APSF/FAER
Mentored Research Training Grant (MRTG)

OVERVIEW & REQUIREMENTS
APPLICATION INSTRUCTIONS
06/06/2018

UPCOMING APPLICATION CYCLE:

2018
Application Deadline: December 14, 2018
Earliest possible funding date: July 1, 2019
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APSF/FAER Mentored Research Training Grant

OVERVIEW
The Anesthesia Patient Safety Foundation (APSF) and the Foundation for Anesthesia Education and Research (FAER) are offering the APSF/FAER Mentored Research Training Grant (MRTG) to develop the next generation of perioperative patient safety scientists. The intention is to fund one APSF/FAER MRTG to the sponsoring institution of a highly promising new perioperative patient safety scientist each year. This grant aims to help anesthesiologists develop the skills and preliminary data they need to become independent investigators in the field of anesthesia patient safety.

The APSF/FAER MRTG is a two-year, $300,000 primary investigator award (no co-investigators) that provides funding to a single sponsoring institution of an anesthesiologist faculty member who is within 10 years of their first faculty appointment. The funds may be split between the two years as necessary to complete the proposed research, with a minimum of $100,000 in each year. The APSF/FAER MRTG requires 60 percent unencumbered research and non-clinical career development time during the duration of the award.

AREAS OF RESEARCH
For the purposes of this grant program, patient safety is defined as the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from health care processes. The ultimate goal is that no patient is harmed in a preventable fashion by the medical care they receive. Patient safety research studies are scholarly endeavors that seek to understand the factors that cause preventable harm to patients or that aim to study interventions to reduce that harm.

Patient safety research includes the basic science of safety (e.g., fundamental understanding of how and why clinicians think and behave within complex healthcare systems, novel solutions to pharmacologic, procedural, or systems-based causes of patient injury), prospective and retrospective observational studies, and interventional (or implementation) studies. Patient safety research can be conducted in the laboratory or in real or simulated care environments. Depending on the research objectives, the project may be hypothesis-generating or hypothesis-testing. Similarly, either qualitative or quantitative methods may be used but the choice must be justified and conducted in a rigorous state-of-the-art manner.

APSF/FAER are interested in funding patient safety research directly relevant to the perioperative care of patients, as well as chronic pain and critical care medicine. While the PI of the proposal must be a board-certified anesthesiologist, patient safety research is usually a multi-disciplinary endeavor and this should be reflected in the proposal and in the composition of the mentorship committee, as appropriate. A senior, experienced patient safety research mentor and a rigorous career development plan will be essential to a successful application.

For the APSF/FAER MRTG, the following types of research will not be considered:
- Proposals involving research on cells, tissues or animals.
- Proposals that do not have a clear and direct link to patient safety as defined above.
- Proposals involving educational initiatives except when education or training are but one component of a broader (e.g., multimodal) intervention intended to improve patient safety in an operational environment.
- Proposals for traditional quality improvement activities unless clearly patient safety focused and structured as rigorous scientific experiments.
- Studies using only retrospective data that do not have a clear and compelling link to front-line patient safety practices.

Note that data science studies which, for example, study large datasets to detect and generate hypotheses about the etiology of rare patient safety events, or those that use retrospective data to create decision support that is then evaluated for its ability to change clinician behavior to avoid unsafe conditions or errors will be considered.

ELIGIBILITY
At the time of the award, applicants must meet all of the following eligibility requirements:
- Be a U.S. citizen, permanent U.S. resident, or holder of H-1 visa with minimum of three years remaining. (A J-1 visa holder does not qualify.)
• Be a graduate physician with an unexpired, permanent, unconditional and unrestricted license to practice medicine or osteopathy in at least one state or jurisdiction of the U. S.*

• Be certified by the American Board of Anesthesiology or in the examination system*

  *APSF/FAER will consider applicants with equivalent training or acceptance into ABA Alternative Entry Path (AEP). The acceptance letter must be provided to FAER at the time of grant application submission.

• Be an active member of the American Society of Anesthesiologists (ASA).

• Hold or be eligible for a full-time faculty position in a Department of Anesthesiology (primary appointments only) at an academic institution in the US

• Have a documented interest in and aptitude for a career as a Patient Safety Investigator. Prior authorship of peer-reviewed journal publications relevant to the field will be considered as one form of evidence toward this requirement.

• Have not previously received a federal or non-profit foundation career development award (equivalent or greater value than this grant) or a major investigator-initiated research grant (R21, R01 or equivalent). Recipients of this grant may not simultaneously be receiving support from a federal source for similar patient safety research. Should the investigator receive such an award during the course of this grant’s funding, the remainder of this grant’s funding would be cancelled and unused funds returned.

Mentor Requirements
• Commitment to mentor the applicant with a minimum of 5% dedicated effort.

• Prior evidence of successful mentorship of doctoral students, post-doctoral fellows or junior faculty.

• Tangible evidence of substantial experience as a patient safety (or related field) scientist including peer-reviewed extramural funding and peer-reviewed publications.

• Hold an accredited doctoral level degree

• Hold a full-time faculty appointment (preferably tenure track) in an accredited US academic institution.

Departmental and Institutional Requirements
• Commitment to provide the Applicant with at least 60% unencumbered research and non-clinical career development time during the duration of the award.

• Commitment to provide the Mentor with at least 5% unencumbered time to mentor the Applicant.

• Unencumbered provision of the facilities and resources required for successful completion of the Applicant’s proposed Career Development Plan and Research Project, as specified in the Application and Budget.

Recipients of this award agree to present their work at the first ASA annual meeting to be held after the conclusion of their grant. The Department Chair must commit to provide recipients with the time to present their research, if accepted for this presentation. Grant awardees will be reimbursed for travel costs up to $2,000 to attend and present at the ASA annual meeting, outside of the grant funding. Grant awardees may also be invited by APSF or FAER to present their work at other forums.

FUNDING
• The total funding amount for the APSF/FAER Mentored Research Training Grant is $300,000.
• Year one will be paid between $100,000 to $200,000. Year two will be paid between $100,000 to $200,000, but not to exceed $300,000 total over the two years.

• Yearly grant payments are made to the institution, not directly to the award recipient.

• Award renewal for the second year is contingent on the favorable review of the interim report.
Preparing the APSF/FAER MRTG Grant Application

Following are the required application elements for the APSF/FAER MRTG Grant Application:

A. COVER PAGE

The cover page should include general application information. It must include the following sections.

- **Title of Research Project**
- **Applicant (Principal Investigator) Information**: Name of applicant including academic degrees, office address, phone number, fax number and e-mail address.
- **Mentor Information**: Names and affiliations of the applicant’s mentor
- **Other Investigators or Consultants**: Names and affiliations of any other investigators or consultants
- **Department Chair Information**: Name, office address, and phone number of departmental chairperson
- **Institution Information**: Sponsoring institution and name, office address, phone number and e-mail address of the responsible institutional financial officer
- **Project Dates**: Start and end dates of proposed project

B. PROJECT ABSTRACT (≤100 words)

The Abstract should explain the proposed research study in language understandable to the average clinical anesthesiologist. The abstract should state the broad long-term objectives and specific aims of the project, its relationship to anesthesiology, as well as the research design and methods. The abstract should be a succinct and accurate description of the proposed work that can be understood when read apart from the application. The abstract will be used primarily for promotional purposes.

C. APPLICANT CAREER PLAN SUMMARY (≤250 words)

The Career Plan Summary should explain the applicant’s current situation, proposed career development activities, and future career plans in language understandable to the average clinical anesthesiologist. The Career Plan Summary must include at least the following elements:

- Applicant’s preferred full name and degrees.
- The submitting academic institution (and medical center if different).
- The preferred full name, degrees, and primary affiliations of the Applicant’s mentor
- The title of the research project and a summary sentence about the proposed project.
- The patient safety topic area(s) and research methods that will be the focus of the Applicant’s career.
- The Applicant’s long-term goals for improving perioperative patient safety.

D. CANDIDATE BACKGROUND (≤3 pages)

The candidate background should include the following elements:

- Career Goals and Objectives (include specific plans for post-award research activities, extra-mural funding and further career development)
- Career Development/Training Activities During Award Period
• Training in the Responsible Conduct of Research
• Timeline of Proposed Activities

E. RESEARCH PLAN (≤8 pages)
The research plan should include the following elements:

• **Significance**: Why is the proposed research important? How will it advance our understanding of and improvements in patient safety? How will it advance the Applicant’s long-term goals for improving patient safety? This section typically includes evidence that the Applicant has a strong fundamental understanding of the relevant patient safety knowledge and evidence.

• **Innovation**

• **Approach**: The Approach must include the following sections presented in the following order:
  
  o **Hypothesis and Specific Aims**: After a brief introduction, this section must articulate the Aims of the study and the hypotheses to be tested. All hypotheses must be stated in a way that they can be tested with empiric data. Note that some types of patient safety research studies may appropriately be hypothesis generating rather than hypothesis testing. In this circumstance, Specific Aims and associated Research Questions would be included in this section.

  o **Detailed Proposed Methods**: This section must include a detailed description of the proposed experimental design, the numbers and nature of study participants, the procedures to be employed, the independent variables to be manipulated, the dependent variables to be measured, and any covariates that will be included. The description should include a rationale for the choice of each dependent variable.

  o **Data Analysis Plan and Sample Size Justification**: This section must include a detailed analytical plan and a rigorous justification for the proposed sample size with sufficient detail to convince the reviewers of a low likelihood of either Type 1 or Type 2 errors. In addition to total sample size, the plan should include a statement of the number of eligible subjects in the study site’s patient population and the feasibility of adequate recruitment during the study period. It would be prudent to provide evidence of the initial and planned ongoing involvement of an experienced biostatistician. Note that investigators proposing use of qualitative or mixed methods will be held to equivalently high standards of rigor.

  o **Interpretation of Results**: This section should describe how the results will address the stated hypotheses, how alternative findings will be interpreted, what the investigator will do if the findings do not confirm the original hypotheses (this is especially important in multi-part studies or aims that depend on each other), and the patient safety significance of the expected results.

  o **Study Limitations**: This critical section must provide a comprehensive and realistic description of the study limitations and the methods by which the investigators have (or will) mitigate these limitations.

  o **Future Directions**: This brief section should describe what future studies are anticipated to flow from APSF’s investment in the conduct of the proposed study and why such future studies are important to long-term improvements in patient safety. Do not duplicate content in the Significance section above.

  o **Project Management and Detailed Timeline**: This section must describe how the PI will organize, plan, and oversee the proposed research. When a team of scientists will be involved, the Project Management plan should describe how the team will communicate and interact. Finally, this section should describe how the team will assure that the project is completed on time and within the proposed budget. The project timeline should be presented in a Gantt chart that includes specific detailed milestones and deliverables.
F. CITED REFERENCES (≤2 pages)

This section should provide evidence that the Applicant is very familiar with the most current relevant literature and will take a rigorous and scholarly approach to the proposed research. Please cite only the most relevant and important literature. References should be cited in the order in which they appear in the Research Plan and should use the format approved by the journal Anesthesiology.

G. MENTOR’S LETTER (≤4 pages)

- The mentor’s letter may be the most critical part of the application. The letter must be a PDF scan of a signed original on institutional stationary. The mentor’s letter must contain all of the following elements:
  - Training and Research Career Development Plan
  - Mentoring Plan
  - Progress Assessment
  - Anticipated Sources of Research Project Support
  - Nature and Extent of Supervision and Mentoring
  - Anticipated Non-Award Activities
  - Plan for Transition to Independence
  - Mentor Qualifications
  - Mentoring History

H. FACILITIES AND RESOURCES (≤2 pages)

This section describes the readily available relevant institutional facilities and resources that will support the Applicant’s career development and proposed research project. Please provide evidence (i.e., specific examples) of how the institution has invested in and supported prior patient safety research projects that have led to peer-reviewed journal publications. The Review Committee considers the institutional infrastructure very important to the success of new patient safety investigators.

I. HUMAN SUBJECTS (≤3 pages)

This section should succinctly address all of the elements typically found in an institutional human subjects committee (or IRB) application.

J. DATA MANAGEMENT PLAN

Describe how your data will be collected, handled, stored and analyzed with respect to HIPPA compliance, participant and patient privacy, confidentiality, and data security.

IMPORTANT NOTE: By the time of application review, the Applicant must provide APSF with evidence that they have undergone and are current with their institution’s approved human subjects/responsible conduct of research training.

FDA and Other Regulatory Compliance (if applicable). If medical devices are to be used on patients in the proposed study in ways that are not currently FDA-approved, the investigators must confer with their IRB regarding the need for an IDE. Similarly, if drugs are to be used in the proposed study in ways that are not currently FDA-approved, the investigators must confer with their IRB regarding the need for an IND. The relevant issues should be addressed in this section.
K. BIOSKETCH (<4 pages each)

Applicant and Mentor: Use the latest version of the current NIH biosketch template. (The template is available at FAER.org/research-grants/apply). Submit one biosketch for the Applicant and one for each mentor.

For the applicant and the mentor(s), the personal statement is an important part of the biosketch. Information provided within the biosketch personal statement is considered during grant review. The personal statement should be tailored to the specific grant application and used to convey information about your relevant qualifications and experience related to your role in the grant. The personal statement is most often written in the first person. For applicants, it should demonstrate your understanding of the project and how it will benefit your career, and for mentors, it should demonstrate your understanding of the project and how it will benefit your mentee’s career.

L. BUDGET (no page limit)

- Budget for each individual year and in total.

- Itemized budget justification. The application should provide sufficient explanation and rationale for each budget item to fully justify the proposed expenditure. Please explain all changes in item-level budgeted amounts between Years 1 and 2.

- Budgeting limitations. The following items can NOT be paid for from funds provided by this grant:
  - Salary or benefits of the Applicant that exceed 25% of the current NIH salary cap.
  - Construction, Renovations, or Furniture.
  - Capital equipment exceeding $10,000.
  - Applicant coursework, training or career development materials that exceed $10,000.
  - Any item considered an Indirect Cost by any Federal granting agency.

IMPORTANT NOTE: No indirect cost will be covered by this grant.

IMPORTANT NOTE: Violations of any of this grant’s financial stipulations will be grounds for immediate revocation of the award and full repayment of the total award by the sponsoring institution.

M. CHAIR LETTER CONTAINING AFFIRMATIONS (≤3 pages)

This letter must be from the Chair of the sponsoring institution’s Department of Anesthesiology. The letter must be a PDF scan of a signed original on institutional stationary. The letter must include the following elements:

1. Application’s significance to Anesthesiology;
2. Guaranteed regular (preferably tenure) track faculty appointment of the Applicant by the start of the second year of funding;
3. Departmental commitment to provide to the Applicant 560% research and academic time for the two-year project duration;
4. Departmental commitment to provide a minimum of 5% dedicated effort of the designated mentor;
5. Resource availability and commitment;
6. Internal peer review completed;
7. Management of awarded funds;
   a. No use of awarded funds for Investigator’s salary or benefits
   b. Commitment to provide specified facilities and resources
   c. Return of unused funds to APSF.

NOTE: No Appendices or supplemental material will be accepted.

NOTE: Applications that do not conform to all of the application requirements will not be considered.

N. RESUBMISSION STATEMENT

If you have previously submitted any research proposal to APSF or FAER, you must include a resubmission statement within your application. If you previously received an APSF or FAER grant, indicate what type of grant and the years of funding.

If you are submitting a revised application, the resubmission statement should provide a summary of the differences between this and the previous application. It should address the critiques of the original application point by point.

Applicants may submit up to two resubmissions of a revised research grant proposal.

If you are reapplying to APSF or FAER with a completely different research protocol, the resubmission statement should indicate how and why this project differs from the previous application.

O. CAREER DEVELOPMENT PLAN

The career development plan should be written by the applicant — in the applicant’s voice — with input from the primary research mentor or mentorship team.

Within the career development plan, the applicant should describe their motivation and commitment to a research career and should outline short-term and long-term career objectives. The career development plan should show clearly how the proposed research will prepare the applicant for an independent career as a physician-scientist. The plan should describe those specific elements planned for the training period, including formal or didactic training through courses, classwork, and participation in institutional research training (e.g., CTSA research training program).

To prepare to write the career development plan, the applicant should conduct a realistic self-assessment to identify research abilities and skills, as well as strengths and areas that need development. Along with the mentor(s), the applicant should discuss current skills and strengths and compare them with those needed for the research career choice.

The career development plan should outline the outcomes of the self-assessment and should define the approaches that the applicant will use to obtain the specific skills and strengths (e.g., courses, technical skills, teaching, supervision) together with anticipated time frames.
Submission of APSF/FAER MRTG Application

DATES & DEADLINES
2018 CYCLE:

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<td>Project start date</td>
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APPLICATION INFORMATION
Grant application information, forms, and templates can be found at [FAER.org/research-grants/apply](http://FAER.org/research-grants/apply).

APPLICATION PORTAL
The APSF/FAER MRTG Application can be accessed via the FAER portal at [https://www.grantinterface.com/Home/Logon?urlkey=faer](https://www.grantinterface.com/Home/Logon?urlkey=faer).

MATERIALS CHECKLIST

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<td>Provide project and contact information. See page 6 for requirements.</td>
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<tr>
<td>Project Abstract</td>
<td>See page 6 for instructions on what should be included.</td>
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<tr>
<td>Applicant Career Plan Summary</td>
<td>See page 6 for instructions and tips on what should be included.</td>
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<td>Candidate Background</td>
<td>See page 6 for instructions on what should be included.</td>
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<td>Research plan</td>
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<td>Cited References</td>
<td>See page 8 for instructions on what should be included.</td>
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<tr>
<td>Biosketch</td>
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<td>File uploads</td>
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<tr>
<td>Budget</td>
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<td>File upload</td>
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<tr>
<td>Chair Letter containing Affirmations</td>
<td>See page 10 for instructions</td>
<td>File uploads</td>
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<td>Resubmission Statement</td>
<td>If you have previously submitted any project to APSF or FAER, a resubmission statement is required. See page 10 for instructions on what should be included in the resubmission statement.</td>
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EVALUATION & AWARD SELECTION

Members of the APSF/FAER Safety Grant Review Committee will evaluate the grant applications for scientific merit using National Institutes of Health criteria and methods. Written critiques will be shared with all applicants.

REPORTING AND POST-AWARD REQUIREMENTS

Interim Report
In order to receive the second year of grant funding, all recipients must submit an interim report to APSF and FAER. This report is due 45 days prior to the completion of year one of the grant (e.g. May 15 for a June 30 completion date, and November 16 for a December 31 completion date).

The Interim Report should be no longer than four pages and should:

- Provide an explanation for any deviation from the original specific aims
- Summarize studies performed, the outcomes of the studies and their relationship to the specific aims
- Summarize accomplishments to date, providing a concise account of the course of the study and other relevant information that illustrates the status of the grant
- List all publications or manuscripts that have been published or are in preparation (APSF/FAER-related and others)
- List all presentations at scientific meetings relevant to the grant
- Provide a complete list of active and pending research support for the years the APSF/FAER grant is in effect
- Provide a financial report that summarizes year-one expenditures and the amount of funding requested to be carried over to year two. Also report any changes in the recipient’s extramural funding.
- Reaffirm commitments by the recipient, research mentor(s) and department chair.

Final Report
All APSF/FAER MRTG recipients must submit a final report to FAER, due 30 days after the completion of the grant.

Elements of the final report include:

- A report, written by the recipient with the mentor’s guidance that describes accomplishments to date and the final status of the project. The report should:
  - Outline outcomes of the specific aims and goals of the research project
  - Include a list of publication(s) resulting from the FAER-funded research project, as well as a list of subsequent research grant applications that are either in the review process or have been funded
  - Summarize the progress made by the recipient in terms of career development and research accomplishments
- A detailed final financial report from the institution’s Office of Sponsored Programs that summarizes all expenditures and notes any unused funds that should be returned to FAER.