PROGRAM ANNOUNCEMENT

DEPARTMENT OF DEFENSE CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

Genetic Studies of Food Allergies Research Program

INVESTIGATOR-INITIATED RESEARCH AWARD

Funding Opportunity Number: W81XWH-09-GSFARP-IIRA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Genetic Studies of Food Allergies Research Program (GSFARP) was established in fiscal year 2009 (FY09) to provide support for scientifically meritorious genetic research focused on food allergies. The FY09 appropriation is $2.5 million (M). The GSFARP challenges the scientific and clinical communities to submit original ideas that foster new directions in basic science or translational research, or novel product development leading to improved therapeutic or diagnostic tools. The GSFARP seeks applications in laboratory, clinical, and epidemiologic studies. Interdisciplinary and integrative approaches are welcomed.

B. Award Description

The GSFARP Investigator-Initiated Research Award (IIRA) mechanism is being offered for the first time in FY09**.**

This award is intended to support genetic studies that make an important contribution to the field of food allergies research and/or patient care. Research projects may focus on any phase of research from basic laboratory through translational research, including preclinical studies in animal models and human subjects, as well as correlative studies associated with an existing clinical trial. Observations that drive a research idea may be derived from a laboratory discovery, population-based studies, or a clinician's first-hand knowledge of patients.

Applications must include data relevant to genetics and food allergies that support the rationale for the proposed project. These data may be unpublished and/or from the published literature.

This award may not be used to conduct clinical trials. Refer to the Application Instructions and General Information, Appendix 6, for helpful information about distinguishing clinical trials and clinical research.

C. Eligibility

Principal Investigators (PIs) must be at or above the level of Assistant Professor (or equivalent). Refer to Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 3 years.
- The maximum allowable funding for the entire period of performance is $500,000 in direct costs.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 3-year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the institution's negotiated rate agreement.

Within the guidelines provided in the Application Instructions and General Information, funds can cover:

- Salary
- Research supplies
- Equipment
- Clinical research costs (clinical trials are not supported)
- Travel to scientific/technical meetings
- Travel between collaborating institutions
- Other direct costs as described in Application Instructions & General Information for Detailed Budget and Justification

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $2.3M of the $2.5M FY09 GSFARP appropriation to fund approximately 3 Investigator-Initiated Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

E. Award Administration

Refer to the Application Instructions and General Information, Appendix 5, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) application submission.

- **Pre-application Submission Deadline: March 26, 2009, 5:00 p.m. Eastern time (ET)**
- **Application Submission Deadline: April 23, 2009, 11:59 p.m. ET**
- **Scientific Peer Review: July 2009**
- **Programmatic Review: October 2009**

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

III. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/) and (2) an application submission through Grants.gov (http://www.grants.gov/).

PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

The Government reserves the right to reject duplicative applications submitted to different award mechanisms within the same program or to other CDMRP programs.

A. Step 1 – Pre-Application Components and Submission

The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the CDMRP eReceipt system by ***5:00 p.m. Eastern time on the deadline date***. Refer to the Application Instructions and General Information for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- Letter of Intent (LOI) Narrative

B. Step 2 – Application Components and Submission

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov).

Each application submission must include the completed application package of forms and attachments identified in www.grants.gov for this US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The package includes:

1. **SF-424 (R&R) Application for Federal Assistance Form**

2. **Attachments Form**

   - Attachment 1: Project Narrative (12-page limit)

     Describe the proposed project in detail using the outline below. Applications must include data relevant to the genetics and food allergies that support the rationale for the proposed study.

     - **Background**: Present the ideas and reasoning behind the proposed research, to include relevant literature citations. Describe previous experience most pertinent to this application.

- **Hypothesis or Objective**: State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project's specific aims. These aims should agree with the primary aims and associated tasks described in the Statement of Work. If the proposed work is part of a larger study, present only aims that the DOD award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***This award may not be used to conduct clinical trials.***

- Attachment 2: Supporting Documentation
  - References Cited
  - Acronyms and Symbol Definitions
  - Facilities & Other Resources
  - Description of Existing Equipment
  - Publications and/or Patent Abstracts: Five-document limit
  - Letters of Institutional Support: Two-page limit per letter

    If the PI is a practicing clinical physician, the institution must clearly demonstrate a commitment to the clinician's research.
  - Letters of Collaboration (if applicable): Two-page limit per letter
  - Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical Abstract: One-page limit
- Attachment 4: Public Abstract: One-page limit
- Attachment 5: Statement of Work (SOW): Three-page limit
- Attachment 6: Detailed Budget and Justification
- Attachment 7: Impact Statement: One-page limit

  Describe the potential impact of this genetic study on the field of research and/or patient care in food allergies. Include an assessment of the likelihood that a successful outcome to the research project will lead to practical applications in patients. The following are examples of ways in which proposed studies, if successful, may have an impact. ***Although not all-inclusive***, these examples are intended to help PIs frame the impact of the proposed research:
  - Has the potential to advance the field of research
  - Has the potential to change the standard of care for food allergies
  - Contributes to development or validation of evidence-based policy or guidelines

for patient evaluation and care

- Attachment 8: Federal Agency Financial Plan (if applicable)
- Attachments 9-13: Subaward Detailed Budget and Justification (if applicable)

3. Research & Related Senior/Key Person Profile (Expanded Form)

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each)
- Key Personnel Current/Pending Support

4. Research & Related Project/Performance Site Location(s) Form

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends applications for funding based on scientific merit, the overall goals of the program, and specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at http://cdmrp.army.mil/fundingprocess

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Institutional personnel and PIs are prohibited from contacting persons involved in the application review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

The Government reserves the right to review all applications based on one or more of the required attachments or supporting documentation (e.g., Impact Statement).

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria, which are listed in order of decreasing importance.

- **Research Strategy and Feasibility**
  - How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, supporting data, and logical reasoning.
  - How the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
  - How the PI acknowledges potential problems and addresses alternative approaches.
- **Impact**
  - Whether the proposed research is focused on food allergies.
  - How the proposed study addresses an important need in genetic studies.
  - The potential contribution of the proposed study to the field of research and/or patient care.

The following will not be individually scored, but may impact the overall evaluation of the application:

- **Personnel**
  - How the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed work.
  - How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
- **Environment**
  - The appropriateness of the scientific environment for the proposed research.
  - How the research requirements are supported adequately by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - The quality and extent of institutional support.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of the award mechanism.
- **Application Presentation**
  - How the writing and components of the application influenced the review.

2. Programmatic Review: The following equally weighted criteria are used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio:

- Adherence to the intent of the award mechanism
- Programmatic relevance
- Program portfolio balance
- Ratings and evaluations of the peer reviewers
- Relative impact

Scientifically sound applications that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by the Integration Panel (IP) members and recommended for funding to the Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC). The highest scoring applications from the first tier of review are not automatically recommended for funding. All applications are carefully considered to ensure that the funds available are allocated to those applications that best fulfill the goals and objectives of the program.

V. ADMINISTRATIVE ACTIONS

After receipt of applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- ***NEW for FY09:*** Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided within 48 hours of the date and time the email was sent. Otherwise, the application will be peer reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- The proposed research is not relevant to genetic studies of food allergies.
- The proposed research project is, or contains, a clinical trial.
- Funding recommendations for the FY09 GSFARP will be made by the Peer Reviewed Medical Research Program (PRMRP) Joint Programmatic Review Panel (JPRP). Therefore withdrawal of an application may occur if an FY09 JPRP member(s) is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY09 JPRP members may be found at http://cdmrp.army.mil/PRMRP/panels/panel09
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this Funding Opportunity/Program Announcement description to an extent that precludes appropriate scientific peer and/or programmatic review.
- Direct costs as shown on the detailed budget form exceed maximum allowed by award mechanism.
- Inclusion of URLs with the exception of links to published references.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. Program Announcement/Funding Opportunity application format, or required documentation: To view all funding opportunities offered by the CDMRP, perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone:	301-619-7079
Fax:	301-619-7792
Email:	cdmrp.pa@amedd.army.mil

B. eReceipt system: Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

Phone:	301-682-5507
Website:	https://cdmrp.org
Email:	help@cdmrp.org

C. Grants.gov contacts: Questions related to submitting applications through the Grants.gov (http://www.grants.gov/) portal should be directed to Grants.gov help desk. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Please plan ahead accordingly, as the CDMRP help desk is not able to answer questions about Grants.gov submissions.

Phone:	800-518-4726, Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time
Email:	support@grants.gov

Grants.gov will notify PIs of changes made to this Program Announcement/Funding Opportunity and/or application package ONLY if the PI subscribes to the mailing list by clicking on the "send me change notification emails" link on the Opportunity Synopsis page for this announcement. If the PI does not subscribe and the application package is updated or changed, the original version of the application package may not be accepted.