# *HFSA/EMF*
# *Acute Heart Failure Young Investigator Mentored Award*

**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.
- Use 12-pt. font and one inch margins
- Evidence of IRB approval, or at least evidence of submission to IRB, from each institution, is included in application packet. 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 HFSA funds.
- Clearly stated research hypothesis
- Statement of Conditions is signed by **Applicant** and **Institutional Fiscal Officer** and 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: Please submit applications at https://www.emfoundation.org/applyforagrant. Late applications will not be considered.

**HFSA/EMF Acute Heart Failure Young Investigator Mentored Award**

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| Deadline for Receipt of Application | June 1, 2017 |
| Notification of Award | August 2017 |
| Funding Period | Sept 1, 2017 – August 31, 2018 |
| Number of Awards Available | 2 |
| Funding Amount | $80,000 each |

## INTRODUCTION

With support from Novartis, the Heart Failure Society of America (HFSA) and the Emergency Medicine Foundation (EMF) have partnered to train future heart failure (HF) investigators, assist them in obtaining preliminary data for subsequent federal funding, and improve acute heart failure (AHF) management. The grant also aims to establish a working relationship between emergency medicine and heart failure investigators. An ideal combination would be either: 1) an emergency medicine junior investigator and a senior non-emergency medicine heart failure mentor or 2) a junior non-emergency medicine heart failure investigator and a senior emergency medicine mentor. While the exact combination is left up to each team of investigators, either the mentee or mentor must be from emergency medicine. Collaboration within the same institution is encouraged, but cross-institutional mentorship is allowed, provided there is evidence of a pre-existing research partnership. Each investigator will only be allowed one grant submission, regardless of whether they are the mentee or mentor. As this is a mentored grant, for purposes of grant submission and awardee notification, the junior investigator will be considered the principal investigator. Only one application per research laboratory will be considered for this award.

This funding mechanism is intended to serve five purposes:

1) Develop a core content area of AHF investigation
2) Develop grantsmanship expertise of the junior investigator
3) Develop an overall methodologic focus
4) Develop the clinical investigation skills of junior faculty
5) Develop preliminary data for subsequent federal funding proposals

## RESEARCH TOPICS

The grant is structured to broadly support patient-oriented research. Studies of primary prospective patient enrollment are preferred. Basic science proposals or primary laboratory investigations that do not involve patient care will be considered non-responsive to this funding announcement. Examples of patient-oriented research include, but are not limited to: 1) prospective randomized clinical trials; 2) retrospective analyses of pre-existing data; and 3) cohort and case control study designs.

## ELIGIBILITY

Eligible applicants must include a junior investigator mentee within 7 years of residency or fellowship completion at the Assistant Professor level or below, and a senior faculty mentor at the Associate Professor level or higher. Exceptions to this will not be made. For submission purposes, the junior investigator will be considered the primary applicant/principal investigator, and their home institution will be the primary grant recipient. Emergency medicine and cardiology investigators can serve as either mentor or mentee for a given submission; however, each investigator can participate in only one application.

## MERIT CONSIDERARTIONS

Application merit will be considered based on the following criteria:

1) **Significance** of the grant proposal, both for the advancement of AHF research and the junior investigator's research career, including subsequent funding opportunities.
2) **Innovation**

3) Rigor of the proposed scientific **approach** and the probability of completing the data acquisition within 12 months.
4) **Accomplishments** of the junior investigator- those applicants who have demonstrated an interest in AHF research through prior pilot funding and peer-review publications will be considered competitive.
5) **Mentorship** plan
6) Demonstration of prior and ongoing Institutional and Departmental/Divisional **support** of the faculty.

**INSTITUTIONAL SUPPORT**

The applicants are required to demonstrate that the project will be successfully completed at their institution. The applicants 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 HFSA funds.**

**EVALUATION OF APPLICATIONS**

Each application will be reviewed by emergency medicine specialists and heart failure specialists who are actively involved in clinical research. Each application will be judged primarily on: (1) the significance of the project to emergency and cardiovascular medicine, (2) innovation, (3) the soundness of the research methodology and the likelihood the project will be completed, and (4) accomplishments of junior investigator, (5) mentorship plan, (6) Institutional support of the applicant. The final funding decision will be made by committee members of the Emergency Medicine Foundation (EMF) and Heart Failure Society of America (HFSA), and all decisions are final.

**TERMS OF THE AWARD**

The grants funds will be disbursed semi-annually over the one-year cycle. Disbursement of payments will be contingent upon satisfactory progress reports.

Limitations on Awards

Grants will total $80,000 each. The funding is meant to be divided into project ($60,000) support, salary (max $15,000) support, and support for the senior mentor who will receive $5,000 for their time spent developing the project and career development of the junior investigator. Project support can be used for patient enrollment, data collection and data analysis. Purchasing of laboratory supplies and instruments is generally discouraged, but this will be considered on an individual basis relative to not only the specific project, but the career development of the candidate.

Funds may be used for materials and supplies and to provide salary support. Capital equipment expenditures (costing more than $5000 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 or Heart Failure Society of America will not be responsible for institutional overhead, cost for publications, renovations, or secretarial support. Detailed audited financial reports may be required. Neither the HFSA nor the EMF is fiscally responsible for additional funds necessary for the project's completion.

Change of Status of Principal Investigator

If the principal investigator ceases research in the field for which the award was made, the award will terminate and the remaining balance will be returned to the Heart Failure Society of America.

Liability of the Heart Failure Society and Emergency Medicine Foundation

The HFSA and EMF assumes no liability, financial or otherwise, if patient care responsibilities of any kind are undertaken by the program faculty or investigator. All research must be approved by the IRB prior to the start of the research and must be done in accordance with institutional policies. The principal investigator and his or her institution acknowledge that the HFSA and EMF are 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 and HFSA will defer to institutional policies where they are in compliance with those of the Federal government. The HFSA and 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 Heart Failure Society and Emergency Medicine 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 and the Heart Failure Society of America. Two reprints of each publication should be forwarded to the Emergency Medicine Foundation and the Heart Failure Society of America.

**PROGRESS REPORTS AND MONEY MANAGEMENT**

The principal investigator is required to submit a six-month progress report and a final progress report within thirty days of the conclusion of the award year. Additional reports may be required. Failure to provide such reports will delay transmission of funds. Furthermore, failure to provide interim and final reports may negatively impact your institution's ability to apply for future HFSA and EMF awards. HFSA and 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 HFSA reserves the right to withhold release of interim funds if >25% of the previous cycle remains unspent. The HFSA 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 supporters will rely on such information to support continuation of the award program.

**ACEP RESEARCH FORUM and HFSA ANNUAL MEETING**

Awardees are required to present their work at the American College of Emergency Physicians Scientific Assembly/Research Forum and the HFSA Annual Scientific Meeting immediately following the completion of the award year as a poster presentation. The Chairs of the PIs are encouraged to write a letter supporting their attendance at these meetings.

## APPLICATION INSTRUCTIONS

Submission in electronic format is required. No paper copies please. Be prepared to submit information about your project including where the name and address of your institution, detailed information about where the check will be sent, and names of your mentor, fiscal officer, etc. **INCOMPLETE PROPOSALS OR PROPOSALS RECEIVED AFTER THE DEADLINE DATE INDICATED UNDER GENERAL INFORMATION WILL NOT BE CONSIDERED.**

> Historically, getting the signatures on the application has been the main delay in meeting the grant deadline due to sick leave, vacations, business travel, etc. We suggest that you start getting the signatures as soon as possible so you do not miss the grant deadline. Once the deadline passes, we cannot accept the application.

Use English only and avoid jargon and unusual abbreviations. For terms not universally known, spell out the term the first time it is used with the appropriate abbreviation in parentheses; the abbreviation may be used thereafter. Type the application, single-spaced, and stay within the margin limitations indicated on the forms and continuation pages. The type must be clear and readily legible, use 12 pt. size font.

Do **not** submit an incomplete application. **An application will be considered incomplete 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.

Number the pages consecutively at the bottom throughout the application. Do not use suffixes such as 5a, 5b. Type the name of both the Senior Investigator and Junior Investigator at the top of each printed page.

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 the Mentor and any associate investigators.

**2. ABSTRACT** (limit 1 page)
Brief summary of research proposal, research hypothesis, specific aims, training plan, and significance.

**3. INTRODUCTION TO REVISED APPLICATION,** if applicable. (limit 1 page)
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 the SRC from guaranteeing that a grant will be reviewed by the same individuals reviewing the original

application.

**4. TABLE OF CONTENTS**

**5. RESEARCH PROPOSAL** (limit 12 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 how 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.
- 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.

*Training Plan*

- Describe the training plan, research environment, and mentors involvement.

*Innovation*

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

*Approach*

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the 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 per investigator)

The applicants 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. LETTERS OF SUPPORT**

The applicant should provide the following letters of support:

a. Letter from primary mentor
b. Institutional Letter of support

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

List both the Senior Investigator and Junior Investigator. 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 www.grants.nih.gov/grants/funding/phs398/phs398.html#

Information is requested for the applicant, Mentor and any associate investigators who will be involved with the projects. The new 5 page NIH format has been adopted. Description of extramurally funded projects ongoing or completed in the past 3 years should include title, funding source, specific aims, overall goals and role/responsibilities of individual on project.

**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 on the internet at www.grants.nih.gov/grants/funding/phs398/phs398.html#

Indicate how the money will be spent. Justify all major expenditures.

**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**

**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 and HFSA Scientific Review Committees (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. 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. 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. LITERATURE CITED

## 15. APPENDIX

Include letters of support from the department chairs, and associate investigators (required). No page numbering is necessary for Appendix. The appendix can include:

- Application for coursework or degree program at an accredited graduate school
- Up to 5 publications, manuscripts (***accepted*** for publication), abstracts, patents, or other printed materials directly relevant to this project. *Do not include manuscripts* ***submitted*** *for publication.*
- Publications in press**:** Include only a publication list with a link to the publicly available on-line journal article or the NIH PubMed Central (PMC) submission identification number. Do not include the entire article.
- Manuscripts accepted for publication but not yet published: The entire article should be submitted and may be stapled.
- Manuscripts published but an online journal link is not available**:** The entire article should be submitted and may be stapled.
- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents. These may be stapled as sets.
- Original glossy photographs or color images of gels, micrographs, etc., provided that a photocopy (may be reduced in size) is also included within the 12-page limit of *Items a-d* of the research plan. *No photographs or color images may be included in the Appendix that are not also represented within the Research Plan.*

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.

Applicant/Preceptor (*Last, first, middle*): _____

**EMERGENCY MEDICINE FOUNDATION**

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**Emergency Medicine Foundation**
**Information Page**

Full Name with Titles:_____

Name of Institution:_____

Grant Category:_____

Project Title:_____

Amount Requesting:_____

Mentor, if applicable:_____

STATEMENT OF CONDITIONS GOVERNING THE

**HEART FAILURE SOCIETY OF AMERICA & EMERGENCY MEDICINE FOUNDATION GRANT**

It is understood that any Emergency Medicine Foundation and Heart Failure Society of America Research Grant approved by both entities will be made with the following conditions:

1. Institutional overhead is not allowed.

2. The principal investigator's institution is associated or 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 Heart Failure Society of America, if applicable.

4. Any discovery that arises from work supported in part by the Emergency Medicine Foundation and Heart Failure Society of America will be submitted for publication. Two copies of each publication will be furnished to each organization.

5. Independent progress reports by the applicant will be submitted to the Emergency Medicine Foundation and Heart Failure Society of America mid-project, and within thirty days of completion of the funding period. Additional reports may be required. The Emergency Medicine Foundation and Heart Failure Society of America will maintain the copyright of all such reports. Failure to comply with submission of progress reports, or demonstration of adequate interval progress, may result in termination of the award and disbursement of funds.

6. Participation in Emergency Medicine Foundation and Heart Failure Society of America annual scientific conferences is required. During each conference the awardee is to give a poster and lightning oral presentation. This event takes place at the end of your project.

7. If all requirements are met, funding will begin on July 1st. The Emergency Medicine Foundation and the Heart Failure Society of America reserves the right to terminate payments under this grant at its sole discretion.

8. If the named principal investigator terminates research in the designated field, all remaining funds revert to the Heart Failure Society of America. If unused funds exist at the completion of the project, all remaining funds revert to the Heart Failure Society of America.

9. Patent rights will conform to institutional standards. If none exist, the Emergency Medicine Foundation and Heart Failure Society of America reserves the right to protect such interests.

10. No research proposal will be funded unless the principal investigator and the Fiscal Officer of the sponsoring institution affirm:

    a. That the investigation(s) proposed in this application are 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

_____ /_____

Date Signature of Senior Investigator Type Name of Senior Investigator

_____ /_____

Date Signature of Junior Investigator Type Name of Junior Investigator

_____/_____

Date Signature of Fiscal Officer Type Name of Fiscal Officer