

EXTRAMURAL RESEARCH DEVELOPMENT AWARD (EARDA) PROGRAM
Development, Submission and Review of EARDA Pilot Research Projects

Key Dates

Letter of Intent: January 15, 2008; March 15, 2008

Pilot project application submission/receipt dates: February 1, 2008; April 1, 2008

Administrative reviews: April/May 2008; June/July, 2008

Anticipated earliest pilot project start date: June 2008; August 2008

1. EARDA Program Background

The Extramural Associates Program promotes the entry and participation of women's colleges and institutions with significant minority student enrollment in biomedical and behavioral research, primarily through the EARDA grant program. The program provides training for academic research administrators, also called Extramural Associates, to develop broad skills in research administration, including but not limited to, enhancing their knowledge of research, research training, and research infrastructure funding opportunities at NIH and related agencies; developing skills in the fundamentals of preparing research grant applications, contract proposals, training grant and fellowship applications; and on effectively guiding students toward careers in science and research. Support is also provided for establishing Offices of Research Development that will work cooperatively with an existing Office of Sponsored Research, or in the absence of such an office, to work independently.

In supporting the establishment of Offices of Sponsored Programs or Offices of Research Development, the EARDA grant program also aims to encourage the development of and/or enhance a culture of research at women's colleges and institutions with significant minority student enrollment, by providing support to encourage the establishment of a seed grant program. 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:

- Pilot or feasibility studies, and
- Development of new methodologies or technologies

Projects identified for support under EARDA are selected at the grantee institution; and it is expected that the data obtained would enable the PIs to develop applications for research support from the NIH and other Federal agencies as well as from foundations or other private funding organizations.

2. Available Funds/Allowable Costs

2(a) Available Funds for Pilot Projects

Annually, up to \$40,000 in direct costs may be requested for the support of 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 allowable for the support of a single pilot research project is \$20,000 (direct costs) per budget period for up to two years. EARDA pilot project support is not renewable. Note that funds allocated for the development of research administration infrastructure and related activities may not be used to support pilot projects.

2(b) Carryover of Pilot Project Funds

Pilot project funds may be carried over into a new budget period ONLY if such funds have been allocated for an approved pilot project prior to the end of the current EARDA grant budget period. For example, if an EARDA PI has \$10,000 in pilot project funds remaining in FY2007, those funds may be used to support a pilot project which begins in FY2008 only if the project for which the funds would be used is submitted to the EA Program, reviewed, and approved prior to the end of the FY2007 budget year.

2(c) Budget Periods and Allowable Costs

The duration of the pilot project budget period is 12 months. However, because the nature and scope of pilot research projects may vary, the project period may extend for up to two years. The PI may request support for his/her level of effort on the project, small equipment, student support, consultant services, and travel for the PI and one student to attend and/or present their work at one scientific conference. Travel support is limited to no more than \$1,500 dollars per budget period.

All funds requested 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.

3. The Pilot Project Application

Potential applicants are encouraged to use PHS Form 398 which may be downloaded at <http://grants.nih.gov/grants/forms.htm> for use. 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 pilot projects is provided below.

3(a) Make sure to capture the EARDA grant number and title of the pilot project in item 1 on the PHS 398 face page. Also capture information about the pilot project PI in items 3a-d.

3(b) 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. All non-exempt research that involves human subjects must include a Target/Planned Enrollment Table.

Because 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, PIs MUST provide IACUC and IRB approvals as appropriate when their projects are submitted for consideration for support.

3(c) Complete Form pages 2, 3, 4, and 5 as appropriate. Be sure to provide a detailed budget and budget justification (Form pages 4 and 5).

3(d) Biographical Sketch Format Page. Include a biographical sketch for the pilot project PI and any key participants. PIs are encouraged to work with mentors or consultants who can provide guidance in regard to the design of the pilot research project and with data analysis. A robust data analysis is highly desirable.

3(e) Research Plan. The research plan describes the proposed research, stating its significance and how it will be conducted. A full discussion on developing the research plan can be found at http://grants.nih.gov/grants/writing_application.htm#developPlan. Excerpts from that document are provided for your convenience.

The research plan component of the application should include the following four sections:

3(e)(1). Specific Aims: what you intend to do

Specific aims are a formal statement of the objectives and milestones of the research project in regard to testing the hypothesis. List your aims and then all the experiments you'll do to support each aim. Keep in mind that your experiments support your aims, and your aims are the test of your hypothesis. The purpose of the Specific Aims section is to clearly and concisely describe what the proposed research is intended to accomplish.

Specific aims should:

- Include specific research objectives
- Be hypothesis-based
- Be obtainable within the proposed timeframe
- Fit together in an overall framework
- Be well-focused rather than broad and diffuse
- Limited to one page.

A strong grant application is driven by a strong, solid hypothesis with clear research objectives. You may also want to make a brief statement concerning the innovation of your proposed research.

3(e)(2). Background and Significance: Why the work is important.

The Background and Significance section should thoroughly describe the literature, particularly any scientific controversies in the field, yet should support your views and hypothesis. Make sure that you have identified key references.

Be sure to critically evaluate existing knowledge that leads to your pilot project, and specifically identify the gaps that the project is intended to fill. Explain why the literature about your research leads you to think this topic needs study. This should not be a thesis, but should provide information that directly pertains to the scientific need for your project.

Make sure the significance of the topic is explicitly stated. What is the payoff to biomedical or behavioral sciences and (if applicable) to public health? State how scientific knowledge or clinical practice will be advanced, if the aims of the application are achieved. Describe the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive your field. In summary, the background and significance—

- Show that you have critically evaluated existing knowledge, including background literature and relevant data.
- Include references that reflect up-to-date knowledge of the field
- Specify existing gaps that the project is intended to fill
- Identify controversies that the project is designed to resolve
- Conveys the importance and relevance of the research aims
- Highlight potential impacts
- Address how research results can be applied

Two to three pages are recommended for the Background and Significance Section.

3(e)(3) Preliminary Studies: What you have already done.

Although the goal of a pilot project or feasibility study is to collect data to support a “full” research grant application, pilot project PIs should not omit this section. Use this section to support your hypothesis and the future direction of your research, and to show your expertise and knowledge of the experimental approach, methods, data collection and analyses to be employed in your project.

“Preliminary” data relevant to the pilot project may consist of your own publications in the field, publications of other researchers, unpublished data from your own laboratory or others, or a combination of these. This section of the application is intended to establish the PI’s experience and competence to pursue the study and the likelihood of success. With this in mind—

- Discuss how previous work leads to the current proposal
- Emphasize how the previous work demonstrates feasibility of proposed methods

If you do not have the required expertise for a scientific methodology, enlist a mentor or consultant and include a letter of support or agreement in the Appendix of the application.

Three to six pages are recommended for the Preliminary Studies section.

3(e)(4) Research Design and Methods- How you are going to do the work

This section is critical for demonstrating that the applicant has developed a clear, organized and thoughtful study design that tests the central hypothesis. (It is not a list of recipes for methods, experiments and data collection.)

Describe any novel concepts, approaches, tools, or technologies for the proposed pilot project. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Provide a tentative sequence or timetable for the project.

The methods section should—

- Provide an overview of the proposed design and conceptual framework
- Include details related to specific methodology; explain why the proposed methods are the best to accomplish the study goals
- Describe any novel concepts, approaches, tools or techniques
- Include details of how data will be collected and the results analyzed
- Consider required statistical techniques
- Include proposed work plan and timeline
- Consider and discuss potential limitations and alternative approaches to achieve study aims

Be clear about the methods and experimental design you will use. Be clear in describing the experimental details of your proposal. Avoid proposing experiments based on general observations.

Human Subjects: If the research will include human subjects, describe the protections put in place to protect the participants from research risks as well as the recruitment and data collection schedule. Also describe the criteria for participant inclusion in the research.

Use of Animals: If vertebrate animals will be used, please describe how the animals are housed. Also indicate when the animal protocol was reviewed and approved as well as the reviewer of the protocol. Confirm that your institution has an Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare and provide the assurance number and effective dates of the assurance.

Biohazards: Identify any select agents to be used in the proposed research and describe institutional procedures for the safe handling and disposal of such agents. Also describe the training that is provided for individuals that handle select agents. (Select agents are hazardous biological agents and toxins that Health and Human Services or the US Department of Agriculture has identified as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products.)

CDC maintains a list of HHS and USDA Select Agents and toxins.

(<http://www.cdc.gov/od/sap/docs/salist.pdf>)

You may not exceed 20 pages for the four sections of the pilot project application—Specific Aims (1 page), Background/Significance (2 to 6 pages), Preliminary studies (3 to 6 pages), Research Design and Methods; however, there is no requirement that all pages allotted be used.

All projects that involve animals or human subjects must be reviewed by the Institutional Animal Care and Use Committee and Institutional Review Board respectively; and a copy of the approval, on the institution’s letterhead, must be submitted with the application. For projects that involve human subjects, a copy of the consent form should also be submitted with the application in addition to the Targeted/Planned Enrollment Table.

3(e)(5). Additional Elements

Bibliography and References Cited: Provide a bibliography of any references cited in the Research Plan. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Make sure that only bibliographic citations are included. Be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application.

Appendix Materials: The Appendix may not be used to circumvent the page limitations of the Research Plan. Essential information should be included within the body of the grant application. The appendices should contain supportive or supplemental information such as letters of support or commitment from collaborators and consultants, and if applicable, IRB approvals, sample consent forms, IACUC approvals as appropriate, etc. Letters of commitment should clearly spell out the roles of the collaborators. For consultants, letters should include rate/charge for consulting services.

For ease of integrating the individual PHS398 form pages into a single file, pilot project PIs are also encouraged to select the MS Word version of the PHS 398 forms. In addition, all pilot research projects must be submitted by EARDA PIs to their respective program officers—Carl V. Hill, Ph.D., MPH or Jean Flagg-Newton, Ph.D.—at nichddsp@mail.nih.gov.

4. Application Information (Content and Forms)

Potential applicants are encouraged to use PHS Form 398. The application forms and the PHS 398 Instructions – 4/2006 Revision can be downloaded at <http://grants.nih.gov/grants/forms.htm> for use. Remember, specific guidance on pilot projects can be found at item 3 above.

Components:

Form Page 1: Face Page

Form Page 3: Research Grant Table of Contents

Form Page 4: Detailed Budget for Initial Budget Period

Biographical Sketch Format Page
Resources Format Page
Checklist Form Page
Personal Data Form Page
Continuation Page
Targeted/Planned Enrollment Table Format Page (If applicable)
Inclusion Enrollment Report Format Page (If applicable)
Personnel Report Format Page

NOTE: The multiple PI model will not be used for pilot projects.

Optional Components: PHS 398 Cover Letter File

5. Submission, Administrative Review and Earliest Start Dates for Pilot Research Projects

There will be two pilot project receipt dates in 2008. However in 2009, the EA Program will transition to one pilot project receipt date annually. EARDA PIs are strongly encouraged to submit all of its pilot projects on either the first (February) or second (April) cycle.

5a. Key Dates

Letter of Intent: January 15, 2008; March 15, 2008

Pilot Project Application submission/receipt dates: February 1, 2008; April 1, 2008

Administrative Reviews: April/May 2008; June/July, 2008

Anticipated earliest pilot project start date: June 2008

June 1 is the earliest anticipated start date for those projects submitted by February 1; and August 1 is the earliest anticipated start date for projects submitted on April 1.

5b. Letters of Intent:

EARDA PIs are encouraged to submit letters of intent (LOIs) either on January 15 or on March 15 by email (nichddsp@mail.nih.gov) advising the EA Program of their intent to submit pilot projects for support under the EARDA grant. The LOIs should list the titles of each project that the EARDA PI plans to submit. EARDA PIs is also strongly encouraged to include an abstract of each pilot project listed in the LOI.

Although the letter of intent and request for abstracts is not required and is not binding, the information provided allows the EA program staff to estimate the potential workload and plan the administrative review.

6. Pilot Project Application Processing

6(a) Submitting Pilot Projects

Pilot research projects should be submitted to EA program staff—Carl V. Hill, Ph.D., MPH or Jean Flagg-Newton, Ph.D.—at nichddsp@mail.nih.gov. Upon receipt of pilot project applications, the assigned program officer on the EARDA grant will acknowledge receipt of the projects, review the applications for completeness, and assign the applications for an administrative review for technical merit.

6(b) Revised Pilot Project Applications

Revised applications must include an “Introduction” that addresses the concerns highlighted in the previous review. Incomplete applications will be returned to the EARDA PI.

6(c) Pilot Projects Submitted to More than One NIH Program

Pilot project applications that are also submitted to other NIH programs (e.g., National Institute on General Medical Sciences SCORE Program, Research Infrastructure in Minority Institutions Program, etc.) will not be assigned for an administrative review. The following procedures will be followed.

- In cases where the peer review of the project in question is pending, EA Program staff in consultation with the scientific review administrator will make a determination in regard to the extent of scientific overlap.
- In cases where the initial review has been completed, EA Program staff in consultation with the program officer at the relevant NIH IC will make a determination in regard to the extent of scientific overlap.

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.

7. Administrative Review of Pilot Project Applications

Pilot projects that have relevance to the NIH mission (i.e., biomedical, behavioral and social sciences research with public health significance, bioinformatics, health disparities research, etc.) will be assigned for an administrative review. The reviews are conducted asynchronously rather than convening a single review meeting to increase participation in the administrative review process.

7(a). Role of NIH Program Staff in the Review of EARDA Pilot Projects

Program staff at NICHD and at other NIH Institutes and Centers (ICs) identified as having expertise in the scientific areas of the pilot projects are asked to assess the scientific merit of the

pilot project proposals. The time frame for completing the reviews is generally ten days from the receipt of the application from the EA Program. Depending on program staff work loads and travel schedules, it may take up to three weeks to complete the reviews.

7(b) Review Criteria

Similar to other proposals submitted to NIH, the scientific merit of EARDA 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 PI may request support for his/her level of effort on the project, supplies, small equipment, student support, and travel for the PI and one student to attend and/or present their work at one scientific conference.)

The administrative review of EARDA pilot projects is documented using a review template designed for pilot projects. The projects are not scored, but an overall evaluation is provided with a recommendation to EA Program staff to consider or not to consider support for a project.

Because the administrative review of pilot projects is conducted asynchronously, it may take up to one month to receive the reviews of all of the projects submitted by an EARDA grantee, especially if five to six projects have been submitted for consideration for support.

8. Role of the EA Program Staff

EA Program staff examines all pilot projects applications to identify projects that involve human subjects or animals and to ensure that IRB or IACUC approvals are included in the appendix of the pilot project applications, as applicable. EA Program staff also: (i) participate in decision-making in regard to the approval or disapproval of pilot projects, (ii) notify EARDA PIs regarding the final status of pilot projects, (iii) request required documents and confirmations for approved projects from the EARDA PI and (iv) notify grants management in regard to the projects approved for support.

8(a) On Identifying Projects that Involve Human Subjects or Vertebrate Animals

The EA program officer assigned to an EARDA grant examines the pilot projects submitted by the EARDA PI 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.

8(b) Decision-Making for Approving/Disapproving Pilot Projects

Upon receipt of the summaries of the review of pilot projects from the reviewers, the EA Program staff convenes a meeting with the director of the EA Program to discuss the reviews of each pilot project.

- Pilot projects that are recommended for support without significant concerns are noted in the review are generally approved for support by the EA Program.

- The EARDA grantee is generally provided the outcomes of the administrative review when the reviews for all pilot projects submitted by the EARDA PI are completed.
- EARDA PIs are provided a summary of the outcome of the review—specifically noting that the project has been approved for support.
- The critique of the review is forwarded directly to the pilot project PI; and the PI is asked to contact the EARDA PI for the status of his/her project.
- Pilot projects that are recommended for support but have significant concerns noted in the review are provisionally approved for further consideration.
 - The pilot project PI is typically given one week to provide clarifying information that addresses the concerns prior to final decision-making in regard to the status of the project.
 - Responses to concerns noted in the review are submitted by pilot project PIs, through the EARDA grantee, to the EA Program staff.
 - In cases where reviewer concerns are adequately addressed, as determined by EA program staff in consultation with the reviewer, the project is approved for support.
- Projects that are not recommended for support by the reviewer are discussed by EA program staff but are unlikely to be approved for support.
 - **Appeals:** There is no formal appeal process; however pending a decision at his/her institution, the PI can resubmit a revised application for consideration in the next administrative review cycle.
 - **Revised Applications:** Revised applications must include an “Introduction that addresses the concerns highlighted in the previous review.”

8(c) Notifying EARDA PIs on Final Status of Pilot Projects

8(c)(1) Final Decisions on Pilot Projects

After all projects submitted by the EARDA PI have been reviewed and pilot project PIs given an opportunity to respond to concerns noted in the review (as appropriate), the EARDA PI is notified in writing of the final status of the pilot projects submitted for consideration for support.

8(c)(2) Requests for Assurances and Certifications

Should any of the approved projects involve human subjects, the EARDI PI is asked to provide:

- ***Evidence of an institutional Federal Wide Assurance (FWA).*** The FWA is an assurance of compliance submitted to and approved by the Office for Human Research Protections for institutions engaged in non-exempt human subjects' research conducted or supported by the Department of Health and Human Services (HHS). Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance.
- ***Certification of human subjects' research education:*** A Certification of human subjects' research education is requested for key person involved in each of the approved pilot projects that involve human subjects.

No further information is required for projects that involve vertebrate animals because IACUC approvals are provided in the application and the required animal welfare assurance is confirmed with OLAW prior to the review of the project.

8(d) Notifying Grant Management Staff on the Status of Pilot Projects

Upon receipt of the requested assurance and certifications from the EARDA PI, EA program staff then notifies the grants management specialist assigned to the EARDA grant on the status of each pilot project submitted by the grantee.

EA program staff will provide the following items (in tabular format) to the grants management specialist assigned to the grant:

- A listing of the title of each project submitted for consideration for support
- Status of the outcome of the administrative review of each pilot project for scientific merit (i.e., whether approved or disapproved for support)
- Notification of the involvement of vertebrate animals or human subjects, if applicable

EA program staff will also provide to the grants management specialist, electronically:

- A review critique for each approved project—in cases where PI responses to reviewer concerns were required, that information is included with the review critique.
- Evidence of an institutional Federal Wide Assurance (...only required when an approved project involves human subjects)
- An IRB approval for each approved project that involves human subjects as well as a planned targeted enrollment table and certification of human subjects' research education for key personnel involved in the project
- An IACUC approval for each approved project that involves vertebrate animals

9. Role of Grants Management Staff

Pending receipt of the items referenced in Item 8(d) (above) from EA program staff, the grants management specialist assigned to an EARDA grant will write to the “responsible” official at the EARDA institution, informing him/her that the restriction on funds allocated for all approved projects has been lifted. The EARDA PI will be copied on this message.