

Emergency Medicine Foundation

FUJIFILM SonoSite COVID-19 Point of Care Ultrasound Acceleration 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 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/AUC 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>

EMERGENCY MEDICINE FOUNDATION
FUJIFILM SonoSite COVID-19 Point of Care Ultrasound
Acceleration Research Grant
Request for Proposal

Application Deadline	August 21, 2020 at 6:00 pm EST
Notification of Award	September 2020
Funding Period	September 2020 – March 2021
Funding Amount Available	A total of \$90,000 is being sponsored by FUJIFILM SonoSite, Inc. Multi-centered studies (3 sites) can request a maximum of \$90,000. Single site studies can request a maximum of \$30,000. In addition to the funds, SonoSite PX, a new high-end ultrasound system with three transducers (phased, linear, curvilinear), will be donated to each study site.
Eligibility	United States–Based Institutions Only
Questions	Contact Cynthia Singh at csingh@acep.org
Link to RFP	https://www.emfoundation.org/apply
Submit Application	https://emfoundation.aibs-scores.org

BACKGROUND

We are in a global COVID-19 pandemic with over 9 million confirmed cases and over 470K deaths as of June 23, 2020. This disease has affected 188 countries with certain countries having a disproportionate morbidity and mortality. Diagnostic imaging for COVID-19 has included X-ray and CT scanning but ultrasound has significant cost and time advantages. Furthermore critically ill patients with COVID-19 can have multi-organ failure in which point of care ultrasound can help for multiple purposes. Within four months, publications have shown the value of point of care ultrasound in COVID-19 patients, but the work is still preliminary and more formal research is necessary. In an effort to further learn and evaluate the role of ultrasound in COVID-19 a dedicated EMF research grant will be sponsored by FUJIFILM SonoSite to encourage study into this deadly disease.

RESEARCH TOPICS

Emergency Medicine Investigators are encouraged to consider all aspects of COVID-19 and the value of point of care ultrasound including:

- Mild to severe illness
- Initial triage, examination and ongoing monitoring
- Multi-organ assessment

Priority will be given to projects studying new ultrasound COVID-19 care pathways that improve:

- Quality of care
- Cost of care
- Patient and/or staff safety
- Care efficiency
- Patient satisfaction

Funding priority will be given to multi-centered studies. All study sites must be based in the United States. A maximum of three point of care ultrasound systems will be donated for this research, subject to the attached ***System Donation Agreement***, with one system provided per study site. The high-end ultrasound systems with three transducers (phased, linear, curvilinear) are new FUJIFILM SonoSite products that will be released in August.

ELIGIBILITY

An emergency physician must be a Principal or Co-Principal Investigator. Co-Investigators from the emergency medicine team or other disciplines are encouraged. The Principal Investigator will make all arrangements for conduct of the proposed research 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(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 basic science and clinical research, including experts in ultrasound. 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 likelihood the project will be completed, and (4) innovation. 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 or FUJIFILM SonoSite.

TERMS OF THE AWARD

One-half of the EMF funds will be disbursed at the start grant award and one-half midterm through the project, 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 and/or FUJIFILM SonoSite will not be responsible for institutional overhead, cost for publications, travel, renovations, or secretarial support. Detailed audited financial reports may be required. The EMF and/or FUJIFILM SonoSite are 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 and FUJIFILM SonoSite

The EMF and/or FUJIFILM SonoSite 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.

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 FUJIFILM SonoSite, or the recommending or arranging for the purchase, lease or order of any item or service from FUJIFILM SonoSite. This RFP and the any grant issued pursuant to it do not obligate EMF, FUJIFILM SonoSite, 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 and a hard copy reprint of each publication should be forwarded to the Emergency Medicine Foundation.

PROGRESS REPORTS AND MONEY MANAGEMENT

The principal investigator will submit a midterm progress report 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 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 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, vertebrate animals verification) do **not** send supplementary material.

The application consists of the following sections:

1. INFORMATION 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 mentors and associate investigators. (See sample Information Page below)

2. ABSTRACT (limit 1 page)

Provide a summary of the research proposal. Include rationale, research hypothesis, specific aims, and significance. **Describe how the research project will be ready to launch by September 2020.**

3. TABLE OF CONTENTS

4. RESEARCH PROPOSAL (limit 6 pages)

Please use the following subheadings:

Specific Aims

- 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.
- Specific Aims are limited to one page.

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.
- 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 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.

5. 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.

6. 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.

7. RESOURCES AND ENVIRONMENT

Describe the research facilities (laboratory space, clinical population, etc.) available for the research.

8. BUDGET

Use the NIH Form Detailed Budget for Initial Budget 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.*

9. 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 IRB at your own institution and is 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 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 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.

10. LITERATURE CITED

11. APPENDIX

Include letters of support from the department chair and associate investigators. Include proof of IRB approval or submission. No page numbering is necessary for Appendix.

12. SIGNED STATEMENT OF CONDITIONS (see below)

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

Table of Contents

_____	Information Page
_____	Abstract
_____	Table of Contents
_____	Research Proposal
_____	Role of Participants
_____	Biographical Sketch
_____	Resources and Environment
_____	Detailed Budget
_____	Ethics
_____	Literature Cited
_____	Appendix
_____	Signed Statement of Conditions

Information Page Sample

Full Name with Titles: _____

Name of Institution: _____

Grant Category: _____

Project Title: _____

Amount Requesting: _____

Mentor, if applicable: _____

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

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 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. 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 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 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.
10. System(s) to be provided by FUJIFILM SonoSite are subject to all conditions of this RFP and Grantee's execution and delivery of an agreement materially in the form of the attached System Donation Agreement.
11. The Grant is subject to all terms and conditions of the RFP.

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