

## 2009 FREA PROGRAM

The Faculty Research Enhancement Award Program supports short term faculty pilot projects. The program is an activity of the Office for Access to Biomedical Research (ABR) which is funded by an EARDA grant (NICHD) awarded to FIU (PI: Sylvia Smith). The purpose of the seed grant activity is to provide opportunities for faculty to carry out the following types of developmental biomedical and behavioral research: (a) Pilot or feasibility studies, and (b) Development of new methodologies or technologies. Projects identified for support under EARDA are initially selected at the grantee institution; and it is expected that the data obtained would enable the FREA PIs to develop applications for research support from the NIH and other Federal agencies as well as from foundations or other private funding organizations.

The 2009 FREA program has approximately \$60,000 available to support pilot research projects that focus on the mission areas of any of the NIH Institutes and Centers and the National Library of Medicine (i.e., biomedical, behavioral, and social sciences research with public health significance, health disparities research, bioinformatics, etc.). (<http://www.nih.gov/icd/>) The maximum amount for the support of a single pilot research project is \$10,000 (direct costs). The duration of the pilot project budget period is 12 months. Pilot project support is not renewable. All funds for the support of pilot research projects are restricted in the Notice of Grant Award, pending the administrative review and written approval of pilot research projects by the Extramural Associates Program, National Institute of Child Health and Human Development.

Because FREA pilot project support is a component in the EARDA grant award and not an independent NIH research award, pilot projects do not follow the just-in-time requirement for IRB approvals. Accordingly, FREA PIs must provide current IACUC and IRB approvals as appropriate when their projects are submitted for consideration for support.

**Animals/Human Subjects.** If animals or human subjects will be used in the study, indicate the Internal Review Board (IRB) or Internal Animal Care and Use Committee (IACUC) Assurance Number and the date reviewed on the Form 398 face page, as appropriate. Also provide the IRB approval and sample consent form or IACUC approval (as appropriate) in the Appendix of your application.

FREA applicants should use PHS Form 398 which may be downloaded at <http://grants.nih.gov/grants/forms.htm> . For ease of integrating the individual PHS 398 form pages into a single file, pilot project PIs are also encouraged to select the MS Word version of the PHS 398 forms. Specific guidance for development of pilot projects and details for FREA proposal preparation are available at <http://www.fiu.edu/~abr>. A hard copy of the guidelines can be obtained from the ABR Office (HLS 392/395). Pilot projects should have relevance to the NIH mission (i.e., biomedical, behavioral and social sciences research with public health significance, bioinformatics, health disparities research, etc.)

## **Key Dates**

Letter of Intent (LOI) submission to ABR Office: **January 20<sup>th</sup>, 2009**

ABR/FREA program LOI to the EARDA program: **February 1<sup>st</sup>, 2009**

Submission of FREA application to ABR: **February 6<sup>th</sup>, 2009**

Completion of internal/external review of FREA applications by ABR: **March 3<sup>rd</sup>, 2009**

Submission (ABR) of selected FREA applications to NIH: **March 6<sup>th</sup>, 2009** (receipt date)

NICHD/EARDA Administrative review: **May/June 2009**

Earliest anticipated date funds will be available through the ABR office: **July 2009**

## **Letters of Intent**

Potential FREA PIs are required to submit submit a letter of intent (LOI) to the FREA program director via email ([smiths@fiu.edu](mailto:smiths@fiu.edu)) by January 20<sup>th</sup>, 2009 to advise the FREA Program of their intent to submit an application for support of a pilot project. The LOI should include the PI's department affiliation, title of the project and an abstract of the proposed project. Although the letter of intent is not binding, the information provided allows the ABR director to estimate the potential workload and plan the internal administrative review.

## **Pilot Project Application Process**

FREA applications, prepared using PHS 398 forms (see FREA application guidelines), should be submitted as a single electronic file to the ABR director, Sylvia L. Smith, Ph.D. at [abr@fiu.edu](mailto:abr@fiu.edu) or [smiths@fiu.edu](mailto:smiths@fiu.edu). Upon receipt of the application, the ABR office will acknowledge receipt of the application, administratively review it for completeness, and assign it for internal/external review for technical/scientific merit. Based on reviewer assessments the applications will be ranked and the top six selected and submitted by the ABR office to the NICHD/EARDA program for approval. It is the policy of the EARDA program that support will not be provided for projects that have significant scientific overlap with projects that are supported by other NIH programs. Incomplete applications will be returned to the FREA PI. Upon approval of a pilot project the FREA applicant will be notified and funds will be available **through the ABR office**. Processing and approval of all pilot project requisitions (once received electronically by the ABR office) and hiring of OPS personnel (upon the recommendation of the FREA PI) will be done by the ABR office staff.

## **Review Criteria**

Similar to other proposals submitted to NIH, the scientific merit of FREA pilot project proposals are based on the review considerations listed below.

1. Background: Is there evidence of a literature search (or previous study) that led the PI to decide that the topic in question needs study?
2. Significance: Does the study address an important public health issue through basic and/or biomedical research? If the aims of the pilot study are achieved, it is likely that the anticipated findings can be used to build a research project? Does the proposed research have potential public health implications? The project relates to the mission of which NIH institute and/or center?

3. Approach: Are the conceptual framework, design, methods, and analyses (including statistical approaches) adequately developed or described, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
4. Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project develop new methodologies or technologies?
5. Investigator: Is the PI well suited in terms of training to carry out the work?
6. Environment: Does the proposed study benefit from any unique features of the scientific environment, or subject populations, or employ complementary expertise through a mentor or consultant?
7. Human Subjects/Animals: Are animals or human subjects involved? Was the study reviewed by the IRB or IACUC at the grantee institution and the results provided? If human subjects are involved, did the PI provide the gender/recruitment plan?
8. Budget: Is the budget appropriate for the proposed study?

The administrative review of FREA pilot projects is documented using a review template designed for pilot projects. The projects are scored and an overall evaluation (cumulative score) is provided to each FREA PI advising him/her whether the pilot project will be forwarded to NICHD/EARDA with a recommendation for support of the project.

The EA program officer assigned to an EARDA grant examines the FREA pilot projects submitted by the EARDA PI (Dr Smith, director, ABR) to identify projects that involve human subjects or animals and to ensure that the necessary IRB or IACUC approvals were submitted with the pilot project application.

- An Institutional Review Board approval must be included in the appendix of the application for non-exempt projects that involve human subjects. A copy of the consent form and the Targeted/Planned Enrollment Table must also be included in the application. Since pilot projects are not supported through typical NIH awards, the just in time concepts for IRB approvals do not apply. Projects must have IRB approvals to be administratively reviewed.
- A current IACUC approval must be included in the application for projects that involve vertebrate animals. An animal welfare assurance must be on file for the project in the Office of Laboratory Animal Welfare prior to submitting a pilot project for consideration for support.