BACKGROUND AND SUMMARY
The mission of the American Medical Society for Sports Medicine (AMSSM) Collaborative Research Network (CRN) is to foster collaborative research to advance the clinical practice of sports medicine. As part of this mission, the CRN aims to help investigators obtain extramural funding (e.g. National Institute of Health (NIH), Patient Centered Outcomes Research Institute (PCORI), Centers for Disease Control and Prevention [CDC] or Department of Defense [DoD], etc.) for conducting high quality and impactful research in topics of relevance to sports medicine physicians. The purpose of this request for proposals (RFP) is to solicit research projects that will prepare a team of investigators to compete for future, extramural funding for a large-scale clinical trial. Investigators must demonstrate preparedness and capability to eventually meet the rigor required to conduct a high-caliber clinical trial. The topic selected for study should align with AMSSM/CRN’s mission and the mission of the targeted funding agency. The CRN will work closely with the investigative team to complete their initial project and to develop a future application, with the ultimate goal of obtaining funding for a sufficiently-powered clinical trial.

General summary
Published Date: January, 2022

Summary: The AMSSM CRN seeks to fund a collaborative research project to address knowledge gaps in sports medicine topics. Proposed studies must show potential to lead to a large extramurally-funded clinical trial and clearly demonstrate the willingness and mechanisms of the awardee to lead collaborative research with other appropriate sites, institutions, and/or AMSSM members.

Eligibility: All Principal Investigators (PIs) must be active members of AMSSM, in good standing. PIs from both private practice and academic institutions are encouraged to apply. Demonstration of the potential to obtain federally funded (or equivalent) research is required. Proposals should involve multi-site collaboration, or clearly indicate how the proposed project will foster future multi-site collaboration, and lead to the improvement of clinical practice in sports medicine.

Key dates:
- Full Application Deadline: March 18, 2022
- Award Announcements: April 12, 2022
- All deadlines are 5pm ET unless otherwise specified
- Maximum Project Budget: $150,000 for up to 2 years
- Maximum Project Timeline: 2 years
- Available Templates: Full Application Cover Page
INTRODUCTION
In furtherance of its mission, the CRN releases this focused RFP to help AMSSM investigators bridge significant gaps that exist between smaller research studies and large-scale funding opportunities for multi-site clinical trials relevant to the practice of sports medicine. This particular RFP will provide support to an investigative team to conduct a focused study of interest to AMSSM and a potential extramural funding agency of their choosing with the purpose of collecting rigorous data to support planning and/or conducting a large multi-site clinical trial.

Given the amount of resources required to perform a robust multi-site clinical trial that has the potential to change clinical practice, sufficient evidence in support of a potential intervention and planning for the trial itself is necessary prior to initiating such a study. Currently, there is a lack of available funding opportunities that allow investigators the opportunity to prepare for this type of research, especially in sports medicine.

Thus, the goal of this RFP is to provide financial support to investigators to conduct a rigorous, multi-center study that would provide the necessary data to prepare a research team for future funding to either (1) plan for a clinical trial (e.g., NIH R34) or (2) conduct a clinical trial (numerous mechanisms). Matching institutional funds are welcomed as additional support to these investigations. As part of this RFP, the CRN and investigative team will commit to working together to develop a strong proposal to an extramural funding source that is most applicable to the proposed research question. Grant awardees will benefit from the varied expertise and experiences of the CRN Leadership Committee in developing such an application. Moreover, if the targeted extramural funding is awarded, the CRN will work collaboratively with the investigative team to successfully plan for and/or implement the clinical trial.

Definition of a Clinical Trial
- A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (NIH)

Key Characteristics of a Clinical Trial
- The study involves human participants
- Participants are prospectively assigned to an intervention
- Study is designed to evaluate the effect of the intervention on participants
- The effect being evaluated is a health-related biomedical or behavioral outcome

NOTE: not all clinical trials are initially suited for randomized controlled trials (RCT). Investigators should consider the established safety and efficacy of an intervention before proposing an RCT.

PURPOSE AND GOAL OF BRIDGE FUNDING FOR A FUTURE CLINICAL TRIAL
This RFP is uniquely designed to help investigators gather the necessary preliminary data and evidence to support the planning and conducting of a future interventional multi-site clinical trial. To effectively complete a large multi-site clinical trial, substantial planning and preparation is required; evidence to support the conduct of such a trial is necessary. Either pilot or preliminary studies are eligible for this RFP. Pilot and feasibility studies are fundamental to the
planning of a future clinical trial and their purpose differs from that of an actual, large-scale trial. For example, the goal of a randomized controlled trial (RCT), often seen in phase III clinical trials, is to assess the efficacy of an intervention when compared to a comparison group (hypothesis-driven); whereas the goal of a pilot or feasibility study is to assess whether a full RCT can and should be pursued (not hypothesis-driven).

- **Pilot Studies:** Pilot studies often operate as miniature RCTs and should be used to evaluate the feasibility of important details, such as recruitment, randomization, retention, new methods and procedures, and/or implementation of a new intervention. It is advantageous for the design of such studies to be similar to that of the proposed larger, subsequent clinical trial.
- **Feasibility Studies:** Alternatively, a preliminary feasibility study that aims to develop necessary interventions or outcome measures for a future clinical trial is also appropriate. The purpose of feasibility studies is to assess whether or not a future clinical trial will be feasible for a particular intervention introduced in a given population.

Although control groups are not required in preliminary studies, the use of a control group allows for a more complete evaluation of the proposed study processes. Interested investigators are strongly encouraged to reach out to the CRN to discuss the appropriateness of their project idea for this Bridge Grant prior to submission.

**POTENTIAL EXTRAMURAL CLINICAL TRIAL FUNDING SOURCES**

The CRN recognizes that different research questions and topics relevant to sports medicine may lend themselves to future funding opportunities from different sources. In an effort to help AMSSM investigators achieve the highest level of funding most suited for their research portfolio, the CRN envisions numerous potential clinical trial funding pathways for grant awardees. Some potential options are specified below; however, funding pathways are not limited to those listed. If an investigator wishes to seek funding through a source other than those already specified, they are encouraged to discuss the proposed source with the CRN prior to submission to ensure it is a good fit for their proposal.

It is anticipated that funding requirements for a future multi-site clinical trial will be minimally $200,000 and may exceed $1 million dollars. Investigators should consider the funding requirements of a future clinical trial for their proposed research question before identifying a planned funding pathway. Please note, at this time, proposed pathways to industry funding will not be accepted.

**National Institutes of Health (NIH)**

The NIH is the largest public funder of biomedical research in the world, investing $32 billion dollars each year. The NIH is comprised of 27 institutes and centers that establish their own research priorities and funding opportunities. Many of these institutes (e.g. NHLBI, NIAMS, NIMHD, NICHD, NINDS) have relevance to topics in sports medicine and could serve as plausible funding sources for future clinical trials. When selecting a potential institute from which to seek funds, investigators are encouraged to peruse that institute’s research priorities and/or supported scientific areas to ensure their proposal fits within the scope of the research supported by that institute.

Importantly, funding mechanisms differ between institutes as not all institutes support the same mechanisms. After identifying an institute, investigators should assess whether a specific funding mechanism is supported by that institute. Multiple NIH mechanisms would support a funding plan for a future clinical trial. Some examples include an R01 (clinical trial required), R21 (clinical trial required), or an R34 (Clinical Trial Planning Grant). Investigators should review the posted announcements to ensure their future clinical trial meets the specified requirements of that particular funding mechanism. For example, certain institutes do not offer the R34 mechanism and some institutes only accept mechanistic clinical trials as part of their R01 and R21 funding.
**Patient Centered Outcomes Research Institute (PCORI)**

PCORI is an independent nonprofit, non-governmental organization authorized by congress in 2010 that aims to answer health questions that patients and clinicians face daily through comparative clinical effectiveness research (CER). Importantly, PCORI focuses on studying outcomes that are important to the patient. PCORI releases funding announcements multiple times per year, many of which are relevant to sports medicine research. Prior to selecting PCORI as a potential funding source for a future clinical trial, investigators are encouraged to review their recently published patient healthcare initiatives. The CRN anticipates most clinical trials proposed by AMSSM members will fall under the CER umbrella in PCORI which funds studies that compare outcomes to determine the effectiveness of two or more approaches to health care. An example of a recent PCORI funding announcement inviting applications for comparative effectiveness research can be found [here](#). Please check the website for more specifics on current and future funding opportunities.

**Other Funding Pathways (e.g. Foundation, CDC, Department of Defense (DoD), etc.)**

It is feasible that an investigator group may wish to seek funding from less heavily-utilized funding sources or sources that are closely aligned with the topic of their research. The CRN fully supports pursuing these opportunities as long as the scope of funding is consistent with the needs of a large-scale clinical trial. Investigators should confirm existing funding opportunities from these sources, or provide a description of the mechanism from which they intend to apply for funds, as part of their funding pathway plan (described below).

In the past, the CDC’s National Center for Injury Prevention and Control (NCIPC) has issued call for proposals pertinent to sports-related concussion. Examples of prior CDC funding announcements can be found [here](#). An important source of DoD funding support is the Congressionally Directed Medical Research Program (CDMRP). Potential sources of DoD/CDMRP support include the Traumatic Brain Injury Program, the Peer Reviewed Medical Research Program, and the Peer Reviewed Orthopaedic Research Program. Current open and prior funding opportunities are [here](#).

**APPLICATION PROCESS**

**Overview:** This grant will be reviewed by a CRN convened scientific review panel based on the criteria outlined below. The panel will include experts in the field, established researchers, community advisors, members of AMSSM leadership, and/or members of the Research Committee. Finalists will be presented to the AMSSM Board of Directors for approval before awards are announced.

**Eligibility:** In addition to meeting all specified requirements for a full application, proposals and investigators must adhere to the following criteria to be eligible for this RFP:

- All PIs must be active members of AMSSM in-good-standing (a PI who is not an AMSSM member is acceptable if a co-PI is an AMSSM member)
- PIs and Co-Investigators may be from academic institutions and/or private practice
- Investigators must demonstrate the ability to conduct high-caliber research that meets the rigor necessary for extramurally funded research via their proposed funding pathway (though prior funding from the proposed funding agency is not required)
- Proposals must involve multi-site collaboration or provide the framework for future multi-site collaboration via a multi-site clinical trial.
- Although RCT designs are not necessary for bridge proposals, the proposal should clearly demonstrate how these funds will be used to plan and implement a future extramurally-funded clinical trial
- Proposals should be relevant to the improvement of the clinical practice of sports medicine

**Expectation of Collaboration with the CRN:** In conjunction with its mission to foster research that ultimately advances the practice of sports medicine, the AMSSM CRN actively promotes collaboration and engagement with the research
network. Investigators will be expected to work closely with the CRN to ensure successful completion of the initial study and to develop a future grant proposal. Additionally, the CRN will expect to be an integral budgeted component of the future multi-site clinical trial. The CRN can offer valuable post-award resources to help investigators, including those in private practice, navigate the complexities of multi-site research and ensure CRN-affiliated research is conducted with the highest quality and rigor possible. The following are examples of CRN resources available to investigators following the review process and notification of award:

- Research coordination and project management across multiple sites (including regulatory support)*
- Comprehensive biostatistical support*
- Assistance with final study design, methodology, and content validity of study outcome measures
- Assistance with central data storage, management and coordination*
- Help with data safety monitoring needs

*this support should be written into your budget. Please talk with AMSSM Research Program Manager, Sarah Sund, if you are interested in these services for your proposal and need help with these line items for budget development.

Investigators are encouraged to think carefully about how the CRN would be most helpful and valuable in the conduct and successful completion of their proposed research study and explicitly identify the potential collaboration with the CRN in the full proposal. Questions regarding opportunities for CRN engagement not listed above can be directed to the AMSSM Research Program Manager at any stage of the application process.

Review Criteria: To encourage consistent, fair and reliable review of proposals, this RFP will follow adapted NIH guidelines for critique and scoring based on the scientific merit of proposals, as shown below. Proposals will also be assessed for alignment with the established scientific priorities of the proposed extramural funding source. Full applications will be scored according to the five criteria identified below. Each criterion will receive an independent score, which contributes to an overall application score.

**Significance & Relevance**: The significance and relevance of proposals will be assessed based on the research questions identified in this RFP and their applicability to the practice of sports medicine in the clinical setting. The application must address an area of scientific interest to AMSSM and the proposed mechanism for future funding. Additionally, the application will be reviewed on its potential to answer or provide critical information towards knowledge gaps in the field as well as the potential for the project to grow to a multi-site clinical trial.

**Innovation**: Innovation of projects will be judged based upon the concepts, methodological approaches, and interventions that are novel in the area of sports medicine or seek to challenge current clinical and scientific thinking/practices.

**Collaboration**: Collaboration will be assessed through the use of multi-site investigations and evidence of an appropriate plan to enhance the probability that multi-site collaboration will be successful and result in scientifically valid conclusions. Additionally, the proposal will be evaluated for inclusion of the CRN in the research process.

**Approach**: The approach will be judged through feasibility, qualifications of the research team, appropriateness of study design and methodology, and justification of approach. A clear understanding of potential limitations and possible alternative strategies should be described.

**Investigators & Environment**: This category will be based on the team of investigators with necessary qualifications to successfully carry-out the project and with the appropriate resources, facilities and equipment
to complete the proposed research study. The investigators must demonstrate ability and commitment to conduct high-quality research at the NIH level.

**Additional Review Criteria:** Other review criteria will not be scored individually but will be considered as part of the overall impact score. These criteria include development of an appropriate study timeline, adequate protection of human subjects (including risk and protection against risk, potential benefits, and importance of knowledge gained), and an appropriate budget justification.

**Number of submissions:** There is no limit to the number of proposals any one investigator, practice or institution may submit or co-investigate in response to this RFP; however, all requirements must be upheld to include being an AMSSM member in good-standing for all PIs and a plan for purposeful, multi-site collaboration.

**Intellectual property, data, and confidentiality:** Investigators retain all intellectual property developed under this award. AMSSM makes no claim to data ownership. However, there is a clear and strong expectation that the work will lead to future, extramural funding requests funding pathways. AMSSM CRN anticipates a collaborative role in assisting with the development of these future funding requests.

**Human Subjects Approval:** Prior Institutional Review Board approval is not required at the time of submission; however, no funds will be dispersed for research purposes until IRB approval is received by AMSSM. Proof of IRB approval will be required within six months of acknowledgement of approval of the award. If you do not have an Institutional Review Board, review of your project by your hospital Human Subjects Committee or equivalent is required for funding. If your hospital or private practice does not have a Human Subjects committee or equivalent, please contact the AMSSM Research Program Manager prior to submission (ssund@amssm.org) to determine alternative options. It is the sole responsibility of the principal investigator(s) and their institution(s) to ensure the work is carried out within the required guidelines.

**Timeline and Award Notification:** All full applicants will need to submit a complete application through the AMSSM Grant Portal by March 18, 2022. Full applications will be scored by a panel of reviewers, and award recipients, upon approval of the AMSSM Board of Directors, will be announced at the AMSSM Annual Meeting on or around April 12, 2022. **AMSSM reserves the right to not award any or all proposals in any grant cycle.**

**Progress Reports:** Progress reports, including annual expenditures, must be submitted to the AMSSM CRN at the conclusion of each year. Any balance of more than $200 must be refunded to AMSSM within 60 days of project completion. No cost extension of unused funds will be considered with appropriate justification and rationale provided by the PI. For 2-year awards, funding for year-2 will be dependent upon review of the progress report by the CRN. A final progress report, including all expenditures, should be submitted to the AMSSM CRN within 90 days of study completion and should include a brief description of study results and significance of findings. Any major changes to study protocol should be discussed with the CRN and must be submitted in writing to the CRN within 30 days of the changes taking place. Communications and progress reports should be sent to the CRN Research Program Manager: ssund@amssm.org.

**Presentations and Publications:** Award recipients are expected to submit their research for presentation at scientific meetings, including the AMSSM Annual Meeting. The AMSSM CRN expects timely publication of research results in appropriate peer-reviewed, scientific journals. All publications resulting in whole or in part from the grant must include a statement similar to: “**Funded in part by a grant from the American Medical Society for Sports Medicine (AMSSM) Foundation and Collaborative Research Network (CRN).** The opinions expressed herein are those of the authors and
do not necessarily reflect the opinions of the AMSSM.” All presentations and posters should include a similar acknowledgement.

Instructions for Submitting Materials: All completed full proposals, must be submitted through the appropriate channel on the AMSSM Grant Portal prior to the stated deadline(s). To begin an application, applicants can enter the grant portal via the 2022 Bridge Funding to Future Clinical Trial grant mechanism on the AMSSM research grants page.

AWARD MECHANISMS AND AMOUNTS

Overview: This RFP will award at least one research study up to a maximum of $150,000 (including direct and indirect costs) over a study period up to 2 years. Additional studies may be awarded based on quality of proposed research, alignment with AMSSM-CRN research priorities and the availability of appropriate research funds. Smaller projects in cost and duration are also encouraged. Although Institutional Review Board approval is not needed at time of submission, no awarded research funds will be dispersed for human subjects research until IRB approval has been received by AMSSM.

Duration of Funded Research Programs: Proposed research projects should be complete within a maximum of 2 years. No cost extensions beyond the 2-year time frame will be considered with appropriate justification and rationale provided by the PI.

Overhead and Indirect Cost Limits: Per policy of the AMSSM CRN, indirect costs will be capped at 15%. Total requested funds, including direct and indirect costs, may not exceed $150,000. The AMSSM CRN welcomes the use of matching institutional or other research funds subject to prior approval of the AMSSM CRN leadership committee. Salaries will not be capped.

Acceptable Use of Research Funds: Research funds may be used to support investigator and research personnel salaries (including fringe benefits), costs of medical procedures required for study endpoints but not considered standard of care, expenses required for travel and communication between collaborating sites, and other necessary costs for clinical supplies. Funds may not be used for equipment purchases necessary for implementation of study aims that cost over $500, unless prior approval from the CRN has been obtained. Up to $1000 may be budgeted for travel to non-AMSSM conferences and other educational meetings for dissemination of research (this budget restriction on travel does not apply to necessary travel between study sites for study related purposes). Comprehensive budgets for each year of the research proposal must be provided with all full applications.

FULL APPLICATION:

General guidelines

- The application should be in PDF format, 11-point font or larger with a minimum of ½ inch margins
- Full applications should not exceed 13 pages in length (not including biosketches, references, and other relevant support) Specifically:
  - Cover Page: 1 page
  - Project Abstract: 1 page
  - Plan for Future Funding Pathway: 1 page
  - Research Strategy: 6 pages
  - Timeline: 2 pages
  - Budget & Budget Justification: 2 pages
- Please number all pages
Components of Full Application:

- **Cover Page** – The cover page should follow the template provided in this RFP and be completed in its entirety.

- **Project Abstract**: The abstract should describe the background and key objectives of the proposed research project. In addition, the research design and methods should be clearly identified with a statement of relevance to the practice of sports medicine within the chosen research topic priority area.

- **Plan for Future Funding Pathway**: The future funding plan should provide a description of the targeted extramural funding pathway that this proposal will support. This plan will minimally include the targeted funding agency and specific grant opportunity within the agency, a general timeline for grant submission and relevance of the research topic to the focus areas or strategic priorities of the selected funding agency.

- **Research Strategy**: The research plan should not exceed 6 pages in length and include the following key areas: Introduction, Significance, Innovation and Approach. The introduction should clearly identify all primary and secondary aims as well as relevant hypotheses. Relevance to sports medicine clinical care and specific active populations should be included in the significance section. Innovative aspects of the project including novel methods, analytic techniques, or interventions should be identified. The approach should clearly outline the overall plan, methodology and analysis proposed to achieve the specific aims. This section should include a description of the proposed collaboration plan, the targeted patient population and sampling/recruitment strategy, statistical considerations including analytical approach and power/sample size justification, and finally limitations and potential alternative strategies to the approach. Preliminary data are encouraged, if available, but not necessary for a competitive application.

- **Timeline**: Include a proposed timeline of key research milestones throughout the duration of the proposed project

- **Project Budget with Justification**: A detailed budget, itemized by expense categories should be supplied for each year of the proposed project. The budget should list the names and roles of all funded personnel to be involved in the project. In situations where an individual cannot be identified at the time of submission, providing the proposed position title and role are sufficient. Fringe benefit costs for the personnel may be included. Additionally, existing grants or other funding sources being utilized for the same project should be listed separately by briefly stating the funding agency, amount, and general description of how the funds will be utilized (including direct and indirect costs)

- **References**

- **Biographical Sketches**: Bio-sketches for all key study investigators should adhere to the current NIH template and should include all pertinent appointments and qualifications. A statement of purpose should be included identifying the investigator’s strengths in answering this RFP as it relates to the chosen research topic. Only publications most relevant to the proposed research project are necessary.

- **Documentation of institutional and other relevant support**: This section should contain other documents pertinent to the proposed research project including letters of support (e.g. from collaborators, institutions, clinics, etc.), proposed questionnaires/surveys, statements identifying conflicts of interest, etc.

**QUESTIONS**

All questions and clarifications related to this RFP or the CRN can be directed to the AMSSM Research Program Manager, Sarah Sund: ssund@amssm.org, phone: 608-265-0027, or Chair of the AMSSM CRN, Irfan Asif, MD: iasif@uab.edu, phone: 301-295-3632.
AMSSM CRN Request for Proposals
COVER PAGE

Title of Research Project:

Primary Institution:

Principal Investigator(s):
Include name, title, institution, address, phone and e-mail

Anticipated Start Date:

Budget Information:
Total Amount Requested (not more than 2 years): Total $_________________ for ___ Years
Year 1: $_____________
Year 2: $________________