

Flight Attendant Medical Research Institute, Inc.



CLINICAL INNOVATOR AWARDS PROGRAM

REQUEST FOR APPLICATIONS

Proposals and Tobacco Disclosure Statements Due: September 4, 2007

Introduction to Flight Attendant Medical Research Institute (FAMRI)

Flight attendants and their survivors brought a Class Action suit in Dade County Circuit Court (Miami) against the tobacco industry seeking damages for the diseases and deaths that have been caused by their exposure to second hand tobacco smoke in airline cabins in October of 1991. 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. Among other substantial benefits provided to class members, the settlement created FAMRI.

The Flight Attendant Medical Research Institute (FAMRI) was formally established 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, including a majority of flight attendants appointed by class counsel, Stanley and Susan Rosenblatt. A Medical Advisory Board and a Lay Advisory Board assist FAMRI in its decision making. The Chair and members of the FAMRI Medical Advisory Board are listed below:

Julius B. Richmond, M.D., Chair
Former United States Surgeon General
John D. MacArthur Professor of Health
Policy, Emeritus
Department of Social Medicine
Harvard Medical School
Boston, Massachusetts

David Sidransky, M.D.
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, M.D.
Director, Sylvester Comprehensive
Cancer Center
University of Miami School of
Medicine
Miami, Florida

Eloise M. Harman, M.D.
Professor of Medicine, Division of
Pulmonary and Critical Care
University of Florida College of
Medicine, Shands Hospital
Gainesville, Florida

David W. Kennedy, MD FACS
Professor and Director,
Division of Rhinology
Department of Otorhinolaryngology:
Head and Neck Surgery
Vice Director for Professional Services
and Senior Vice President
University of Pennsylvania Health
System
Philadelphia, Pennsylvania

Michael C. Fiore, MD
Professor of Medicine
University of Wisconsin
Director, Center for Tobacco Research
and Intervention
Madison, Wisconsin

David D. Waters, MD
Professor of Medicine
University of California, San Francisco
Chief, Division of Cardiology
San Francisco General Hospital
San Francisco, California

Mission

FAMRI is an independent not-for-profit foundation sponsoring medical and scientific research to combat the diseases caused by exposure to tobacco smoke and to ensure that health care providers ask the right questions of their patients about second hand tobacco smoke exposure.

ATTENTION ALL APPLICANTS

FAMRI hopes that a byproduct of funded FAMRI research is greater public awareness of the life-threatening dangers presented from breathing others' tobacco smoke and that one day soon all medical/scientific institutions will be completely smoke free and will refuse all tobacco industry funding. To avoid all conflicts, any principal investigator 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: The Clinical Innovator Awards (CIA) Program was established to stimulate novel medical and clinical scientific research studies on the topic of second hand tobacco smoke. New technologies to detect second hand tobacco-caused illnesses and novel therapies to treat these diseases are of high priority to FAMRI.

While considerable government and non-government funding is available to support established mainstream biomedical research projects, funds for high-risk projects are generally quite limited. Scientific peer review, while critical for maintaining the quality and rigor of the research enterprise, usually emphasizes preliminary data and feasibility of expensive innovation and risk taking. Despite this, scientific progress is often characterized by steady incremental advances or even plateaus interrupted by innovative breakthroughs in technology or thought that rapidly

move a field to a new plane of inquiry. 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. It is these types of innovative breakthroughs and creative collaboration that FAMRI is hoping to foster with the Clinical Innovator Awards.

Research Scope

FAMRI's primary focus is on tobacco smoke studies. FAMRI will support research in five main areas relating to exposure to second hand tobacco smoke: respiratory disease (with emphasis on chronic sinusitis), cancer, cardiovascular diseases, epidemiology and public health, and reproductive diseases. FAMRI's primary interest is to support areas of investigation related to translational and clinical research. Basic research with bearing on second hand tobacco smoke exposure is also encouraged. Animal use for basic research is restricted to mice and rats unless the animals are not sacrificed as part of the research. **This research must be related to and have direct application to the prevention, early detection, treatment, and cure of diseases caused by tobacco smoke exposure.**

A list of study areas of interest with respect to diseases currently associated with exposure to tobacco smoke includes, but are not limited to:

Chronic sinusitis	Cilia abnormalities or alterations
Chronic bronchitis	Chronic obstructive pulmonary disease (COPD)/Emphysema
Aggravation of asthmatic conditions and allergies	Heart disease/cardiovascular disease
Alzheimer's Disease	Complications in pregnancy
Endocrine diseases	Infertility
Inflammatory Diseases (Arthritis)	Chrohn's Disease
Cervical cancer	Bladder cancer
Breast cancer	Ovarian cancer
Prostate cancer	Head and neck cancer

Lung cancer

FAMRI is interested in clinical and translational research, from basic molecular mechanisms of disease to occupational health. These areas include:

Studies on the etiology and pathogenesis of these tobacco-caused diseases in man

Therapeutic interventions

Clinical trials

Research to establish a protocol for inquiry regarding second hand smoke exposure by all health care professionals

Regardless of the research proposed, it is important for the proposal and abstract to discuss the role of tobacco smoke, including second hand smoke, in the disease proposed for study and how the research proposal will further the current understanding of issues related to tobacco smoke.

Eligibility

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, or other associations with, the tobacco industry**; therefore, if an applicant has current tobacco funding that will cease prior to receiving a FAMRI award, the applicant is still considered ineligible. If the applicant has a pending grant under consideration by the tobacco industry, the FAMRI proposal will be deemed ineligible. Applicants are considered eligible for a FAMRI award if their institution has past tobacco industry funding. However, if the institution has current tobacco industry funding, FAMRI reserves the right to withhold funding until a mutual remedy is agreed upon (see Grant Policies and Conditions of the Award).

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-grantees) should be devoted to the research project described in the application.

Other Funding

An award will not be made if, prior to the commencement of this award, the applicant becomes the Principal Investigator on a peer-reviewed grant with the same general aims that are proposed in the application to FAMRI. Furthermore, an award will not be made if the applicant currently is receiving funding from the tobacco industry or its affiliates. (See Grant Policies and Conditions of the Award).

Funding Level

The award will provide \$100,000 per year for up to three years with a possibility of a no-cost extension for one year. Awardees will receive \$100,000 per year for direct costs plus no more than 8.5% for indirect costs. Awardees will be sent progress report forms in April for delivery by late May.

Criteria for Review and Selection

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

- Evidence of the applicant's ability to conduct the proposed research
- Potential importance of the proposed research in the field and to health in general
- Originality of the research proposal
- Appropriateness of the methodology and scope of the project for the length of the award
- Relevance of the proposed research to the study of tobacco smoke exposure

INSTRUCTIONS

2007 CLINICAL INNOVATOR AWARD PROPOSALS

Proposals that do not comply with the prescribed format will not be considered.

The Clinical Innovator Award application form and FAMRI's Tobacco Disclosure Statements (TDS) may be downloaded from the FAMRI Web site: <http://www.famri.org>

Application Forms

Please use the application form provided for your proposal. The applicant's name should be on the upper right corner of each page. Please use 12-point font. Submit applications with the signed signature page electronically as a pdf file to famri@aibs.org by September 4, 2007, 5 pm Eastern Time. Send the completed and signed tobacco disclosure forms as a separate pdf file to famri@aibs.org by September 4, 2007, 5 pm Eastern Time. (See Submission Instructions).

Applications must contain the following items:

1. Title Page

Investigator Information: Name; Degree; Job Title; Contact Information; (institutional address, telephone, email)

Project Title: (No more than 50 characters)

Project Area (check the most appropriate category)

Clinical Research Type (check all applicable categories)

Is the proposal a resubmission?

Animal Usage:

Projected AALAC Approval Date (if applicable)

Human Subject Usage:

Projected IRB Approval Date (if applicable)

PI Signature:

Institutional Official to be Notified if Awarded:

Institutional Official Signature:

2. Table of Contents (Please number the pages of your proposal and insert the page numbers in the Table of Contents)

3. Abstracts

Technical Abstract

State the broad long-term objectives and specific aims, making reference to their relatedness to one or more of the disease/disorder areas (refer to Research Scope). Briefly describe the research design and methods for achieving the goals.

Layman's Abstract

Research by investigators funded by FAMRI is of interest to a large audience outside the scientific and medical communities. For this reason each application should provide a brief summary written for the general public describing the project's objectives, proposed methodology, anticipated results, and practical significance. Provide the specific number of subjects to be tested and a description of them, i.e., the number of voluntary smokers and involuntary smokers, including those involuntary smokers with higher levels of exposure, recognizing that virtually everyone is exposed to some degree of second hand tobacco smoke. The Abstract should also include an explanation as to why the research is relevant to the subject of second hand tobacco smoke.

If the application is funded, these abstracts may be used in FAMRI publications.

4. Budget and Budget Justification

Budget forms for Years 1, 2, and 3 are included within the downloadable proposal form.

5. Other Research Support

List all current or pending internal and external sources of funding (including government, corporate, and other) that would overlap the funding period of this award. Each listing must follow the format below:

Source of funding (e.g., agency and grant #)

Project title

Funding period

Applicant's role in the project (principal investigator, co-investigator, etc.)

Annual direct costs

Total amount of the grant

Amount of funding available to the applicant

The project's relationship to the work in this application. Specifically address overlap.

6. List of Acronyms

Please include a list of all acronyms used in the application

7. Research Plan (Maximum 10 pages)

The research plan should be divided into:

Hypothesis and specific aims – indicate the hypothesis that forms the basis for the research and specific aims that you intend to accomplish with this award and the relationship to tobacco smoke.

Background and significance – discuss the scientific knowledge that led to the stated hypothesis and specific aims, why this project is novel, the importance of the proposed research, and its potential relevance if successful.

Preliminary results – it is not expected that the applicant have preliminary results in the proposal, however if results are available they should be described.

Research design and methods – briefly describe the procedures and methodologies that will be used to accomplish the study aims, and discuss how potential pitfalls might be avoided.

Time frame – provide an estimated time for accomplishing key goals. If the proposed work is likely to take longer than three years, indicate the total time frame and overall scope of the project and what you hope to accomplish in the first three years.

8. Literature cited

Provide a list of all references used (no page limit).

9. Resources

Specify what general laboratory/office facilities are at your disposal to conduct your research. Indicate what specialized equipment and facilities are required.

10. Biographical Sketches

Principal Investigator (No Page Limit) The biographical sketch should include the applicant's name, position, and title. This should be followed by education/training information (earliest training and degree first) and research and professional experiences including the applicant's current position. Please include complete references to all scientific, medical publications during the past four years as well as pertinent earlier publications. You must include a category with any research of work funded by a tobacco company, Council for Tobacco Research or other tobacco industry affiliate.

All Co-investigators Include biographical sketches of all key personnel who fall into this category, as described, above.

11. Consultants/Collaborative/Contractual Agreements

Include letters verifying any consulting, collaborative or contractual agreements necessary for the conduct of the research. Indicate in a list format the attached letters. If feasible, please include a biographical sketch of your references.

12. Resubmissions

If you are submitting a proposal that has been reviewed previously, you should respond to the reviewers' comments in a section preferably no more than five pages long.

Tobacco Disclosure Statement

FAMRI does not support individuals who have current or pending funding from or other associations with the tobacco industry.

FAMRI requires one copy of the institutional TDS form and one individual TDS from each institution and every investigator/staff personnel named in the project. Please send completed, signed forms as a pdf file (separate from the application) to famri@aibs.org to arrive by 5 p.m. EST on September 4, 2007.

Even if an applicant has current tobacco funding that will cease prior to receiving a FAMRI award, the applicant is considered ineligible. If the applicant has a pending grant under consideration by the tobacco industry, the FAMRI proposal will be deemed ineligible. Applicants are currently considered eligible for a FAMRI award if their institution has past tobacco industry funding. If the institution has current tobacco industry funding, FAMRI reserves the right to withhold funding until a mutual remedy is agreed upon. FAMRI also reserves the right to suspend current funding if its policy on tobacco affiliations is violated.

Applicants must disclose their institutions' (all colleges, schools, etc.) prior, current, and pending support by any tobacco company or affiliate as set forth on the FAMRI Web site: www.famri.org. The disclosure should include the title of the grant, the time period, the total funding provided and the department of the institution that has received or has applied for the grant. The institutional TDS must be signed by both the applicant and the institution's Grants Administrator/Officer. In addition, all investigators associated with the project must each submit an individual TDS disclosing his or her personal affiliations with the tobacco industry or affiliates listed on the FAMRI Web site and using the above cited criteria. Information provided on the TDS will not affect the scientific review of your application, but will be maintained as part of your permanent files with FAMRI should an award be made. If an award is made, violation of FAMRI's policy on tobacco affiliations will result in the institution's and candidate's ineligibility for future awards.

If you have any questions regarding completion of the TDS and eligibility, please contact Elizabeth Kress, FAMRI Executive Director. Phone (305) 379-7007; e-mail ekress@famri.org.

Timeframe for Submission, Notification, Awards and Annual Symposium

September 4, 2007	Proposals are due
September 4, 2007	Tobacco Disclosure Statements due
March 1, 2008	Grantees are notified
July 1, 2008	Start date of award
Spring, 2008	Annual Symposium

Grant Policies and Conditions of the Award

Please read the following conditions of the Award which constitute the Grant Agreement. The applicant and Grantee Institution's delegated officer will need to agree to these terms and indicate their agreement by signing the face page of the application when submitting a proposal.

Successful applicants are considered a party to the Agreement and will be required to sign said Agreement concerning the conditions and policies under which the grant is awarded prior to notice of award being issued. The award itself will be granted to the grantee's institution and not to the individual. The investigator will be responsible for the scientific conduct of the research, and the institution will be responsible for financial and administrative matters. FAMRI will issue each year's grant payment in one installment, on or before July 1. Annual progress reports will be due six weeks in advance of issuing each funding installment. The institution is responsible for administration of funds in accordance with acceptable policies and procedures for sponsored projects, accounting and in accordance with the terms and conditions of the award. A separate financial account, available for audit, must be maintained for this award, and a financial report issued, if requested.

Use of Funds

The funds are to be used in general agreement with the research budget plan submitted with the application, but the foundation will allow the investigator to re-budget reasonable amounts in accordance with his or her needs. However, the investigator's effort cannot decrease 15% without FAMRI's approval.

Funds from Tobacco-Related Entities

The Principal Investigator and the Grantee Institution agree that it, he or she, and any person who works on Principal Investigator's research or administrative staff, and any affiliated contractors, associates or agents, shall not accept any grant, consultancy fees or other gifts of value from any tobacco manufacturer, distributor, or other tobacco-related entity and will not work as a paid or unpaid consultant for any tobacco company.

Conditions Necessitating a Refund to FAMRI or Withholding of Grant Funds

If any of the following circumstances occur, FAMRI may, at its discretion, in addition to other remedies available to it, require that Grantee Institution immediately repay the full amount of the Grant funds that were unspent as of the date of the occurrence, and FAMRI shall have no further obligation to distribute any unpaid portion of the Grant to the Grantee Institution:

1. The purpose of the Grant has been fully completed prior to the time that all funds in the Grant have been expended or the period of time indicated in the Grant Agreement for the completion of the purpose of the Grant has expired (without being extended with the consent of FAMRI).
2. The Grantee Institution is no longer exempt from federal taxation or becomes a private foundation as defined in Section 509(a) of the Internal Revenue Code.
3. The Grantee Institution, for any reason, becomes unable to carry out the purpose of the Grant stated in the Grant Agreement, or otherwise violates the terms of the Grant Agreement.

4. Any party named in this Agreement accepts a grant, serves as a consultant, or accepts other gifts of value from a tobacco manufacturer, distributor, or other tobacco-related entity.
5. The Principal Investigator is no longer employed by, or associated or affiliated with, the Grantee Institution, or announces that he/she will no longer undertake the Research Project at the Grantee Institution, in which event the Grant Institution shall suspend all work under the Grant until FAMRI has made an independent determination of any future expenditure of funds under the Grants, and any revision of the Grant, including reversion of unobligated amounts to FAMRI. The Grantee Institution agrees to notify FAMRI immediately upon the occurrence of any of the circumstances mentioned above.

Authorizations

The signers of the Grant Agreement represent and warrant to FAMRI, without reservation, that they have full and complete authority to commit and obligate the Grantee Institution and the Principal Investigator, as the case may be, to all of the terms and conditions of this Agreement and that there exists no understanding, law, regulation, or other restriction on their ability to do so and on the abilities of them or their organizations to comply in all respects with each and every term and condition of this Agreement.

General

The Grant Agreement is governed by the laws of the State of Florida. Upon bankruptcy of Grantee Institution, or any effort to attach or claim any or all of the proceeds of the Grant, any remaining funds held by Grantee Institution under the Grant immediately shall revert to and become the property of FAMRI. This Agreement is the entire agreement of the parties regarding the Grant. No other oral or written understandings exist. The Agreement may be modified only in a writing that is fully executed by both parties. Award of the Grant and any and all communications between the Principal Investigator, the Grantee Institution, FAMRI and others shall not constitute any implied or actual promise of future funding by FAMRI for any work of the Principal Investigator or the Grantee Institution. Principal Investigator and Grantee Institution shall not do anything in reliance on future funding unless and until they receive and execute a written grant agreement from FAMRI that provides for such funding.

Human and Animal Subjects, Safety, and Environmental Health Issues

All research conducted as a part of the FAMRI award involving human subjects shall follow Public Health Service guidelines and shall have the approval of the appropriate institutional review board (IRB). All research shall also be performed in accordance with all relevant institutional and federal policies and guidelines relating to radiation and environmental health and safety. Pending IRB approval or copies of IRB approval must be submitted prior to funding of a grant involving human subjects.

FAMRI will only support animal research that utilizes mice or rats. Research involving other animals will not be considered unless the animals will not be sacrificed as a result of the research. All research shall be performed in accordance with all relevant institutional and federal policies and guidelines. Pending Association for Assessment of Laboratory Animal Care (AALAC) approval must be submitted prior to funding of a grant involving animal subjects.

Grantee Progress Reports

Reviews of work and progress will be made on an annual basis. A non-competitive progress report form will be sent to each grantee in the spring. This form must be completed, submitted, and approved.

Publications

All publications (as well as posters and abstracts at scientific meetings) that result from the support provided by FAMRI must acknowledge that support in writing.

Collaboration

All grantees (YCSA, CIA, Distinguished Professors and Centers of Excellence investigators) are encouraged to collaborate with fellow grantees and may be required to participate periodically in FAMRI's collaborative efforts.

Patents, Licensing, and Copyrights

If any idea conceived and reduced to practice as a result of the Grant results in material subject to patent or copyright, the disposition of any such rights, and income derived therefrom, shall be subject to the policies and procedures of the Grantee Institution. FAMRI's participation in intellectual property and inventions resulting from its funding will be governed by the provisions of the National Institutes of Health model based on the Bayh-Dole Act of 1980.

Early Termination or Transfer of Research Funds

If the grantee decides to discontinue the research project or leave his/her institution, FAMRI must be notified immediately. If the awardee accepts funds from the tobacco industry during the pendency of the FAMRI grant, he/she must notify FAMRI that they are terminating his/her award.

Indemnification

The Grantee Institution agrees to hold FAMRI and its employees and trustees/directors harmless from and indemnify them for any and all losses, expenses and/or attorney fees and costs, including any appeals, incurred as a result of claims against them arising out of the funded proposal.

Independence of Parties

The parties agree that all of their relationships, including but not limited to the granting or payment of the subject award is not a joint venture, partnership or any other form of business association between the parties. FAMRI agrees that the Grantee Institution is an independent organization over which FAMRI has no control or right of control. The parties further agree that the research to be performed is independent research over which FAMRI has no control or right of control.

Questions

Please submit questions regarding this award to famri@aibs.org, and refer to the Clinical Innovator Awards Program. You will receive a prompt response.

Submission Instructions

The application and TDS forms may be downloaded from <http://www.famri.org>. Each individual and institution listed on the proposal must submit a tobacco disclosure form.

The full application with the signed signature page should be sent electronically in a PDF file to famri@aibs.org by September 4, 2007, 5 pm Eastern Time. The completed, signed institutional and individual tobacco disclosure forms should be sent as a separate PDF file to famri@aibs.org and must be received by September 4, 2007, 5 pm Eastern Time.