

CALL FOR PRE-PROPOSALS AND PROPOSALS FOR: ORTHOPAEDIC CLINICAL RESEARCH NETWORK GRANT

PURPOSE

The Orthopaedic Section has developed an RFP for the Orthopaedic Clinical Research Network (CRN) grant. A clinical research network is defined as a network of clinicians and researchers who work collaboratively to conduct clinical project(s) using an established infrastructure of clinical centers for data collection and a data management center. The primary purpose of this orthopaedic CRN grant is to develop a clinical research network and perform multi-center clinical project(s) which examine the diagnosis/ classification, prognosis, and/or patient-centered treatment outcomes of interventions delivered by physical therapists in patients with musculoskeletal conditions commonly managed by orthopaedic physical therapists. Secondly, the purpose is to develop a CRN that is sustainable for future use by Orthopaedic Section members to conduct multi-center clinical projects.

TARGETED RECIPIENT OF THE CRN GRANT

The CRN grant program is designed to provide funding to an Orthopaedic Section member and co-investigators who have the ability to develop a CRN to examine a well-defined clinical practice issue related to diagnosis/classification, prognosis or treatment outcomes. The Orthopaedic Section has earmarked up to \$300,000 to support a CRN Grant.

GUIDELINES

1. **First priority:** *perform clinical research project(s)* within the framework of the developed orthopaedic CRN to answer an important question and high impact for orthopaedic physical therapy clinical practice.
 - a. Projects should address commonly seen diagnoses by orthopaedic physical therapists. The 3 most common regions are: spine, shoulder, or knee musculoskeletal disorders; if project(s) propose to focus on another region justification should be provided.
 - b. Projects should examine at least one of the following:
 - 1.) The effectiveness of a scientifically founded treatment approach studied on a well-defined sample of patients.
 - 2.) Patient diagnosis/ classification procedures for the purposes of determining an appropriate treatment.
 - 3.) Prognosis of well-defined sample of patients undergoing physical therapy.
 - c. Project must involve multi-center to represent:
 - 1.) More than 1 geographical region
 - 2.) A broad-base of subjects (rural and urban, socioeconomic status, etc...)
 - d. Project must involve Orthopaedic Section member participation by soliciting clinician interest:
 - 1.) Via mechanisms in place within the Orthopaedic Section, and if appropriate by other means
 - 2.) In larger hospital based practices as well as small private practices
2. **Second priority:** the developed CRN infrastructure that met the guidelines listed in "First Priority" should be *sustainable for use in future studies* by Orthopaedic Section members to examine other relevant clinical questions. The CRN should have:
 - a. Clinical centers / Clinicians
 - b. Centralized data management core
 - c. Data collection methods described in detail in a Manual of Procedures (MOP) for the defined project(s)

- d. Data collection via web-based or hand-held synchronized tools
- e. Well developed data management strategies
- f. Multi-center approach for data acquisition
- g. Data monitoring process by an external committee, if appropriate
- h. High promise of sustainability assessed by:
 - High likelihood of future success for use of the CRN in collaborative research and future funding by the proposed researchers or other researchers.
 - Past performance of investigators in clinical studies and participation in prior clinical research networks

Eligibility

1. The grant should clearly address 1 of 3 areas described above in the “First priority” of these guidelines.
2. Principal investigator must be a member of the Orthopaedic Section of APTA. Multiple PIs are allowed (co-PI). One of the co-PIs must be an Orthopaedic Section of the APTA.

Funding

The CRN grant proposals are limited to a maximum 3- year period of funding. The maximum budget for total costs is \$300,000, with an approximate **maximum of \$100,000 per year**. Projects receiving additional funding from other sources are also eligible for funding by the Orthopaedic Section; however the applicant must justify the need for additional funding from the Orthopaedic Section and must provide assurances to avoid overlap in funding.

Allowable use of funds is specific and defined:

- 1 – Personnel – Investigators (PI, co-PI, co-I)
- 2 – Personnel – Other than investigators
 - a. Consultants
 - b. Statisticians
 - c. Clinicians
 - d. Data technician
 - e. Research assistant
- 3 – Patient
 - a. Recruitment
 - b. Compensation for assessment time
 - c. Compensation for completion of outcome measures
- 4 – IRB fees
- 5 – Travel
 - a. Training of study related data collection
 - b. Meetings related to study development
- 6 – Equipment

Examples: computers resources, dynamometers, sensors.
- 7 – Supplies – consumables necessary to complete the research
- 8 – No In-directs are allowed

The budget should reflect the total costs for performing the research, with a breakdown for costs for year 1, year 2, year 3. If the grant proposal budget includes proposed *in-kind* services, letters from appropriate supervisors or clinical entities indicating the approval of in-kind services or percent effort of researcher / clinician must accompany the grant.

If the grant is funded, monies will be released only after evidence of approval from the appropriate IRB(s). Monies will be distributed yearly or semi-yearly (year 1, 2, 3). Reporting of progress and budget will be required for release of funding.

Requirements if funded

Physical therapists receiving funding from this program will be expected to report their findings at a Combined Sections Meeting within 4 years of receipt of funding. A list of all abstracts and manuscripts that results from this funding must be provided to the Orthopaedic Section.

GRANT PRE-PROPOSAL AND PROPOSAL FORMATS

Step 1 – Pre-proposal

All investigators interested in submitting a grant application for the Clinical Research Network RFP must first submit a pre-proposal. Evaluation and review of the pre-proposals will be used as a time-efficient method to determine interest of the proposed grant by the Orthopaedic Section, and assess for potential collaboration among investigators. A sub-committee of the research committee of the Orthopaedic Section will evaluate the pre-proposals on the required components. Based on this evaluation, the committee will invite the three - five top-ranked proposals to submit a full grant proposal. Only pre-proposals reviewed and invited to submit a full application will be considered for full review. *DUE 1 May, 2012*; see page 5. Pre-proposal components:

- Abstract - 1/2 page
- Specific aims – 1 page
- Significance, innovation, and approach – 2 pages
 - Significance –importance of the problem, how the proposed project will improve knowledge and clinical practice, and how clinical practice will change if the aims are achieved
 - Innovation – describe how will the project will shift clinical practice paradigms, any novel approach being used, and if there are any new or refined approaches or methods being used
 - Approach
 - Generally describe the approach to answer the specific aims to include the overall strategy, methods, and analyses.
 - Unique aspects to describe: 1.) how clinicians will be recruited (beyond assistance from the Orthopedic Section), trained, integrated into the CRN, and retained over time; 2.) how IRB approval will be obtained for multi-site study; will the PI's institution take oversight for all data collection sites or will an independent IRB be required.
- Maximum length: 4 pages
- Single or double-spaced, margins 1 inch, font either Times New Roman 12 point or Arial Regular 11 point.
- Appendix: NIH biosketches for each investigator (limit: 4 pages per investigator)

Step 2 – Full application – a full application can **ONLY be submitted if a pre-proposal was submitted AND invited for a full application**. Applications should contain, in this order:

Cover Sheet:

- Title of the grant
- Name and address of each PI and co-investigator
- Dollar amount requested

Table of Contents (with corresponding page numbers for each section listed below)

- Section 1: Abstract
 - 1 page maximum
 - Background, Purpose, Design, Methods, Data Analysis, Significance
- Section 2: Specific Aims (1 page)
- Section 3: Significance, Innovation, Approach (NIH format)
 - 12 page maximum
 - Approach to include
 - Preliminary data (if available)

- Design
 - Subjects
 - Methods
 - Data analysis
 - Power Analysis
 - Limitations
 - Anticipated or potential problems
- Section 4: Bibliography
- Section 5: Appendices
 - Appendix A: Timeline
 - Milestones: clear, measurable goals for every 6 months of the grant (Year: 0.5, 1, 1.5, 2, 2.5, 3)
 - To be included on timeline should be, but not limited to: MOP (manual of operating procedures), IRB approval, targeted recruitment numbers, planned meetings, etc.
 - Appendix B: Budget and Budget Justification
 - Appendix C: Biosketches and Role of each investigator
 - Role of each investigator: list name and role of each investigator (1 page)
 - Biosketches: NIH format (3 page maximum for each):
 - Name and Position Title
 - Education / Training (Institution and Location, Degree, Year, Field of Study)
 - Positions Held and Honors
 - Publications **relevant to the proposed grant**
 - Funding History; to include: funding agency, title of the project, a brief description of the project, amount of funding, percentage effort, year(s) of funding.
 - Appendix D: Facilities
 - Appendix E: IRB Informed Consent
 - IRB Informed Consent Form with statement of IRB approval or submittal for approval
 - Appendix F: Data collection forms.

Formatting:

Margins must be at least 1 inch. Font must be either Times New Roman 12 point or Arial Regular 11 point. The applicant's last name and page number should appear at the top of every page, starting with page 1 with the first page of Section 2 (Specific Aims and Hypotheses).

CRITERIA FOR REVIEW OF APPLICATIONS

Priority will be given to applications that meet the following criteria:

- The first and foremost criterion is scientific merit of the proposed clinical project(s) using an orthopaedic CRN.
- The second priority is the development of a CRN infrastructure that is sustained for use by Orthopaedic Section members for future clinical projects.
- Have a specific and well-designed purpose that is judged to be consistent with the purpose of the CRN Grant
- The sample to be studied must include patients/clients with impairment of the musculoskeletal system, and delivery of care must be provided by a physical therapist.
- Demonstrated high likelihood of success.

GRANT MANAGEMENT

This CRN grant is a cooperative agreement award mechanism. The principal investigator (PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project(s) with the Orthopaedic Section being substantially involved as a partner with the principal investigator to assist the PI in achieving a successful outcome. The Orthopaedic Section will provide guidance and support to the principal investigator's activities by involvement in and working jointly in a partnership role, but not assuming direction,

primary responsibility, or a dominant role in the project(s). The PI will have the responsibility of directing all aspects of the project(s) to include design, conduct of study, quality control, data analysis and interpretation, publications, dissemination of data, and development of CRN infrastructure for data collection. The Orthopaedic Section will provide support and guidance in design, technology services, soliciting clinician member involvement, purchasing equipment, obtaining vendors for services needed such as but not limited to technology services for the central database core, and other support and guidance. The Orthopaedic Section will review the progress of the study periodically by examining the data collected, annual reports, participant enrollment, compliance to study protocol and data collection, etc. A steering/ oversight committee consisting of research scientists and clinicians will be formed to assist the Orthopaedic Section in these duties. The Orthopaedic Section will cover all costs of the steering/ oversight committee.

The PI will retain all rights to the data generated from this study, and retain all primary rights to publication of the data from this grant. The Orthopaedic Section will have access to the data generated from this grant to periodically review and access to the final dataset. The Orthopaedic Section and the PI will retain rights to use of the CRN infrastructure as described under Guidelines 2, Second Priority. The PI will make all study materials and MOP available for Orthopaedic Section member use.

REVIEW PROCESS

An External Grant Review Committee formed by the Orthopaedic Section Research Committee will review and rate each pre-proposal and then the full grant proposals, using the criteria for review stated above. The highest rated application will be selected for funding. All applicants will be notified of the results in December, 2012. Grants should indicate a start time no sooner than 31 December, 2012.

SUBMISSION DEADLINES

The deadline for submission of the **Pre-Proposal is 1 May, 2012 at 12 noon EST**. The application should be emailed as single pdf to Tara Fredrickson at: **tfred@orthopt.org by 1 May, 2012 at 12 noon EST**. The pdf should be contained within a single pdf document. Label the pdf in the following format: PI's last name_CRN pre proposal_Six word abbreviated title_year of submission.

Ex: Fredrickson_CRN_pre proposal_Diagnosis of patellar tendinopathy_2012

IF your pre-proposal was reviewed and requested for a FULL proposal, the due date for the full proposal will be 1 August, 2012 at 12 noon EST.

FURTHER INFORMATION, CONTACT THE ORTHOPAEDIC SECTION OFFICE:

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