CLINICAL INNOVATOR AWARD PROGRAM

REQUEST FOR APPLICATIONS

Applications are due: 5 PM ET
November 4, 2016

Introduction to Flight Attendant Medical Research Institute, Inc. (FAMRI)

In October of 1991, non-smoking flight attendants brought a Class Action suit in the Circuit Court of the Eleventh Judicial Circuit, Miami-Dade County Florida against the tobacco industry seeking damages for the diseases and deaths that have been caused by their exposure to secondhand tobacco smoke in airline cabins. The Class Action lawsuit filed by Miami attorneys Stanley M. Rosenblatt and Susan Rosenblatt, resulted in a partial settlement in October 1997 after four months of trial, which created FAMRI and provided other substantial benefits to class members.

FAMRI was formally established pursuant to Order of the Dade County Circuit Court as a not-for-profit, independent private foundation under the laws of Florida and Section 501(c)(3) of the Internal Revenue Code. Other than the initial funding, FAMRI has no connection with any tobacco company. FAMRI is governed and directed by a Board of Trustees, with a majority of non-smoking flight attendants, appointed by class counsel, Stanley M. and Susan Rosenblatt. Following peer review, FAMRI is assisted with its funding decisions by a prestigious Medical Advisory Board.

Medical Advisory Board

David Sidransky, MD, Chair
Director, Head and Neck Cancer Research
Professor, Otolaryngology, Head and Neck Surgery, Oncology, Pathology, Urology, and Cellular and Molecular Medicine
Johns Hopkins School of Medicine
Baltimore, Maryland

W. Jarrard Goodwin, MD
Chief Medical Officer
Sylvester Professor in Otolaryngology
University of Miami Miller School of Medicine
Miami, Florida
MISSION

FAMRI sponsors scientific and medical research for the early detection, prevention, treatment and cure of diseases and medical conditions caused from exposure to tobacco smoke.

To avoid all conflicts, any Principal Investigator (PI) or other participating applicant who is currently accepting tobacco industry funding, has recently applied for tobacco funding, or has any other association or consulting position with a tobacco company or affiliate of the tobacco industry is not eligible for FAMRI funding. All prior funding and/or association with tobacco companies must be disclosed and will be considered on a case-by-case basis.

Purpose of the Clinical Innovator Award (CIA) Program

The purpose of FAMRI’s CIA is to stimulate novel medical and clinical scientific research studies. The awards made beginning July 1, 2017 will be of a translational nature in sinusitis that are non-surgical and non-steroidal focused on better treatments or cures in the area of sinusitis. The emphasis is on the development of feasible interventions, to improve sinusitis treatments and cures.

Some of these breakthroughs occur when investigators from one field bring their expertise to bear on research questions in another field and form new cross-disciplinary collaborations. Through the
CIA Program, FAMRI wishes to foster these types of innovative breakthroughs and creative collaborative efforts.

**Research Scope for 2016-2017**

FAMRI’s interest is to support areas of investigation related to translational and clinical research as well as to have direct application to non-surgical and non-steroidal treatments and cures of sinusitis.

The specific topic for this award will be for an effective new treatment of sinusitis that is non-surgical and non-steroidal. FAMRI invites applications for preclinical or clinical studies to investigate optimal therapeutic strategies in sinusitis.

Promising areas of research include studies to:
- develop highly innovative molecular or cellular analysis technologies for clinical sinusitis research;
- develop novel capabilities involving biomarkers for targeting and treating sinusitis;
- accelerate clinical treatment of sinusitis;
- develop technologies that may be intended to have widespread applicability but must be focused on improving treatment of sinusitis;
- apply a biomedical engineering approach to the solution of sinusitis treatment;
- integrate, optimize, validate, translate or otherwise accelerate the adoption of promising tools, methods and techniques for effective treatment of sinusitis;
- apply an integrative approach to solve the problem in clinical or translational science relating to treatment and cure of sinusitis;
- facilitate the translation of innovative and promising treatment approaches for sinusitis into early clinical testing;
- conduct research with the potential to lead to new therapeutic interventions, diagnostics, or prevention strategies of sinusitis; and
- plan and speed to clinical translation and development (grants with a committed commercial partner will be viewed particularly favorably).

**Eligibility**

General eligibility for a FAMRI CIA requires a signed statement from an authorized institutional official and by the potential applicant that they can accept the terms of FAMRI’s non-negotiable, three-party Grant Agreement.

*See below Instructions for CIA Submissions for 2016-2017.*

Researchers with an advanced degree (MD, PhD or MD/PhD, or the equivalent) who work in not-for-profit institutions with US affiliation, such as an academic medical center, are eligible to apply. FAMRI will not support individuals who have current or pending funding from the tobacco industry or its affiliates.

In addition, researchers who apply to FAMRI for funding need not be US citizens. Investigators normally apply through and with an institution or organization that is qualified under United States
tax laws to receive grants from FAMRI, a US-based not-for-profit, independent private foundation. The applying institution receives and administers FAMRI’s funds and supervises the work of the PI. If the applying institution is organized under the laws of a country other than the United States, it must provide FAMRI any and all documentation that FAMRI may require, inform and content acceptable to FAMRI, to ensure that any grant from FAMRI shall be a “qualified distribution” under Internal Revenue Service laws and regulations, including but not limited to affiliation with a qualified US-based institution, a current affidavit from the applicant or an opinion of qualified legal counsel stating the facts and circumstances of the applicant’s organization and activities and certifying that any grant from FAMRI shall be a “qualified distribution.”

FAMRI does not accept submissions from PIs who are currently being funded by a FAMRI award; however, if their grants end by June 30, 2017, then they are eligible to apply. In addition, investigators with a FAMRI award that is in a no-cost extension period are also eligible to apply.

Research Requirements
The grantee must devote a minimum of 50% of professional time to research during the period of this award, and at least 15% of the grantee’s time (or a total of 15% of the combined times of the co-investigators) should be devoted to the research project described in the application.

Other Funding
An award will not be made, or withdrawn if made, if any of the following conditions exist:

1) the applicant becomes the PI on another peer-reviewed grant with the same general aims as those proposed in the application to FAMRI;

2) the applicant currently is receiving funding from the tobacco industry or its affiliates;

3) the applicant or applying school of the institution accepts funding from the tobacco industry or its affiliates (See Terms of Grant Agreement).

Funding Level
The total duration of the research plan is for up to three years, although payment will be made on a yearly basis and continuation of the project will be at FAMRI’s sole discretion, based on yearly acceptable progress, including peer-reviewed publication record. No-cost extension requests up to twelve months will be considered.

FAMRI plans to provide annual support up to $100,000 for direct costs plus no more than 8.5% for indirect costs. All forms regarding progress will be sent to the PI via FAMRI’s grant consultant, the American Institute of Biological Sciences (AIBS), at the appropriate time.

In the case of a transfer, when the PI notifies FAMRI of the change, he/she must supply a copy of the engagement letter, authority from the new institution that it accepts the terms of FAMRI’s non-negotiable, three party Grant Agreement and contact information for the new institution.

Both institutions are required to sign FAMRI’s Assignment of Grant.
Criteria for Review and Selection

Review and selection by FAMRI will be based on the following criteria:

- Evidence of the applicant’s commitment to a clinical or translational research career.
- Quality of the applicant’s formal research training (completed or proposed) and laboratory experience.
- Evidence of the applicant’s original research in the relevant area.
- Importance of this research to area of sinusitis.
- Originality of the research application.
- Appropriateness of the scope of the project.
- Quality of the research strategy and methods proposed.
- Commitment of the applicant’s department and institution to the area of research and to the applicant.
- Resources available to the applicant.

INSTRUCTIONS FOR CIA SUBMISSIONS FOR 2016-2017

Prior to submitting an application, a signed statement from an authorized institutional official and by the potential applicant that they can accept the terms of FAMRI’s non-negotiable, three party agreement is required. Please note that an application will not be considered if you and your institution cannot comply with the terms of FAMRI’s Grant Agreement.

Please visit [http://www.famri.org/researchers/current_and_upcoming_awards.html](http://www.famri.org/researchers/current_and_upcoming_awards.html) in order to download a copy of the Grant Agreement for the CIA Program as well as the Statement of Acceptance form.

Approval of Grant Agreement is due by 5 PM, ET, September 23, 2016.

An applicant may only serve as PI or co-PI on a single application.

Grant Policies and Conditions of the Award

While duration of the research plan is for up to three years, payment will be made on a yearly basis at FAMRI’s sole discretion and continuation of the project will be based on progress reports and publication record. Payments will be made by FAMRI in two installments on July 1 and January 1. The PI will be responsible for the scientific conduct of the research, and the Institution will be responsible for financial and administrative matters in accordance with acceptable policies and procedures for sponsored projects accounting and with the terms and conditions of the award. A separate financial account, available for audit, must be maintained for this award, and financial reports issued.

Questions

Please submit questions regarding this award to famri@aibs.org and refer to the Clinical Innovator Award Program. You will receive a prompt response.
Submission Instructions
You will be notified of your eligibility to submit a full application by September 23. This invitation will include a link for the full application submission site, as well as information on accessing the submission instructions. CIA applicants will need to follow the instructions provided for the CIA program.

Important Dates for FAMRI Submissions

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<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>5 PM EDT, September 23, 2016</td>
<td>Grant Agreement–Statement of Acceptance form due</td>
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<tr>
<td>September 23, 2016</td>
<td>Applicants notified</td>
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<tr>
<td>September 23, 2016</td>
<td>Eligible individuals granted access to full submission website</td>
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<tr>
<td>5 PM ET, November 4, 2016</td>
<td>Full applications and Tobacco Disclosure forms due</td>
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