

# REQUEST FOR PROPOSALS: ORTHOPAEDIC CLINICAL RESEARCH NETWORK (CRN) PROJECT GRANT

## PURPOSE

The Orthopaedic Section is requesting proposals for a Clinical Research Network (CRN) Project Grant. This project grant will leverage the resources and infrastructure from the larger Orthopaedic Section CRN Grant, recently funded by the Orthopaedic Section. A clinical research network is defined as a network of clinicians and researchers who work collaboratively to conduct clinical projects using an established infrastructure of clinical centers for data collection and a data management center. The CRN Project Grant is designed to fund a project that will answer a well-defined question(s) of high impact to orthopaedic physical therapy practice and utilizes the transferable infrastructure and resources developed by the Orthopaedic Section's currently funded CRN Grant. The current CRN project "Creation of the Orthopaedic Physical Therapy – Investigative Network (OPT-IN) for the Optimal Screening for Prediction of Referral and Outcome (OSPRO) Cohort Study" is being conducted by Steve George (PI) and co-investigators, Jason Beneciuk, Joel Bialosky, Trevor Lentz, Samuel Wu, Robert Rowe, and Giorgio Zeppieri (University of Florida, Brooks Institute of Higher Learning, and Shands Rehab Centers).

## TARGETED RECIPIENT OF THE CRN GRANT

The CRN Project Grant is designed to provide funding to an Orthopaedic Section member and co-investigators who have the ability to use the developing network to examine a well-defined orthopedic clinical practice question related to diagnosis/classification, prognosis, or treatment outcomes. The Orthopaedic Section has earmarked \$30,000 to support the CRN Project Grant. The CRN Project Grant is distinct from the Section's small grant program.

## GUIDELINES

Perform a clinical research project within the framework of the developing Orthopaedic Section CRN to answer a question of high impact for orthopaedic physical therapy clinical practice.

- a. Projects should address commonly seen diagnoses or conditions treated by orthopaedic physical therapists.
- b. Eligible studies will address one of the four areas:
  1. Examine the effectiveness of a treatment approach on a well-defined sample of patients with orthopaedic problems
  2. Examine patient classification procedures for the purposes of determining an appropriate treatment
  3. Further establish the meaningfulness of an examination procedure
  4. Examine the role of the orthopaedic physical therapist in the health care environment
- c. Projects must extend an invitation for participation to those clinicians/clinics that have previously participated in the original CRN grant. The project must also invite Orthopaedic Section member participation by soliciting additional clinicians/facilities.
- d. The network will ideally include a broad base of participants (rural and urban, socioeconomic status, etc...) consistent with the goals of a CRN.

## ELIGIBILITY

The principal investigator (PI) must be a member of the Orthopaedic Section of the APTA. Multiple PIs (co-PIs) are permitted and while membership in the Orthopaedic Section is not required of all principle investigators, it is encouraged if they are a physical therapist.

## FUNDING

CRN Project Grant proposals are limited to a maximum 2-year period of funding. The maximum budget for total costs is **\$30,000** with an approximate **maximum of \$15,000 per year**. Projects receiving additional funding from other sources are encouraged and 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.

## TRANSFERABLE ASSETS FROM THE CURRENT CRN PROJECT

Potential resources available from the current CRN Project (George et al) include:

- 4-5 Primary Clinical sites and 4 secondary sites that may be invited to participate in the CRN Project Grant
- Data collection methods used for the OSPRO cohort study including data collection templates, screening tools, and RedCap forms.
- Sharing of strategies: IRB navigation, clinician involvement, participant recruitment strategies, and methods for collecting follow-up data and reducing loss to follow-up.

### Allowable use of funds is specific and defined:

1 – Personnel – Investigators (PI, co-PI, co-I). The total for the investigators cannot exceed 30% of the total funds requested.

2 – Personnel – Other than investigators

- a. Consultants
- b. Statisticians
- c. Clinicians
- d. Data technician
- e. Research assistant

3 – Patient/Participants

- a. Recruitment
- b. Compensation for assessment time
- c. Compensation for completion of outcome measures

4 – IRB fees

5 – Travel

- a. Travel related to training and data collection
- b. Meetings with clinical sites related to study development/completion
- c. Funds may not be used for conference related travel. Recipients will receive \$400 to assist with the costs for presentation of the work at a Combined Sections Meeting (do not include this in the budget). All abstracts and manuscripts that result from this funding must be provided to the Orthopaedic Section.

6 – Equipment

Examples: dynamometers, sensors, etc

7 – Supplies – consumables necessary to complete the research

8 – There are no indirects for this grant

The budget should reflect the total costs for performing the research, with a breakdown of costs for year 1 and year 2. If the 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 proposal.

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

### REQUIREMENTS IF FUNDED

The investigators receiving funding from this program will be expected to report their findings at a Combined Sections Meeting within 3 years of receipt of funding. A list of all abstracts and manuscripts that result from this funding must be provided to the Orthopaedic Section.

## PROPOSAL FORMATS

Applications should consist of the following, in this order:

- Cover Sheet (see form on [www.orthopt.org](http://www.orthopt.org)):
  - a. Title of the grant
  - b. Name and address of each PI and co-investigator
  - c. Dollar amount requested
  - d. Purpose (from the 4 listed for funding) that the grant addresses
  - e. Sponsored Programs official and signature
- Table of Contents (with corresponding page numbers for each section listed below)
- Section 1: Abstract
  - a. 1 page maximum
  - b. Background, Purpose, Design, Methods, Data Analysis, Significance
- Section 2 – 5: Research Plan (8 page maximum)
  - Section 2: Specific Aims and Hypotheses
    - o Make sure to state the purpose (from the 4 listed for funding) of the grant in this Section
  - Section 3: Significance
  - Section 4: Innovation
  - Section 5: Approach
    - o This should include: design, participants, methods, variables, data analysis, power analysis, limitations, potential problems, and risks
  - Section 6: Bibliography
  - Section 7: Participant recruitment plan (also see Appendix G)
  - Section 8: Plans for sustaining the Clinical Research Network (1 page maximum)
- Appendices
  - o Appendix A: Timeline
  - o Appendix B: Budget and Budget Justification. If you have a 2-year grant, your budget must be broken down into Year 1 and Year 2. (Carefully read the paragraph on funding above as it relates to allowable use of funds)
  - o Appendix C: Biosketches and Role of each investigator
    - Role of each investigator (Limit: 1 page)
    - Biosketches: NIH format (3 page maximum for each):
      - o • Name and Position Title
      - o • Education / Training (Institution and Location, Degree, Year, Field of Study)
      - o • Positions Held and Honors
      - o • Publications
      - o • 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.
  - o Appendix D: Facilities
  - o Appendix E: IRB Informed Consent and Approval statement of submittal for approval. IRB Informed Consent Form with statement of IRB approval OR the consent form which will be/is submitted for approval
  - o Appendix F: Other: Data collection forms, surveys, etc.
  - o Appendix G: Letters of support from clinical partners and referring sources to support ability to recruit participants
  - o Appendix H: Previously funded by the Orthopedic Section?
    - Please submit as Appendix H, a brief summary (1 paragraph per project, with a total of 1 page maximum), to include: title of the funded project, date of funding and results of previous funding, and number abstracts and publications as a direct result of funding.
  - o Appendix I: Resubmission. Was this grant previously submitted to the Orthopedic Section? Please submit Appendix I: Resubmission. This section is limited to 2 pages, and should address the major differences between the current and previous grant application. It should address the reviewer's comments and clearly identify how these comments were addressed in the current grant application. Do not use text shading or any indication in the grant application as to the changes made, but rather indicate section and page as needed where previous review comments were addressed.

**Formatting:**

When formatting the application, 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 that uses the developing clinical research network.
- The second priority is the potential for sustainability of the CRN infrastructure that may be used by Orthopaedic Section members for future CRN Project Grants.
- Demonstrated high likelihood of success.

**REVIEW PROCESS**

An External Grant Review Committee formed by the Orthopaedic Section Research Committee will review and score each proposal using the criteria for review stated above. The highest rated application will be recommended to the Orthopaedic Section Board of Directors for final approval. All applicants will be notified of the results by March 18, 2016. Grants should indicate a start date no sooner than May 1, 2016.

**SUBMISSION DEADLINES**

The deadline for submission of materials is **November 13, 2015**. The original of the application should be mailed, postmarked by the due date, to the Orthopaedic Section office. Additionally, a pdf version of the application must also be e-mailed to Tara Fredrickson at: [tfred@orthopt.org](mailto:tfred@orthopt.org) by November 13, 2015 at 12 noon CST. The pdf version of the grant application should contain the entire grant application in a single pdf document. Please label the pdf in the following format: PI's last name\_Six word abbreviated title\_year of submission. Ex: Fredrickson\_Diagnosis of patellar tendinopathy\_2015

**CONTACT THE ORTHOPAEDIC SECTION OFFICE:**

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