Emergency Medicine Foundation

Investigator Initiated Research Grant Request for Proposal

Please read these instructions carefully. Applications that do not follow these instructions with regards to type size, length, format, and supporting documentation will be summarily rejected. No extension of the deadline will be granted.

Before submitting your application, please be sure that the following items have been addressed:

- Information page is included as the first page of the application packet and is fully completed (sample attached)
- Type size is 11 pt. font, single-spaced and margins are one- half (.5) inch
- Evidence of IRB approval, or at least evidence of submission to IRB, from each institution, is included in application packet (for multi-centered studies, approval from or evidence of submission to IRB/AUC for all sites is required)
- Clearly stated research hypothesis
- Statement of Conditions is signed by **Principal Investigator** and **Institutional Official** and is included in application packet (see below)
- Letter of support from Emergency Medicine Chair is included in application packet
- Letter of support from each co-investigator is included in application packet
- Other grant support for all investigators is included in application packet
- Submission via the on-line application system is required. Late applications will not be considered. Submit application at https://emfoundation.aibs-scores.org

EMERGENCY MEDICINE FOUNDATION INVESTIGATOR INITIATED RESEARCH GRANT

Letter of Intent Deadline October 31, 2023

Application Deadline January 19, 2024, by 6:00 pm EST

Notification of Award June 2024

Funding Period July 2024 – June 2026

Funding Amount Per Award \$250,000 Number of Awards One

RESEARCH TOPICS

The goal of the EMF Investigator Initiated Research Grant is to fund work that will meaningfully impact emergency care research and is intended for a broad audience, including both clinical and basic science fields researchers.

EMF encourages application partnerships between research universities and community emergency departments along with the engagement of operational and policy partners.

ELIGIBILITY

The principal investigator must have a primary faculty appointment in Emergency Medicine (this includes Pediatric Emergency Medicine). The principal investigator will make all arrangements for conduct of the proposed research projects and assumes responsibility for conducting the research projects and supervising the work of all associate investigators.

INSTITUTIONAL SUPPORT

The applicant is required to demonstrate that the project will be successfully completed at their institution. The applicant must demonstrate that access to a suitable caseload, patient population or database will be available for study during the funding period. Research must be approved by the institutional review board (IRB), or its equivalent, and a copy of the approval or pending approval sent with this application. IRB approval must be documented prior to dispensation of EMF funds.

The applicant must also submit a letter from the Chair/Director of Emergency Medicine stating that adequate funds and time will be available to the applicant to complete the proposed project.

EVALUATION OF APPLICATIONS

Each application will be reviewed by research scientists who are actively involved in emergency medicine research. Each application will be judged primarily on: (1) the significance of the project to emergency medicine, (2) the research strategy, (3) feasibility, and (4) innovation. The final funding decision will be made by the Emergency Medicine Foundation Board of Trustees and all decisions are final. Applications not funded can be resubmitted the following cycle with a response to prior reviewer comments.

TERMS OF THE AWARD

The EMF Investigator Initiated Research Grant funds will be disbursed semi-annually over the two-year cycle. Disbursement of payments will be contingent upon satisfactory progress reports.

Limitations on Awards

Funds may be used for materials and supplies and to provide salary support. Capital equipment expenditures (costing more than \$5,000 and a life of over one year) must be justified in the budget. Payments will be made to the principal investigator's institution that will be responsible for administering the funds. The Emergency Medicine Foundation will not be responsible for institutional overhead, cost for publications, travel, renovations, or secretarial support. Detailed audited financial reports may be required. The EMF is not fiscally

responsible for funds necessary for the project's completion.

Change of Status of Principal Investigator

If the principal investigator changes affiliations or ceases research in the field for which the award was made, the award will terminate, and the remaining balance will be returned to the Emergency Medicine Foundation.

<u>Liability of the Emergency Medicine Foundation</u>

The EMF assumes no financial liability if patient care responsibilities of any kind are undertaken by the program faculty or investigator. The principal investigator and his or her institution acknowledge that the EMF is not legally liable for the conduct of the institution, the principal investigator, the program faculty, or any associate investigators.

Patent Policy

The principal investigator and institution acknowledge that, though unlikely, if a patentable invention or discovery is conceived, or conceived and reduced to practice by EMF-supported personnel during the award year, the EMF must be apprised of the invention and the institution's plans for protecting such invention under existing institutional patent policy. The EMF will defer to institutional policies when they are in compliance with those of the Federal government. The EMF reserves the right where the organization has no patent policy, or policies not in compliance with those of the federal government, to claim rights and interests in the invention or discovery.

SUPPORT FACILITIES

The applicant must submit letters of support if the proposed project uses facilities not routinely available to or directly under the supervision of the sponsoring program.

PUBLICATIONS

All discoveries resulting from work supported in part by the Foundation should be made available to the public and scientific community through scientific and/or public policy channels such as national meetings and peer-reviewed publications. Manuscripts accepted for publication must acknowledge the support of the Emergency Medicine Foundation. Two electronic reprints of each publication will be forwarded to the Emergency Medicine Foundation.

PROGRESS REPORTS AND MONEY MANAGEMENT

The principal investigator will submit six-month progress reports and a final progress report within thirty days of the conclusion of the award. Additional reports may be required. Failure to provide the reports will delay transmission of funds. Furthermore, failure to provide interim and final reports to the Foundation may negatively impact your institution's ability to apply for future EMF awards. EMF will maintain the copyright of all such reports. Progress reports must include an accounting report using Generally Accepted Accounting Procedures showing the distribution of funds with a signature from an institutional official (e.g., accountant, grants manager, administrator from the Office of Sponsored Research). The EMF reserves the right to withhold release of interim funds if >25% of the previous cycle remains unspent. The EMF allows up to 25% of funds to be carried over from one cycle to the next.

SURVEYS

The principal investigator and the institution will be surveyed periodically following completion of the award regarding career paths, subsequent grants/contracts obtained, and publications. The principal investigator and the institution will be expected to respond to these surveys as the Foundation will rely on such information to support continuation of the award program.

ABSTRACT PRESENTATION – ACEP RESEARCH FORUM

Awardees are required to present their work at the American College of Emergency Physicians (ACEP) Scientific Assembly/Research Forum immediately following the completion of the award. At the time of

submission, abstracts must not have been accepted for publication in any journal. Also, abstracts may not be presented at any U.S. nationwide emergency medicine meeting or major international emergency medicine meeting prior to the ACEP Scientific Assembly. Presentation at non-emergency medicine meetings is allowed after presentation at ACEP. Funds cannot be requested to cover the travel cost nor registration to Research Forum.

GRANTEE WORKSHOP

Grantees are expected to attend a grantee workshop. The workshop is designed to bring together EMF grant recipients to present their progress and discuss any problems they may be facing. Senior researchers and faculty will be available to help solve problems, such as enrollment efforts, managing staff and life-work balance. NIH program officers participate in this workshop to discuss funding opportunities, provide research career advice and network with the grantees. Travel expenses will be reimbursed by the Emergency Medicine Foundation.

CONTACT INFORMATION

Please address questions to Cynthia Singh, MS, Deputy Executive Director at csingh@acep.org.

LETTER OF INTENT INSTRUCTIONS Deadline is October 31, 2023, by 6:00 pm EST

Provide the following:

- Grant Category (Investigator Initiated or Early Career)
- Project Title
- Principal Investigator Name
- Co-Principal Investigator (if applicable)
- Mentor Name (if applicable)
- PI Title/Position
- PI Institution
- PI Email
- Project Summary (one-half page limit)
- Submit to: https://emfoundation.aibs-scores.org

APPLICATION INSTRUCTIONS

Do not submit an incomplete application. An application will be considered incomplete if it is illegible, if it fails to follow instructions, or if the material presented is insufficient to permit an adequate review. Unless specifically required by these instructions (e.g. human subjects certification, vertebrate animals verification) do not send supplementary material.

The application consists of the following sections:

1. COVER PAGE

Name the **one** person responsible to the applicant organization for the scientific and technical direction of the project. Choose a title that is descriptive and specifically appropriate, rather than general. List the mentor and any associate investigators. (See sample below)

2. ABSTRACT (limit 1 page)

The abstract should succinctly describe every aspect of the proposed project. Include rationale, research hypothesis, specific aims, study design, study population, setting, intervention(s), outcome measures, data analysis, and significance.

3. TABLE OF CONTENTS

4. INTRODUCTION TO REVISED APPLICATION, if applicable (limit 2 pages)

EMF will consider revised proposals, and two additional pages are provided to introduce reviewers to the revised proposal. Key things to keep in mind when submitting a revised grant:

- a. The introduction to the revision should provide a concise summary of reviewers' comments from the previous application and should, point-by-point, discuss how the revised application has addressed these concerns.
- b. Revised applications are not reviewed outside of the normal review process. Such applications may be more competitive than first-time submissions, but not necessarily so.
- c. Revised applications are reviewed as new science. Revised applications will not automatically be considered better applications within the review process.
- d. In the event of a resubmission, the committee will attempt to return applications to their original reviewers when possible. However, regular turn-over of the committee membership prevents guaranteeing that a grant will be reviewed by the same individuals reviewing the original

application.

5. RESEARCH STRATEGY (limit 12 pages)

Please use the following subheadings:

Specific Aims (limit 1 page)

- State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.
- List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Significance

- Explain the impact of the condition on the health of individuals and populations or the practice of emergency medicine.
- Explain how the potential for the study to improve healthcare and outcomes or the practice of emergency medicine.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

Innovation

• Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

<u>Approach</u>

- Describe overall strategy, methodology, and analyses to be used to accomplish specific aims of project.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
- Preliminary Studies. Include information on Preliminary Studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. Preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project.

6. PERSONAL STATEMENT (limit 1 page)

The applicant should compose and submit a personal statement that addresses:

- a. the applicant's interest in the topic and this project
- b. the applicant's perception of his/her role in the project
- c. any additional pertinent experience or interests the applicant wishes the committee to consider

7. **ROLE OF PARTICIPANTS** (limit 1 page)

List the principal investigator, co-investigator, mentor and others involved in the research. Include a brief description of how and to what extent each will be involved in the proposed project.

8. BIOGRAPHICAL SKETCHES

Use the NIH Biographical Sketch Format Page available on the internet at https://grants.nih.gov/grants/forms/biosketch.htm Information is requested for the applicant, mentor and any associate investigators who will be involved with the projects.

10. RESOURCES AND ENVIRONMENT

Describe the research facilities (laboratory space, clinical population, etc.) available for fellowship training. If computer access or statistical support is available, it should be described in this section.

11. BUDGET

Use the NIH Form Detailed Budget for Initial Budget Period available at www.grants.nih.gov/grants/funding/phs398/phs398.html# Provide a budget narrative to indicate how the money will be spent. Justify all major expenditures. Use the current NIH salary cap. Institutional overhead is not allowed.

12. OTHER SUPPORT

List all current and pending intramural and extramural research funding for the applicant, mentor and co-investigators. For each item indicate the grant identification number, grant type, PI, funding source, annual direct costs, funding period, percent effort, grant title, and brief description of project. For all items indicate whether there is any scientific or budgetary overlap with the current proposal.

13. ETHICS (limit 4 pages)

Human subjects. For all research involving human subjects, a part of the peer review process will include careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities, and children. The EMF Scientific Review Committee (SRC) will assess the adequacy of safeguards of the rights and welfare of research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application. This evaluation will be factored into the overall score. The information on the protection of human subjects that you are required to provide in this section is identical to information that you will be required to provide for IRB at your own institution and are required by most Federal agencies. This section must address the following items. These can be copied and pasted directly into your application.

The applicant should include specific measures on how protected health information (as defined by the Human Health Services) will be handled in accordance with the Privacy Rule of the Health Insurance Portability Accountability Act (HIPAA).

1. RISKS TO THE SUBJECTS

a. <u>Human Subjects Involvement and Characteristics</u>

Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins. List any collaborating sites where human subjects research will be performed and describe the role of those sites in performing the proposed research.

b. Sources of Materials

Describe the research material obtained from living human subjects in the form of specimens, records, or data.

Describe any data that will be recorded on the human subjects involved in the project.

Describe the linkages to subjects and indicate who will have access to subject identities.

Provide information about how the specimens, records, or data are collected and whether material or data will be collected specifically for your proposed research project.

c. Potential Risks

Describe the potential risks to subjects (physical, psychological, social, legal, or other), and assess their likelihood and seriousness to the subjects.

Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent

Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.

Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. Informed consent document(s) need not be submitted to the PHS agencies unless requested.

b. Protection Against Risk

Describe planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

Discuss the potential benefits of the research to the subjects and others.

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

5. DATA AND SAFETY MONITORING PLAN (if applicable)

If your research includes a clinical trial, create a heading entitled "Data and Safety Monitoring Plan." Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring.

Vertebrate Animals. For all applications involving vertebrate animals, the applicant must address the following five items. These five points may be copied and pasted directly into the application.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

- 2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
- 3. Provide information on the veterinary care of the animals involved including the name of the supervising veterinarian. Include information from the Association for Assessment and Accreditation of Laboratory Animal Care International: the name of the accredited parent organization (e.g., University of X) and the certificate number and date of last inspection.
- 4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
- 5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations

14. LITERATURE CITED

15. APPENDIX

Include letters of support from the department chairs and associate investigators (required). Include proof of IRB approval or submission. Copies of questionnaires and relevant testing forms should also be included as appendices. No page numbering is necessary for Appendix. Do not use appendix to circumvent page limitations for research plans. Do not include experimental methods, protocols or figures that should be incorporated within the research project description.

16. SIGNED STATEMENT OF CONDITIONS (see below)

Principal Investigator (Last, first, middle):				
Table of Contents				
		Cover Page		
		Abstract		
		Table of Contents		
		Introduction to Revised Application (if applicable)		
		Research Strategy		
		Personal Statement		
		Role of Participants		
		Biographical Sketch		
		Resources and Environment		
		Detailed Budget		
		Other Support		
		Ethics		
		Literature Cited		
		Appendix		
		Signed Statement of Conditions		

Cover Page Sample

Full Name with Titles:			
Name of Institution:			
Grant Category:			
Project Title:			
Amount Requesting:			
Mentor, if applicable:			

		OF CONDITIONS GOVERNING THE EMERGENCY MEDICINE FOUNDATION GRANT that any Emergency Medicine Foundation Research Grant approved by the Emergency Medicine		
Foundat	tion will	be made with the following conditions:		
1.		ional overhead is not allowed.		
2.	The pri organiz	ncipal investigator's institution is organized for humanitarian purposes and is not a profit-making ation.		
3.	All reports of work achieved with this grant will acknowledge the support of the Emergency Medicine Foundation and any co-sponsors.			
4.	Any discovery that arises from work supported by the Emergency Medicine Foundation will be submitted for publication. Two electronic reprints of each electronic publication will be forwarded to the Emergency Medicine Foundation.			
5.	Independent progress reports by the applicant will be submitted to the Emergency Medicine Foundation mid- project, and within thirty days of completion of the funding period. Additional reports may be required. The Emergency Medicine Foundation will maintain the copyright of all such reports.			
6.		pation in the Emergency Medicine Foundation Grantee Workshop is expected. The Emergency Medicine tion will reimburse travel expenses.		
7.	Researc	es must submit the abstract of the funded project to the ACEP Research Forum at the end of the project. Ch Forum is held each year during the American College of Emergency Physicians Scientific Assembly. Lunds may not be used for registration nor travel.		
8.	If the n	amed principal investigator leaves the institution or terminates research in the designated field, all ing funds revert to the Emergency Medicine Foundation. If unused funds exist at the completion of the all remaining funds revert to the Emergency Medicine Foundation.		
9.	Patent rights will conform to institutional standards. If none exist, the Emergency Medicine Foundation reserves the right to protect such interests.			
10.				
	sponsor	ring institution affirm:		
	a.	That the investigation(s) proposed in this application are endorsed by the Animal and/or Human Subjects Committee or other designated body of the preceptor's institution, and		
	b.	That any research involving human subjects conforms with the principles of the Helsinki Code of the World Medical Association, and		
	c.	Research involving animals or human subjects must be approved by the institutional review board (IRB), or its equivalent, and a copy of the approval or pending approval sent with this application. IRB approval must be documented prior to dispensation of Emergency Medicine Foundation funds.		
	d.	That research involving vertebrate animals will conform with the "Guiding Principles in the Care and Use of Animals" as approved by the Council of the American Physiological Society.		
	e.	Research involving vertebrate animals must have approval from the Institutional Animal Care and Use Committee.		

Date	Signature of Principal Investigator	Type Name of Principal Investigator
Date	Signature of Mentor, if applicable	Type Name of Mentor, if applicable
Date	Signature of Institutional Official	Type Name of Institutional Official