Emergency Medicine Foundation Research Grant
Coagulation and DOAC Reversal Agent Knowledge Gaps

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:

- Cover 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 one-half (0.5 inch) margins
- 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 for all sites is required)
- 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 appendix
- Submission via the on-line application system is required. Late applications will not be considered. Submit application at https://emfoundation.aibs-scores.org

Funding for this project made possible with grant support from AstraZeneca.

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Request for Proposal

Application Deadline	January 20, 2023, by 6:00 pm EST
Notification of Award	June 2023
Funding Period	July 1, 2023 – June 30, 2024
Funding Amount Available	One $150,000 Grant
Eligibility	United States based institutions only
Questions	Contact Cynthia Singh at csingh@acep.org
Apply	https://emfoundation.aibs-scores.org

SPECIFIC AREAS OF RESEARCH INTEREST

EMF invites emergency medicine investigator-initiated human subjects research proposals that addresses the research priority of closing gaps in knowledge of reversal of anticoagulation. Priority areas of research interest include, but are not limited to:

- Time to diagnosis and decision to treat hemorrhagic stroke in emergency department and pre-hospital settings
- Incorporation of reversal agent in emergent treatment of patients with current anticoagulation/NOAC treatment (such as stroke, trauma, or GI bleed)
- Facilitating research that will improve awareness and improved quality of treatment as well as applicability and use of reversal agents
- Health disparities in the access to reversal agents for DOAC related life-threatening bleeds
- Assessing anticoagulation activity and determining the candidacy for emergent surgery/emergent reversal

Studies should not be designed to exclude women, minorities, and individuals based on age unless there is a scientific or ethical reason not to include them.

ELIGIBLE APPLICANTS

Eligible applicants for this grant opportunity are academic or community-based **established emergency medicine investigators and institutions** within the United States with a demonstrated record of ongoing clinical research and publication in the proposed study area. This grant mechanism allows an investigator to define the scientific focus or objective of the research based on a particular area of interest and competence.

INSTITUTIONAL SUPPORT

The applicant is required to demonstrate that the project will be successfully completed at their institution(s). **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 emergency medicine specialists who are actively involved in clinical research. Each application will be judged primarily on: (1) the significance of the project to emergency medicine, (2) the soundness of the research methodology, (3) the feasibility of execution and completion of the project, (4) innovation, (5) applicant experience, and (6) research environment. The final funding decision will be made by the Emergency Medicine Foundation Board of Trustees and all decisions are final. There is no guarantee of award and EMF may elect to award any, or no, grant in its sole discretion based on its evaluation of the applications.

APPLICANT COSTS

Costs for developing proposals are entirely the responsibility of the applicant and are not chargeable in any manner to EMF.

TERMS OF THE AWARD

A portion of the EMF grant funds will be disbursed at the start grant award and subsequent payments will be made 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 Emergency Medicine Foundation 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.

Liability of the Emergency Medicine Foundation

The Emergency Medicine Foundation 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 Emergency Medicine Foundation is not legally liable for the conduct of the institution, the principal investigator, the program faculty, or any associate investigators.

Non-Inducement

The parties acknowledge and agree that nothing in this RFP nor any resulting grant is intended to be nor shall it be construed as, an offer or payment made, whether directly or indirectly, to induce the referral of patients, the purchase, lease or order of any item or service from AstraZeneca, or the recommending or arranging for the purchase, lease or order of any item or service from AstraZeneca. This RFP and the any grant issued pursuant to it do not obligate EMF, AstraZeneca or Applicant to make referrals to or purchases from the other(s).

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. Multi-centered studies must submit letters of support from each study site.

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. Publications will acknowledge the support of the Emergency Medicine Foundation. An electronic reprint of each publication should be forwarded to the Emergency Medicine Foundation.

PROGRESS REPORTS AND MONEY MANAGEMENT
The principal investigator will submit quarterly progress reports and a final progress report within thirty days of the conclusion of the research project. 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 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 because 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 research findings at the American College of Emergency Physicians (ACEP) Scientific Assembly/Research Forum. Funds cannot be requested to cover the travel cost to attend the Research Forum.

CONTACT INFORMATION
Please address questions to Cynthia Singh, MS, Deputy Executive Director at csingh@acep.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), 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 any associate investigators or consultants. (Cover Page template below)

2. PROJECT SUMMARY ABSTRACT (limit 1 page)
The purpose of the project summary abstract is to describe succinctly every aspect of the proposed project. It should contain a statement of rationale, objectives, methods to be employed, innovation and significance. For methods, include hypothesis, specific aims, study design, study population, setting, intervention(s), outcome measures and data analysis. Indicate how the project relates to the above noted specific areas of research interest. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and use of the first person. This abstract should be a succinct and accurate description, in layman's terms, of the proposed work. All content of the abstract – including investigators, roles, and abstract body – should not exceed one page.

3. TABLE OF CONTENTS

4. 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 the broad, long-term objectives and the goal of the specific research proposed (e.g. to test a stated hypothesis, solve a specific problem, challenge an existing paradigm or clinical practice, or address a critical barrier).

5. RESEARCH STRATEGY (limit 10 pages)
Please use the following subheadings:

Significance
- Explain the impact of the condition on the health of individuals and populations
- Explain the potential for the study to improve healthcare and outcomes
- 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.

Approach

- Describe overall strategy, methodology, and analyses to be used to accomplish specific aims of project. Include the following subsections: study design, population, setting, intervention(s), data sources, outcome measures, and statistical design and power.
- 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 any preliminary studies. Discuss the 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. STUDY TIMELINE (limit 1 page)

Provide a description or diagram describing the study organization and timeline. The timeline should be general (e.g., "3 months after notice of award") and should not include specific dates.

7. KNOWLEDGE TRANSFER (limit 1 page)

State the specific goals for dissemination and knowledge transfer and the expected impact of the activities to advance the translation of research results into knowledge, products, and procedures that improve human health.

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

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

9. 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 and any associate investigators or consultants who will be involved with the project. Biosketches should include all three sections: A. Personal Statement; B. Positions, Scientific Appointments and Honors; C. Contribution to Science. Each biosketch should not exceed five pages.

10. RESOURCES AND ENVIRONMENT

Demonstrate that the resources are in place to conduct the proposed work. List the facilities to be used and their capacities, pertinent capabilities, relative proximity and extent of availability. List also the major equipment items already available, including the location and present pertinent capabilities of each. If your proposal seeks funding for new equipment, provide evidence of institutional support with respect to providing new space to accommodate the equipment.

11. BUDGET

Use the NIH Form Detailed Budget for Entire Proposed Project Period available at www.grants.nih.gov/grants/funding/phs398/phs398.html# Indicate how the money will be spent. Justify all major expenditures. Use the current NIH salary cap. ***Institutional overhead is not allowed***.

12. BUDGET JUSTIFICATON

Provide a budget justification to include justification for personnel, consultants, equipment, supplies, travel, participant/trainee support, and other direct cost categories.

13. ETHICS

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 the Institutional Review Board (IRB) or Research Ethics Board (REB) at your own institution and is required by most Federal agencies. This section must address the following items. These can be copied from your IRB/REB applications and pasted directly into this application.

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

1. RISKS TO THE SUBJECTS

a. Human Subjects Involvement and Characteristics

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 U.S. Public Health Service (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.

14. INTELLECTUAL PROPERTY

State whether or not you expect the project to result in the development of anything deemed patentable. EMF is committed to transparency in its research grant program, and evaluates all actual, potential, or perceived conflicts of interest. A Disclosure Statement of financial interests must be completed and submitted for all key personnel.

15. LITERATURE CITED

16. APPENDIX

Copies of publications (not to exceed three) pertinent to the proposed research by the principal investigator may be included. They must be published or in press. Letters of support and copies of questionnaires and relevant testing forms should also be included as appendices. Appendices should not be used to circumvent the page limits specified above. Reviewers are not obligated to read the appendices. Include proof of IRB approval or submission. No page numbering is necessary for Appendix.

17. SIGNED STATEMENT OF CONDITIONS (see form below)

Principal Investigator (*Last, first, middle*): _____

APPLICATION CHECKLIST

_____	Cover Page
_____	Abstract
_____	Table of Contents
_____	Specific Aims
_____	Research Strategy
_____	Study Timeline
_____	Knowledge Transfer
_____	Role of Participants
_____	Biographical Sketch
_____	Resources and Environment
_____	Detailed Budget
_____	Budget Justification
_____	Ethics
_____	Literature Cited
_____	Appendix
_____	Signed Statement of Conditions

EMF RESEARCH GRANT COVER PAGE

Principal Investigator Name and Title: _____

Name of Institution: _____

Project Title: _____

Amount Requesting: _____

Mentor Name, if applicable: _____

STATEMENT OF CONDITIONS GOVERNING
THE EMERGENCY MEDICINE FOUNDATION GRANT

It is understood that any Emergency Medicine Foundation Research Grant approved by the Emergency Medicine Foundation will be made with the following conditions:

1. Institutional overhead is not allowed.
2. The principal investigator's institution is organized for humanitarian purposes and is not a profit-making organization.
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. An electronic reprint and hard copy reprint of each publication will be forwarded to the Emergency Medicine Foundation.
5. Independent progress reports by the applicant will be submitted to the Emergency Medicine Foundation quarterly, 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. Grantees must submit the abstract of the funded project to the ACEP Research Forum at the end of the project. Research Forum is held each year during the American College of Emergency Physicians Scientific Assembly. Grant funds may not be used for registration nor travel to this meeting.
7. If the named principal investigator leaves the institution or terminates research in the designated field, all remaining funds revert to the Emergency Medicine Foundation. If unused funds exist at the completion of the project, all remaining funds revert to the Emergency Medicine Foundation.
8. Patent rights will conform to institutional standards. If none exist, the Emergency Medicine Foundation reserves the right to protect such interests.
9. No research proposal will be funded unless the Principal Investigator and the Institutional Official of the sponsoring institution affirm:

    a. That the investigation(s) proposed in this application is endorsed by the 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 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.

_____ _____

Date Signature of Principal Investigator Date Type Name of Principal Investigator

_____ _____

Date Signature of Institutional Official Date Type Name of Institutional Official