AMSSM CRN REQUEST FOR PROPOSALS

"The Stephen I. Katz Bridge to R34 Grant"

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 national funding, including the level of the National Institute of Health (NIH), 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 for a competitive submission of an NIH R34 Clinical Trial Planning Grant and then to an NIH U01 Clinical Trial Implementation Grant via the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). Investigators must demonstrate preparedness and capability to eventually meet the rigor required for an NIH caliber multisite clinical trial. The topic selected for study should align with AMSSM/CRN's mission and NIAMS' scientifically supported research areas. The CRN will work closely with the investigative team to complete their initial project and to develop an R34 submission, with the ultimate goal of obtaining a U01 Clinical Trial Implementation Cooperative Agreement Award.

General summary

Published Date: March 2021

Letter of intent due: June 15, 2021

Letters of intent (LOI) will be reviewed in relation to criteria outlined in the RFP. Only applications selected after initial review will be allowed to submit a full application. The invitation to submit a full proposal will be sent to investigators no later than July 16th, 2021. An invitation to submit a full proposal does not guarantee a research award.

Summary: The AMSSM CRN seeks to fund a collaborative research project to address knowledge gaps in sports medicine topics that are supported scientific areas for NIAMS. Proposed studies must show potential to lead to a multi-site U01 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. The ability to conduct NIH quality research is required. Proposals should involve multi-site collaboration and lead to the improvement of clinical practice in sports medicine.

Key dates:

LOI Deadline: June 15, 2021

LOI Status Notification: July 16, 2021

Full Application Deadline: October 15, 2021

Award Announcements: December 6, 2021

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, Biographical Sketches

INTRODUCTION

In furtherance of its mission, the CRN releases this RFP as a viable pathway towards conducting an NIH funded multi-site clinical trial (U01) 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 both AMSSM *and* NIAMS with the purpose of collecting rigorous data to support planning for a future large multi-site clinical trial.

To effectively complete a large multi-site clinical trial, substantial planning and preparation is required. This planning must be complete before significant investment in monetary and human resources is made; therefore, in order to appropriately develop and plan for a clinical trial award (U01), NIAMS encourages a two-step process beginning with its R34 clinical trial planning grant mechanism (part 1) followed by an application for U01 clinical trial funding (part 2). The R34 grant mechanism, however, does not allow for collection of data on human subjects; rather it supports protocol development, such as testing and refining patient enrollment procedures, assessment procedures, and power calculations. As such, investigators are expected to have preliminary data supporting the need for a large multi-site clinical trial prior to the R34 submission. Thus, the goal of this RFP is to provide financial support to investigators to conduct a strong study that would provide the necessary data to prepare the team for an R34 submission and ultimately a U01 submission. 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 NIH-NIAMS for R34 funding. If an R34 is awarded, the CRN will work collaboratively with the investigative team on preparation for a U01 clinical trial application. Successful completion of an R34 award does not guarantee a successful U01 application, but regular interaction with NIH Program Officials can help ensure a competitive application.

This research pathway opportunity is focused on topics of interest to NIAMS. NIAMS supports many scientific areas of interest to the field of sports medicine including (but not limited to) osteoarthritis, bone health, muscle repair and regeneration, regenerative medicine, fitness, and musculoskeletal rehabilitation.

A potential research-pathway timeline for this RFP is as follows:

- ***Fall 2021***: Award "Bridge to R34" grant to Investigative Team
- ***Jan 2022***: Study launches & R34 development begins w/ CRN
- ***Feb 2023***: R34 proposal submission to NIH NIAMS
- ***Feb 2025***: R34 awarded and U01 planning begins
- ***Fall 2025***: U01 submission with CRN to NIH NIAMS
- ***Fall 2026***: Begin U01 multi-site clinical trial

Key Aspects of a NIAMS R34 Clinical Trial Planning Grant

- Supports administrative planning and development of a clinical trial implementation cooperative agreement (U01).
- Up to $300,000 in direct costs over 2 years
- Activities of R34 may include:
  - Finalizing research team & collaborations
  - Development of tools for data management and oversight of the trial
  - Development or refinement of the trial design
  - Development of essential study elements including protocol, manual of operations, informed consent forms, recruitment strategies, etc.

IMPORTANT NOTE: *An R34 grant is not appropriate for conducting research with human subjects for the collection of preliminary data or the collection of prospective data to support the rationale for a clinical trial.*

NIAMS R34 Funding Opportunity Announcement

NIAMS Clinical Trial Implementation Cooperative Agreement (U01)

What is a NIAMS U01?

A U01 is a cooperative agreement with NIAMS for the implementation of investigator-initiated clinical trials. Applications for clinical trials are generally expected to go through a two-part process beginning with an R34 planning phase (part 1) and followed by a U01 application (part 2). These trials must have the potential for high impact within the NIAMS research mission and be hypothesis-driven. Additionally, these cooperative agreements are for larger, more complex trials which require substantial planning and preparation. Once a U01 is awarded, investigators are expected to be able to conduct the trial without further planning.

NIH Clinical Trial Definition

The NIH defines a clinical trial as "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"

When applying for this AMSSM RFP, investigators should strongly consider the potential of their project to proceed to a NIAMS U01 cooperative agreement. To ensure programmatic fit, investigators are encouraged to discuss their proposed projects with the CRN and NIH-NIAMS program officers prior to LOI submission.

ABOUT STEPHEN I KATZ, MD, PhD

Dr. Katz was a long-time director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). He was a worldwide leader in the field of dermatology and will be remembered as not only a strong leader at NIH, but perhaps more importantly, an outstanding public servant and friend to many. The CRN Leadership Committee had the great honor of meeting with Dr. Katz last October, experiencing his deep affection for the NIH and his staff, and learning more about his vision and mission for NIAMS. Dr. Katz passed away suddenly in December 2018; his loss has had a profound effect on the NIH community and the broader community of researchers. The CRN is honored to name this RFP in memory of Dr. Katz who was instrumental in developing the idea of providing this pathway for our members to gather necessary pilot data to pursue an R34 planning grant and ultimately a U01 clinical trial.

The naming of this grant in his honor does not imply any preferential treatment or interest from the NIH-NIAMS on future applications for an R34 or U01 award via this CRN mechanism; it does however express the CRN's gratitude for the time, attention, and careful thought he afforded to the CRN – which ultimately led to the vision for this RFP.

PURPOSE AND GOAL OF BRIDGE TO R34 GRANT

This RFP is uniquely designed to help investigators gather the necessary preliminary data and evidence to support planning and conduct of a future interventional clinical trial. Because the NIAMS R34 award mechanism does not allow for data collection to support the rationale and feasibility for a clinical trial, investigators can use this Bridge Grant funding opportunity to gather essential support. Either pilot or preliminary studies are eligible for this RFP. Pilot and feasibility studies are fundamental to the planning of a randomized clinical trial (RCT) and their purpose differs from that

of an actual, large-scale RCT. The goal of an RCT 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 often operate as miniature RCTs and should be used to evaluate the feasibility of such things 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. Additionally, preliminary feasibility studies that aim to develop necessary interventions or outcome measures for a future clinical trial are also appropriate. The purpose of these studies is to assess whether or not an RCT 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 and to NIH NIAMS program officers to assess programmatic interest in the proposed topic *prior to LOI submission*.

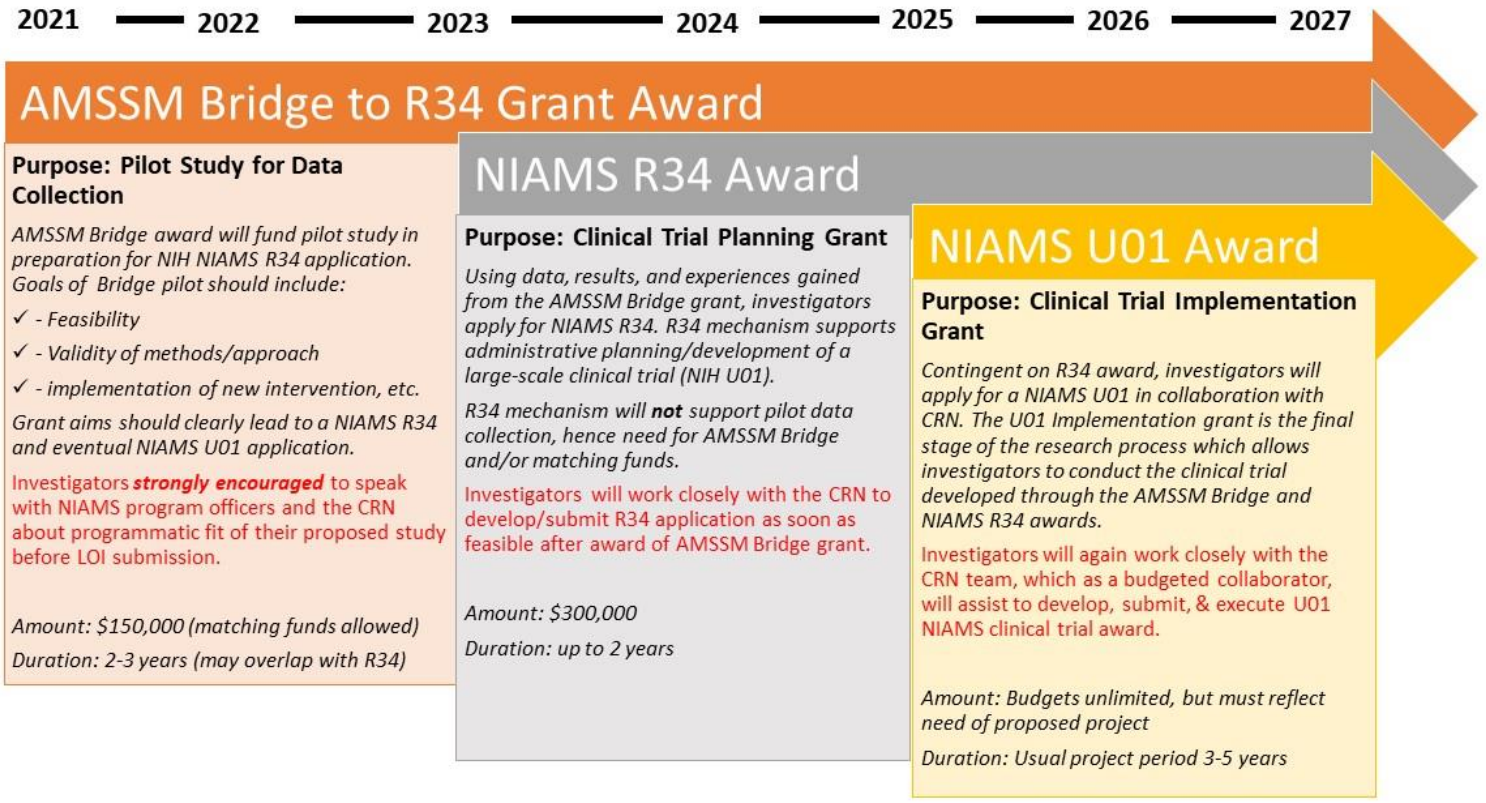

Figure 1: AMSSM to NIAMS Clinical Trial Research Process and Potential Timeline

APPLICATION PROCESS

Overview: This RFP for the Bridge Grant will involve a two-stage submission process. The first stage will require a LOI application which will be reviewed by the CRN Leadership Team based on criteria outlined below. Successful LOI applications will be invited to submit a full application which will be reviewed by a panel of reviewers as commissioned by the AMSSM CRN. The panel will include experts in the field, established researchers, community advisors, members of AMSSM leadership, and 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 complete LOI and/or 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 ability to conduct NIH caliber research (though prior NIH funding is not required)
- Proposals must involve multi-site collaboration
- Proposals should clearly and directly lead to improvement of the clinical practice of sports medicine and fall within one of NIAMS supported scientific areas

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 the R34 grant proposal. *Additionally, should the R34 be awarded and a U01 application developed, the CRN will expect to be an integral budgeted component of the 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 Director, Dr. Stephanie Kliethermes 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 LOI and full proposal. Questions regarding opportunities for CRN engagement not listed above can be directed to the AMSSM Research Director at any stage of the LOI or full 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. Proposals will also be assessed for alignment with NIAMS supported scientific areas. Letters of Intent and 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 more broadly to the practice of sports medicine in the clinical setting. The application must address an area of scientific interest to NIAMS and AMSSM. 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 (refer to NIAMS U01 FOA).

Innovation: Innovation of projects will be judged based upon the concepts, 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, justification of approach, and the clarity of responses in the LOI template. 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.

Adherence to all requirements of the LOI and full application is essential; failure to comply will result in proposals not being scored.

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 via the NIAMS R34 and U01 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 Director prior to submission (skliethermes@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 LOIs submitted in response to this RFP will be due no later than 5p.m. ET on June 15, 2021. After completion of the initial screening process, all applicants will receive a LOI status notification on or before July 16, 2021. Those applicants invited to submit a full application will need to submit a complete application through the AMSSM Grant Portal by October 15, 2021. Full applications will be scored by a panel of reviewers, and award recipients, upon approval of the AMSSM Board of Directors, will be announced on or around December 6, 2021.

Progress Reports: Progress reports, including annual expenditures, must be submitted to the AMSMM 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 Director: skliethermes@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 LOI applications, and subsequent 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 2021 Bridge to R34 grant mechanism on the AMSSM research grants page.

POTENTIAL SCIENTIFIC AREAS OF INTEREST

NIAMS publishes their supported scientific areas on their website, many of which relate to the practice of sports medicine. These scientific areas are further described in the NIAMS Long Range Fiscal Plan (2020-2024) where the institute's five core mission areas are identified: (1) systematic rheumatic and autoimmune diseases, (2) skin biology and diseases, (3) bone biology and diseases, (4) muscle biology and diseases, (5) joint biology, diseases, and orthopaedics. Although the plan is not comprehensive, it provides a broad and detailed scope of research topics that are of interest to NIAMS. Investigators should read this plan and determine how their proposed project(s) serve to advance NIAMS research priorities. *Additionally, investigators are strongly encouraged to discuss the programmatic fit of their proposed project with the CRN prior to LOI submission. Proposed projects must show clear and unequivocal potential to receive a NIAMS U01 clinical trial award.* U01 awards are cooperative agreements for trials that involve a large number of subjects, greater complexity, or higher risk. Proposals must be hypothesis-driven and have the potential for high impact within the scope of the NIAMS research mission. Note that NIAMS's prior track record of funding indicates that injuries and related musculoskeletal conditions (e.g. overuse-related injuries) are included in their expansive view of "musculoskeletal disease".

NIAMS RESEARCH MISSION

To support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases; the training of basic and clinical scientists to carry out this research; and the dissemination of information on research progress in these diseases

Although clinical sports medicine related proposals that fit within any of the 5 core NIAMS mission areas are eligible for this RFP, certain mission areas lend themselves more directly to research needs of sports medicine physicians. The following are examples of certain topic areas of interest to NIAMS that might lend themselves to strong U01 sports medicine clinical trial applications. The topics identified below are meant to provide examples of research areas relevant to sports medicine that might be appropriate for a large NIAMS clinical trial, but do not represent all possible topics. *Note: Investigators should consult the NIAMS Strategic Plan to ensure their topics align with NIAMs' priorities.*

Bone

- The role of BMI and body composition on bone strength
- The effect of physical activity on bone and muscle health
- Therapeutic approaches that have the potential to improve bone and muscle health and function
- Environmental and behavioral impacts on childhood/adolescent bone formation and growth
- Development of clinical tools to better assess bone quality and fracture risk
- Impact of nutritional status on bone health and fracture risk

Muscle

- Development of exercise regimens, biomechanical or behavioral interventions with potential to advance muscle-disease treatments
- Study of nutrition, exercise or physical therapy interventions on muscle diseases
- The relationship between mechanical function and energy use

Musculoskeletal

- Biomechanical factors (including gait) that influence early onset and progression of OA
- The role of biomechanical factors in joint deterioration after injury
- Role of obesity in development of OA in children and adults
- Pain pathways as a result of OA stress in joints
- The role of regenerative medicine in treatment and prevention of OA
- Identification of biomarkers that lead to heightened risk of disease onset, progression, or treatment response
- Association between personalized medicine and musculoskeletal health
- Behavioral therapies for treating chronic musculoskeletal conditions and injuries
- Implementation of strategies to sustain effective behavioral interventions (e.g. weight loss)
- Prevention of childhood/adolescent injuries
- Characterizing sex differences in ultra-high performance sports for development of programs to prevent injury and overuse disorders
- Development of optimal physical activity guidelines to promote musculoskeletal health
- Rehabilitation strategies for soft-tissue injuries with the goal of return to maximal function

The above list should not be considered exhaustive. Like all NIH institutes, NIAMS is open to investigator ideas that fall broadly within their scope but are not included within the above list. Cardiac conditions/diseases and brain-related injuries/conditions/disease are in the domain of other NIH institutes and thus are clearly outside the scope of NIAMS and hence outside the scope of this RFP. However, scientific projects that cross the domains of multiple NIH institutes may be eligible for joint funding by two or more institutes and could fall within the scope of this RFP.

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. LOIs should include approximate budget requirements for direct costs only.

LETTER OF INTENT APPLICATION:

Overview: The LOI is required as the first step in the RFP process. All sections of the LOI template must be answered completely. Omitted or incomplete sections will result in the LOI not being reviewed. The goal of the LOI is for the CRN scientific review committee to understand the aims and approach of the study prior to reviewing a full application; therefore, focus should remain on important components of the proposed research study.

General guidelines

- The application should be in MS WORD or PDF format, 11-point font or larger with a minimum of ½ inch margins on all sides.
- Complete LOIs should not exceed 4 pages in length (not including references)
- All sections should be answered as clearly and thoroughly as possible
- Do not include supplemental material such as letters of support or supporting journal articles as part of the LOI submission

Components of LOI

PART I: Not to exceed 2 pages in length

- ***Title***: Specify the title of the proposed research study such that the proposed research topic addressed is easily identifiable
- ***Relevance***: What aspect of sports medicine and NIAMS scientific priorities does your study aim to address and how will it provide evidence to fill existing knowledge gaps?
- ***Aims***: Identify the specific aims of the study
- ***Methods***: This section should describe the study design and multi-site approach including inclusion/exclusion criteria for the study population, primary outcomes to be measured, statistical approach and sample size/power justification

PART II: Not to exceed 2 pages in length

- ***Investigators***: A list of investigators, their affiliations and roles on the projects as well as any relevant experience should be included.
- ***Conflict of Interest Statement***: All relevant conflicts of interest for each co-investigator should be disclosed at the LOI stage. If no collaborators have conflicts of interest, a statement should be made a statement should be made declaring no known conflicts.
- ***Study Timeline and Approximate Budget***: This section should contain a proposed timeline for the research study and an approximate budget for direct costs only.

Note: a cover page or cover letter is not required for an LOI submission. All relevant information should be provided in the 4-page allotment

FULL APPLICATION:

Overview: The full application is only applicable for those invited to submit a full proposal based on results of the LOI review process.

General guidelines

- The application should be in MS WORD or PDF format, 11-point font or larger with a minimum of ½ inch margins
- Full applications should not exceed 12 pages in length (not including biosketches, references, and other relevant support) Specifically:
    - Cover Page: 1 page
    - Project Abstract: 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.
- **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
- **References**
- **Biographical Sketches:** Bio-sketches for all study investigators should not exceed 5 pages in length 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. NIH biosketches will be accepted
- **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 Director, Stephanie Kliethermes, PhD: skliethermes@amssm.org, phone: 608-262-7800, 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

Budget Information:

Total Amount Requested (not more than 2 years): Total $_____ for ___ Years

Year 1: $_____

Year 2: $_____

BIOGRAPHICAL SKETCH

Should not exceed 5 pages

NAME	POSITION TITLE
ROLE IN PROJECT	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY

EMPLOYMENT HISTORY

PERSONAL STATEMENT:

SELECT RESEARCH FUNDING HISTORY:

RELEVANT PUBLICATIONS: