrolls, must be available at all times to representatives of POSNA.

5. Grantee may terminate a grant prior to normal expiration date by notifying POSNA in writing and stating the reasons for termination. Unexpended funds must be returned to the POSNA within sixty (60) days, together with a final report of expenditures. POSNA reserves the right to terminate grants at any time upon three months written notice.

# C. <u>Policy on Animals in Research</u>

1. Use of animals and number requested for project must be justified by institution. If applicable, provide IRB statement from your institution's animal care committee approving use of and number of animals requested for project.

2. All animals used in research supported by POSNA grants must be acquired lawfully and be transported, cared for, treated and used in accordance with existing laws, regulations and guidelines. Decisions as to the kind and sources of animals that are most appropriate for particular studies must be made by scientists and institutions. POSNA policy requires that such decisions be subject to institutional and peer review for scientific merit and ethical concerns and that appropriate assurances be given that NIH principles governing the use of animals are followed.

# D. Policy on Human Subjects in Research

1. Use of human subjects and sample size must be justified. If applicable, IRB statements from your institution's human subjects committee must be provided. IRB approval is required for patients' X-rays.

2. POSNA grantees are entrusted to assure adequate protection of human subjects. NIH regulations regarding human subjects should be followed.

## E. <u>Policy on Transfer of Grant</u>

If the grant has not started at the first institution and the principal investigator moves to a new institution, the grant <u>will be canceled</u>. The principal investigator can re-apply from the new

institution for the following year's funding.

# F. <u>Policy on Extensions</u>

- 1. Grant extensions are allowed
  - a. Must be justified with a specific reason(s) as to why an extension is required.
  - b. A timetable as to when this specific barrier(s) will be addressed.
  - c. A progress report of all work accomplished up to the time of the extension request.
- 2. If an extension is granted
  - a. A report on the progress of resolving the barrier must be submitted according to the timetable set in 1.b.
  - b. An overall progress report must be submitted within 6 months of resolving the barrier(s).

## G. Policy on Changing Aims of Grant

If the principal investigator and collaborators find that the original aims of the grant cannot be accomplished, and that to continue the project <u>substantial</u> changes in aims or methodology must be considered, the principal investigator must write to POSNA, requesting permission to change the procedure and state the reasons for the change. The Research Committee will respond to the principal investigator.

#### H. <u>Final Report of Findings and Achievements</u>:

- 1. Grantees must submit a final report by September 1 (following the end of the grant period), using a standard report form, which will be provided at the time the grant is awarded. A written notation should be made to the Chair of POSNA research committee, if there have been any problems or delays with meeting the stated objectives of the grant in the originally proposed time frame. It is extremely important that the investigator report these accomplishments. Failure to submit a report will result in ineligibility to apply for future POSNA grants or awards either as a principal investigator or as a Co-PI.
- 2. POSNA reserves the right to deny additional grants to any institution where the final reports have not been submitted within six months.
- 3. In the year after the grant period, the awardee of any of the Research Grants will be **required to submit an e-poster** summarizing the results of their investigation for the POSNA Annual Meeting. (i.e., a grantee awarded a POSNA research grant in 2019 would be required to submit an e-poster for the 2021 or 2022 Annual Meeting).
- 4. The grantee(s) of a Directed Research Grant will be required to submit an Abstract(s) summarizing the results of their investigation for the upcoming POSNA Annual Meeting.
- 5. According to POSNA's policy, any current grant or award recipient cannot apply for a future grant as a PI or Co-PI until the current award/grant research is completed and all final reports and expense reports have been submitted and accepted.

6. In the year after the grant period, the grant recipient is required to submit a short 2-3 paragraph summary of the work for possible submission for the AAOS Unified Research Agenda.

"Unified Orthopaedic Research Agenda (URA): The mission of the URA is to advance science and research in musculoskeletal care through a unified research strategy. Continued and additional funding of these research priorities is necessary to improve function and mobility and reduce the socioeconomic burden of orthopaedic disorders. The URA was developed as a communication tool for organizations like the Academy, specialty societies, and individual researchers. Two versions of the URA are updated annually by the AAOS Research Development Committee, with input from the Board of Orthopaedic Specialty Societies – a "Public" version which is used as a leave behind summary on Capitol Hill, and a "Federal Funding Agency" version that we provide to various NIH institutes, etc. The URA is sent to the AAOS Council on Research and Quality for review, and then the AAOS Board of Directors for final approval. Current versions (approved December 2015) are available for review online at http://www.aaos.org/ura."

#### I. <u>Publication</u>

1. POSNA encourages free publication of research findings by grantees but requires that the following acknowledgment be used as a footnote on the first page of the text: **"AIDED BY A GRANT FROM the Pediatric Orthopaedic Society of North America"** Also, when a grantee presents a paper at a professional scientific meeting, the above credit line must be included.

# POSNA should be sent reprints of all papers and publications resulting from work done under a grant, even those that appear after the grant has been terminated.

POSNA imposes no restrictions on copyrighting publication by grantees.

#### J. <u>Patents</u>

1. If any patents accrue from investigations supported by grants funded by the POSNA, the POSNA reserves the right to negotiate a proportionate interest in the royalties.