EMERGENCY MEDICINE FOUNDATION
REQUEST FOR PROPOSALS

TREATING AGITATION IN THE EMERGENCY DEPARTMENT

GENERAL INFORMATION

Deadline for receipt of application	April 1, 2016
Notification of award	June 2016
Funding period	July 1, 2016 - June 30, 2018
Award Maximum	$490,000

Please fill out the information questionnaire and upload the completed application through our online grant portal at http://www.emfoundation.org/applyforagrant

INTRODUCTION

The Emergency Medicine Foundation endeavors 1) to promote research within the specialty of Emergency Medicine, 2) to advance emergency medical care, and 3) to facilitate the academic growth and development of emergency medicine faculty and thereby invest in the future of the specialty of emergency medicine.

Agitation is estimated to involve close to 1.7 million psychiatric emergencies per year.[1,2,3] Agitation is commonly a complication associated with psychiatric disorders. In the United States, 2.4 million adults have schizophrenia, and 5.7 million adults have bipolar disorder, and agitation is often associated with schizophrenia or bipolar disorder.[4,5] Several pharmacological treatments for agitation are available, including intramuscular haloperidol, aripiprazole, olanzapine, ziprasidone and lorazepam, along with loxapine inhalation powder.

There is a general gap in scientific evidence describing the patterns and cost of care for agitated patients with schizophrenia and bipolar I disorder treated with various pharmacological agents delivered through different routes of administration.

This program is sponsored in full by, and developed in concept in collaboration with Teva Branded Pharmaceutical Products R&D, Inc. Applicants may apply for up to a total of $490,000 for a two-year period. Both scientific review and awarding decisions will be made independent of the sponsor.

References:
1Allen MH, Currier GW. Use of restraints and pharmacotherapy in academic psychiatric emergency services. *Gen Hosp Psychiatry.* 2004;26:42-49.

2Marco CA, Vaughan J. Emergency management of agitation in schizophrenia. *Am J Emerg Med*. 2005;23:767-776.

3Sachs GS. A review of agitation in mental illness: burden of illness and underlying pathology. *Journal Clinical Psych*. 2006;67(10):5-12

4American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders.* Fifth ed. Arlington, VA: American Psychiatric Publishing; 2013

5U.S. Census Bureau., Population Division. Annual Estimates of the Resident Population for Selected Age Groups by Sex for the United States, States, Counties, and Puerto Rico Commonwealth and Municipios. Washington, D.C.: U.S. Census Bureau; 2013

RESEARCH TOPICS

Applications should propose a comparative effectiveness study evaluating the impact of use of the inhaled therapy option (loxapine inhalation powder) on the patterns, outcomes and cost of care of agitated patients with schizophrenia or bipolar I disorder compared to the use of intramuscular injectable therapies.

Some of the components of care patterns and outcomes of agitated patients with schizophrenia or bipolar I disorder could include time to administration of drug treatment, time to psychiatric evaluation use and time in restraint and/or seclusion, time to disposition and discharge, use of concomitant medications, rate and treatment of adverse events, total length of stay, and admission status.

ELIGIBILITY

The principal investigator is recognized as an accomplished investigator in emergency medicine, and must have proven ability to pursue independent research as evidenced by original research publications in peer-reviewed journals or funding from extramural sources. The principal investigator must have a primary faculty appointment in 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. Furthermore, the investigator's facility must be enrolled in the ADASUVE® (loxapine) inhalation powder Risk Evaluation and Mitigation Strategy program.

INSTITUTIONAL SUPPORT

The applicant is required to demonstrate that the project will be successfully completed at their institution. Given the scope of this project, multi-institutional collaborations are allowed. 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(s) (IRB), or its equivalent and a copy of the approval or pending approval sent with this application. IRB(s) 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, clinical or health services research. Each application will be judged primarily on: (1) the significance of the project to emergency medicine, (2) adherence to the goals of this directed grant, (3) the soundness of the research methodology, and (4) the likelihood the project will be completed. The final funding decision will be made by the Emergency Medicine Foundation Board of Trustees and all decisions are final.

TERMS OF THE AWARD

The EMF/Teva Pharmaceutical Industries Ltd Directed Research Grant award will be disbursed semi-annually over the two year cycle. Disbursement of payments will be contingent upon satisfactory progress of the research.

<u>Limitations on Awards</u>

Funds may be used for materials and supplies, research personnel support 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 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.

Liability of the Emergency Medicine Foundation

The EMF and the sponsor assume 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 and the sponsor are not legally liable for the conduct of the institution, the principal investigator, the program faculty, or any associate investigators.

Research Project Documentation

To the extent permitted by applicable law; including but not limited to the Health Insurance Portability and Accountability Act ("***HIPAA***") and other health privacy laws, rules or regulations, the Underwriter shall have access to and be entitled to copies of the documentation and compilation of information generated by Grantee in connection with the Research Project, including but not limited to statistical analysis documentation, data obtained in connection with the performance of quantitative analysis and summaries of information that might be prepared or relied upon by the Grantee in connection with the Research Project.

EMF shall receive progress reports (every six (6) months into the Research Project) and upon completion of the Research Project, EMF shall provide the Underwriter a written report of the results of the Research Project ("***Final Progress Report***").

Publications & Copyright

All discoveries resulting from The results of the Research Project supported in part by EMF and the Underwriter will may be made available to the public and scientific community through approved scientific channels such as national meetings and peer reviewed publications. Publications will acknowledge the financial support and development contributions of the Underwriter and EMF and EMF shall ensure full and complete disclosure of Underwriter's input into and contribution to the development of the Grant, such disclosure to be substantially similar to the following: "This study was funded by a Grant from and developed in concept in collaboration with Teva Pharmaceuticals."

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 and sponsor must be apprised of the invention and the EMF and Sponsor reserve the right to claim rights and interests in the invention or discovery.

Any inventions, concepts, discoveries, technology, know-how, processes, tools, products, developments, methods, improvements, program source code, patents, trademarks or other intellectual property that is conceived, discovered, reduced to practice, made or developed by EMF or Grantee in the course of performing the Research Project to or otherwise arising out of use of Underwriter's product in the Research Project shall be the property of Underwriter (collectively "Inventions"). While creating an

invention is not contemplated under the terms of the Research Project between EMF and Grantee, should Grantee create an invention, during the course of the research project the sole and exclusive right to any inventions, whether patentable or not, arising directly or indirectly, in the performance of the Research Project under this Agreement related to or otherwise arising out of use of Underwriter's product in the Research Project shall be the property of Underwriter (collectively "Inventions"). The Grantee will promptly notify EMF and Underwriter in writing of any such Inventions, and at Underwriter's request and expense, EMF and/or Grantee will cause to be assigned to Underwriter all right, title, and interest in and to any such Inventions and provide reasonable assistance to obtain patents including causing the execution of any invention assignment or other documents. Inventions shall not include concepts, discoveries, technology, know-how, processes, tools, products, developments, methods, improvements, program source code, patents, trademarks or other intellectual property that is conceived, discovered, reduced to practice, made or developed by Grantee in the course of outside of performing the Research Project, as such materials are the property of the Grantee under the terms of the Grant.

Liability and Indemnification

Grantee shall defend, indemnify, and hold EMF and Underwriter, its affiliates, officers, directors, employees, permitted subcontractors and agents harmless from and against any demand, claim, suit, loss, damage, expense or cost of judgments (including reasonable attorney fees) that may be made or instituted against any of them arising from or related to: (i) the obligations, representations, or warranties of Grantee under this Agreement; or (ii) design, content, or implementation of the Grant; (iii) any injury (whether or not Grant related) to persons or damage to property involved in the Research Project; (iv) the performance of the Research Project; provided however, such obligation shall be to the extent such demand, claim, suit, loss, damage, expense or cost of judgments are not caused by or result from the negligence or intentional misconduct of Underwriter, EMF, its affiliates, officers, directors, employees, permitted subcontractors or agents in performing Underwriter's obligations under this Agreement. Grantee agrees that neither EMF, Underwriter nor any of its affiliates or subsidiaries, their respective officers, directors, or employees will bear any responsibility or liability for claims, losses, injuries, or other damages arising under this Agreement and the related Research Project, research, and/or meetings or publications regarding the same.

Insurance

The Grantee must maintain in full force and effect through the performance of the Research Project (and following termination or expiration of this Agreement to cover any claims arising from the Research Project) the following minimum required insurance coverage: (i) medical malpractice liability with limits of $5,000,000 per occurrence and $5,000,000 in the annual aggregate for individuals performing duties as directed by the Grantee; (ii) general liability in the amount of $1 million and $3 million in the aggregate; and (iii) workmen's compensation, in accordance with all applicable legal and regulatory requirements. The Grantee shall be solely responsible for the payment of any deductible or self-insured retention under any such policies. The minimum required insurance coverage required hereunder shall not be construed to create a limit of the Grantee's liability with respect to its indemnification obligation in this Agreement. The Grantee shall provide evidence of such insurance to EMF prior to the commencement of the Research Project. The Grantee agrees to provide written notice to EMF within fifteen (15) business days in the event of becoming aware of any material change in their insurance program that prevents compliance with the obligations set forth herein. Failure to maintain the minimum required insurance set forth herein may be deemed a material breach.

Debarment, Discipline and Disqualification

Neither the Grantee, nor any person employed or engaged by the Grantee, including, without limitation, Grantee's trustees, employees, contractors, consultants or agents (collectively "Personnel") has ever been, or is currently, debarred by the FDA pursuant to 21 U.S.C. § 335a (a) or (b) ("Debarred Individual").,

Neither the Grantee, nor any Entity or Personnel who will provide services under this Agreement has ever been and is not currently the subject of a sanction, disciplinary action, or agreement by or with any federal, state or local agency, including state licensing authorities or regulatory authorities, medical societies, or specialty boards, that restricts their ability to practice medicine ("Disciplined Individual or Entity"); or that causes them to be disqualified by FDA as a clinical Grantee pursuant to 21 C.F.R. § 312.70 or 21 C.F.R. § 812.119 ("Disqualified Individual or Entity").

Neither the Grantee, nor any Entity or Personnel has ever been and is not currently excluded, suspended or otherwise ruled ineligible to participate in any Federal health care program (as in defined in 42 U.S.C. § 1320a-7b(f)) and neither the Grantee, nor any Entity or Personnel has engaged in any activity that could lead to it becoming excluded, suspended or otherwise ruled ineligible to participate in any Federal health care program.

Neither it nor any Entity or Personnel has been excluded from participation in any federal healthcare program under Section 1128 of the Social Security Act, as that Section may be amended from time to time, or any other local, state or federal Health Care Fraud and Abuse Laws or False Claims Acts or applicable regulations; and neither it nor any Entity or Personnel has been convicted of a criminal offense that falls within the scope of mandatory exclusion from participation in any Federal healthcare program under 42 U.S.C. § 1320a-7(a).

Neither the Grantee, nor any Entity or Personnel has ever been and is not currently excluded, suspended or otherwise ruled ineligible to participate in any Federal health care program (as in defined in 42 U.S.C. § 1320a-7b(f)) and neither the Grantee, nor any Entity or Personnel has engaged in any activity that could lead to it becoming excluded, suspended or otherwise ruled ineligible to participate in any Federal health care program. Neither it nor any Entity or Personnel has been excluded from participation in any federal healthcare program under Section 1128 of the Social Security Act, as that Section may be amended from time to time, or any other local, state or federal Health Care Fraud and Abuse Laws or False Claims Acts or applicable regulations; and Neither it nor any Entity or Personnel has been convicted of a criminal offense that falls within the scope of mandatory exclusion from participation in any Federal healthcare program under 42 U.S.C. § 1320a-7(a).

The Grantee shall not employ or subcontract with any individual or Entity subject to any such exclusion. The Grantee, shall notify EMF immediately if it or any Entity or Personnel should, during the term of this Agreement, be excluded, suspended or otherwise ruled ineligible to participate in any Federal health care program or if any action is taken that could lead toward it or any Entity or Personnel being excluded, suspended or otherwise ruled ineligible to participate in any Federal health care program. Upon receipt of such notice by EMF, or if EMF or Underwriter becomes aware of a threatened or actual exclusion, suspension or ineligibility, EMF shall have the right to terminate this Agreement immediately. Underwriter reserves the right to screen the Grantee against the Office of the Inspector General and General Services Administration exclusion databases and any other relevant databases.

The activities under this Agreement do not and will not involve the counseling or promotion of a business arrangement or other activity that violates any local, state or federal law.

The Grantee, and all of Entity and Personnel will comply in all material respects with all applicable foreign and United States federal and state statutes and regulations, including but not limited to: (i) the Anti-Kickback provisions of the Social Security Act, 42 U.S.C. § 1320a-7b, and the relevant regulations at 42 C.F.R. Part 1001 ("Healthcare Fraud and Abuse Laws"); (ii) the False Claims Act, 31 U.S.C. § 3729; and (iii) statutes or regulations relating to the confidentiality and security of personal and medical data, including but not limited to, the health information privacy regulations promulgated under the provisions of the Health Insurance Portability and Accountability Act of 1996, 45 C.F.R. § 160-164 and

any other laws and/or regulations relating to the maintenance, use, transmission or other activity concerning patient records and confidentiality of personal and medical data.

In accordance with the Physician Payments Sunshine Act of 2009, as amended or may be amended hereafter, and in accordance with other federal and state disclosure laws, rules and regulations, and/or any other European and national applicable legislations, Underwriter may be required to disclose to various federal and/or state authorities payments made to Health Care Providers, as well as others who may receive payments or receive other forms of value, in connection with the services performed hereunder. In addition, Underwriter may also be required to disclose to a government authority a Health Care Provider's participation in the services performed hereunder. The determination of whether, when and to what extent Underwriter should comply with their respective federal or state disclosure requirements will be made exclusively by Underwriter, as applicable. EMF agrees that it shall provide to Underwriter any information and in such format as Underwriter, as applicable, reasonably requests in connection with Underwriter's disclosure obligations in accordance with this provision. For purposes of this section, "Health Care Providers" means any person certified, registered or licensed to prescribe pharmaceutical products or who otherwise exercises skill or judgment or provides a service relating to the treatment or care of patients, including a related entity supporting the Health Care Providers, i.e., Healthcare Organization. This includes, but is not limited to, physicians, physician assistants, nurse practitioners, nurses, pharmacists, teaching hospitals, hospital consultants, social workers, and practice administrators, consultants, principal investigator, sub-investigator, study coordinator and any other person or related entity (entity by or in which any Health Care Providers receiving payments (i.e.- compensation, items of value, reimbursed expenses or comparable payments) is employed, has tenure, or has an ownership interest) performing clinical study-related procedures.

In the event of the enactment, promulgation, rescission, modification or interpretation of any federal, state and local laws, regulations, ordinances and guidances after the date hereof which would materially adversely affect the manner in which either party is obligated to perform under this Agreement, each party shall have the right to enter into good faith negotiations with the other in order to seek to agree on reasonable terms for maintaining the intent of this Agreement without the effect of such enactment, promulgation, etc. Agreement on any such terms shall be in the sole discretion of each party.

Adverse Event Reporting

The Grantee acknowledges that Underwriter is required to comply fully and promptly with all regulatory safety reporting requirements regarding its products. The Grantee being the sponsor of the study has sole responsibility for reporting of adverse events to the FDA. For informational purposes any correspondence to the FDA regarding adverse events or other safety issues will be simultaneously copied to the Underwriter via email (us.clinops.sae@tevapharm.com) or facsimile (215-795-4243). The Grantee will communicate the occurrence of any serious adverse events which he or she believes to be definitely, likely or probably related to the Study Product to Underwriter within 24 hours of becoming aware of the event. Please note that the reporting period begins when a patient signs the informed consent, and ends 30 days after the discontinuation of dosing or completion of the patient's participation in the Study if the last scheduled visit occurs at a later time. In addition, the Grantee must notify Underwriter of any serious adverse events that may occur after this time period which he or she believes to be definitely, likely or probably related to the Study Product.

The MedWatch 3500A form should be utilized to report serious adverse events to the FDA.
A serious adverse event or reaction is any untoward medical occurrence that at any dose:

- Results in death;
- Is life-threatening (meaning that the patient was at immediate risk of death as the event occurred, but not including events that could cause death if they occurred in a more severe form);
- Requires inpatient hospitalization or prolongation of existing hospitalization;

- Results in a persistent or significant disability/incapacity;
- Is a congenital anomaly or birth defect;
- Results in the development of drug dependency or drug abuse;
- An important medical event that may not result in death, be life threatening, or require hospitalization, but may jeopardize the patient and require medical intervention to prevent one of the outcomes listed above.

For the purpose of this Agreement, these terms shall have the same meaning as the terms used in the provisions of the Code of Federal Regulations governing drug and biologic safety reporting. See 21 CFR 314.80(a); 600.80(a). Additionally, the following will also be deemed to be adverse events for purposes of this Agreement: pregnancy exposure, infant exposure during breastfeeding, overdose, abuse, misuse, medication errors, lack of efficacy, transmission of an infectious agent, as well as all reports of accidental pediatric exposure, and any other safety information as reasonably requested by Underwriter. Grantee shall use his/her judgment to determine the relationship between the serious adverse event and the Study Product. In the event the IRB requests additional safety information from Grantee, Grantee shall notify Underwriter of such request within one (1) business day.

The Grantee further agrees to report all Adverse Events in compliance with all applicable legal and regulatory requirements, and in accordance with any requirements provided by Underwriter.

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. Publications will acknowledge the support of the Emergency Medicine Foundation and Teva Pharmaceuticals. Two reprints of each publication should be forwarded to the Emergency Medicine Foundation.

PROGRESS REPORTS AND MONEY MANAGEMENT

The principal investigator is required to submit a progress report every six months 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 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.

GRANTEE WORKSHOP

The Emergency Medicine Foundation will host a grant workshop. Grant recipients will be expected

to attend the 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 that are potentially bogging down research projects, manage staff, and balance life. Travel expenses will be reimbursed by the Emergency Medicine Foundation.

RESEARCH FORUM

The Emergency Medicine Foundation hosts an EMF Research Showcase each year at the American College of Emergency Physicians Scientific Assembly/Research Forum. Awardees are required to present their work at the Research Forum immediately following the completion of the award year. Funds cannot be requested to cover the travel costs to attend, although the Scientific Assembly/Research Forum registration fee is waived for the presenters.

GRANT SUBMISSION

Submission via our on-line application system is required. Late applications will not be considered.
http://www.emfoundation.org/applyforagrant

APPLICATION INSTRUCTIONS

Submission in electronic format is required. No paper copies please. Please fill out the detailed questionnaire about your grant application on the link on our EMF grant page. 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. Once the "questionnaire" is completed, you will need to press submit then you will be guided to the next page where you can upload your application in a PDF format.

INCOMPLETE PROPOSALS OR PROPOSALS RECEIVED AFTER THE DEADLINE DATE INDICATED UNDER GENERAL INFORMATION WILL NOT BE CONSIDERED.

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, no smaller than 15 characters per inch. (If in doubt, use 12 pt. size font.) Finally, there must be no more than six lines of text within a vertical inch. Use black type; do **not** use photo-reduction.

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 is to be submitted using the enclosed forms. Number the pages consecutively at the bottom throughout the application. Do not use suffixes such as 5a, 5b. Type the name of the Investigator at the top of each printed page. **AN APPLICATION WILL NOT BE CONSIDERED IF PAGE LIMITATIONS ARE NOT OBSERVED**.

The application consists of the following sections:

1. **INFORMATION PAGE** (form attached)
   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**
   Brief summary of educational program and research proposal. Include research hypothesis, specific aims, and significance. This section must be no longer than 30 lines of text.

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 the SRC from guaranteeing that a grant will be reviewed by the same individuals reviewing the original application.

5. **RESEARCH PROPOSAL** (limit 12 pages)
   Use NIH form Continuation Format Page available on the internet at
   www.grants.nih.gov/grants/funding/phs398/phs398.html#

   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 importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- 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 how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- 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)

Use the NIH form Continuation Format 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)

Use the NIH form Continuation Format Page

List the Mentor and each associate investigator and consultant. 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

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 4 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.

9. RESOURCES AND ENVIRONMENT

Use the NIH Resources format Page available on the internet at
www.grants.nih.gov/grants/funding/phs398/phs398.html#

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.

10. 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. Provide a written justification of all major expenditures.

11. OTHER SUPPORT

Use the NIH form Continuation Format Page available on the internet at
www.grants.nih.gov/grants/funding/phs398/phs398.html#

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.

12. ETHICS

Use the NIH form Continuation Format Page (no page limit) available on the internet at
www.grants.nih.gov/grants/funding/phs398/phs398.html#

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. 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

13. 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 25-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.

14. SIGNED STATEMENT OF CONDITIONS (form attached)

Emergency Medicine Foundation
Information Page

Full Name with Titles:_____

Name of Institution:_____

Grant Category:_____

Project Title:_____

Amount Requesting:_____

Mentor, if applicable:_____

TABLE OF CONTENTS

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_____ Ethics

_____ Appendix

_____ Signed Statement of Conditions (see form below)

Applicant/Preceptor (*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 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 his or her co-sponsor, if applicable.

4. Any discovery that arises from work supported in part by the Emergency Medicine Foundation will be submitted for publication. Two copies of each publication will be furnished 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. Participation in Emergency Medicine Foundation recognition reception during the American College of Emergency Physicians Scientific Assembly is required. Grant money may not be used for travel to this event.

7. Participation in the Emergency Medicine Foundation Grantee Workshop is required. The Grantee Workshop will be held in Dallas, TX. Grant funds may not be used for travel, however, the Emergency Medicine Foundation will reimburse travel expenses.

8. Participation in Research Forum to give a poster and lightning oral presentation is required. This event takes place at the end of your project. Research Forum is held each year during the American College of Emergency Physicians Scientific Assembly. Grant money may not be used for travel.

9. If all requirements are met, funding will begin on July 1st. The Emergency Medicine Foundation reserves the right to terminate payments under this grant at its sole discretion.

10. 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.

11. Patent rights will conform to institutional standards. If none exist, the Emergency Medicine Foundation reserves the right to protect such interests.

12. 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 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
_____	/_____	
Date	Signature of Fiscal Officer	Type Name of Fiscal Officer