

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Genetic Studies of Food Allergies Research Program

Idea Award

Funding Opportunity Number: W81XWH-10-GSFARP-IA

TABLE OF CONTENTS

I.	Funding Opportunity Description	2
	A. Program Description.....	2
	B. Award Description	2
	C. Eligibility.....	3
	D. Funding.....	3
	E. Award Administration.....	4
II.	Timeline for Submission and Review	4
III.	Submission Process	4
	A. Step 1 – Pre-Application Components	4
	B. Step 2 – Application Components.....	5
IV.	Information for Application Review	8
	A. Application Review and Selection Overview	8
	B. Review Criteria.....	9
V.	Administrative Actions	10
VI.	Contact Information	12
VII.	Application Submission Checklist	13

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Genetic Studies of Food Allergies Research Program (GSFARP) was established in fiscal year 2009 (FY09) with a \$2.5 million (M) appropriation to provide support for scientifically meritorious genetic research focused on food allergies. The FY10 appropriation is \$1.875M.

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 research. Interdisciplinary and integrative approaches are welcomed.

B. Award Description

The GSFARP Idea Award mechanism is being offered for the first time in FY10.

The Idea Award is designed to support innovative ideas and high-impact approaches relevant to the genetics of food allergies. This award mechanism is designed to support new ideas, not ideas that are extensions of existing work. Applications should have a high probability of revealing new avenues of investigation. Research projects should include a well-formulated, testable hypothesis based on strong scientific rationale.

Clinical trials are not allowed. Research involving human subject use is permitted under this funding opportunity, but is restricted to studies without clinical trials. In general, a clinical trial is defined as a prospective study in which an intervention (e.g., device, drug, behavioral, surgical procedure, or other) is tested on human subjects for a measurable outcome. The FY10 GSFARP is not offering an award mechanism that will support clinical trials. Refer to the General Application Instructions, Appendix 5, for additional information about studies involving human subjects, human subjects data, or human anatomical substances.

The GSFARP seeks applications from all areas of basic, preclinical, and epidemiological research. The following are significant features of this award mechanism:

- 1. Innovation:** Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities. This may include high-risk, potentially high-gain approaches to the genetics of food allergies, provided that there is the potential for significant impact on the field of research and/or patient care. Research that is an incremental advance upon published data is not considered innovative and will not be considered for funding under this award mechanism.
- 2. Impact:** Research that has high impact will, if successful, significantly advance current methods and concepts within this field of research.
- 3. Preliminary Data:** Preliminary data, unpublished results from the laboratory of the Principal Investigator (PI) or collaborators named on this application, and/or data from the

published literature that is relevant to the proposed research project should be included. Although groundbreaking research often involves a degree of risk due to unforeseen difficulties or results, applications should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature.

C. Eligibility

Investigators at or above the level of an Assistant Professor (or equivalent) are eligible to submit applications. Refer to General Application Instructions, 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 **\$300,000** 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 organization's negotiated rate agreement.

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

- Salary
- Research supplies
- Equipment
- Clinical research costs (Clinical trials will not be supported)
- Travel between collaborating institutions
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings
- Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$0.9M of the \$1.875M FY10 GSFARP appropriation to fund approximately 2 Idea 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

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2011. Refer to the General Application Instructions, Appendix 4, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

- **Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), June 24, 2010**
- **Application Submission Deadline: 11:59 p.m. ET, July 8, 2010**
- **Scientific Peer Review: August 2010**
- **Programmatic Review: October 2010**

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline.

III. SUBMISSION PROCESS

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt system (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

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

A. Step 1 – Pre-Application Components

All pre-application components must be submitted through the CDMRP eReceipt system by **5:00 p.m. ET on the deadline.**

The pre-application consists of the following components, which are organized in the CDMRP eReceipt system by separate tabs: (Refer to the General Application Instructions for additional information on pre-application submission.)

- **Proposal Information – Tab 1**
- **Proposal Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

- **Required Files – Tab 4**

Letter of Intent (LOI) Narrative (one-page limit): Provide a brief description of the research to be conducted. LOI Narratives are used for program planning purposes only (e.g., reviewer recruitment) and *will not be reviewed* during either the peer or programmatic review sessions.

- **Submit Pre-application – Tab 5**

- **Other Documents Tab**

Not applicable.

B. Step 2 – Application Components

Applications are submitted by the Authorized Organizational Representative (AOR) through Grants.gov (<http://www.grants.gov/>). Applications must be submitted **by 11:59 p.m. ET on the deadline.**

Each application submission must include the completed application package of forms and attachments identified in Grants.gov for this Program Announcement/Funding Opportunity.

The Grants.gov application package consists of the following components (Refer to the General Application Instructions, Section II.B., for additional information on application submission):

1. SF 424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section II.B., for detailed information.

2. Attachments Form

- **Attachment 1: Project Narrative (six-page limit):** Upload as “ProjectNarrative.pdf.”

Describe the proposed project in detail using the outline below.

Background: Present the ideas and reasoning behind the proposed research; include relevant literature citations. Preliminary data, unpublished results from the laboratory of the PI or collaborators named on this application, and/or data from the published literature that is relevant to genetic research of food allergies and the proposed research project should be included.

Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.

Specific Aims: Concisely explain the project’s specific aims to be funded by this application.

Research Strategy: Describe the experimental design, methods, and analyses, including appropriate controls and statistical plan, in sufficient detail for analysis. Include specific examples of innovative elements incorporated into the research design. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a

plan for the recruitment of subjects or the acquisition of samples, and document the experience of the PI and/or key collaborators in recruiting human subjects for similar projects. *This award may not be used to conduct clinical trials.*

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *Each component has no page limit unless otherwise noted.*
 - References Cited List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.
 - List of Acronyms and Symbols: Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).
 - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information.
 - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then they must be included. Extra items will not be reviewed.
 - Letters of Organizational Support: Provide a letter (or letters if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project. If the PI is a clinician, the organization must clearly demonstrate a commitment to the clinician’s research.
 - Letters of Collaboration (if applicable)
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.” Clearly describe the proposed research projected including the following elements: Background, hypothesis or objective, study design, innovative aspects of the proposed research, and the relevance of the project to the genetics of food allergies.
- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.” Clearly describe, in a manner readily understood by lay persons, the central critical problem or question to be addressed, the innovative aspect of the research, and the relevance of the project to the genetics of food allergies. Do not duplicate the

technical abstract; the public abstract is used by consumer peer reviewers along with other components of the application package.

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 6: Detailed Budget and Justification (no page limit):** Upload as “Budget.pdf.” Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as “SubBudgets.pdf.” Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 8: Innovation Statement (one-page limit):** Upload as “Innovation.pdf.”

Summarize how the proposed work is innovative. Investigating the next logical step or an incremental advancement on published data is not considered innovative.

Although not all-inclusive, the following examples are ways in which proposed work may be innovative; these examples are intended to help PIs frame the innovative features of the research proposed:

- Study concept – Investigation of a novel idea and/or research question
 - Research method or technology – Use of novel research methods or new technologies, including technology development, to address a research question
 - Novel method or technology – Development of a novel method or technology for prevention, detection, diagnosis, or treatment
 - Existing methods or technologies – Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended
- **Attachment 9: Impact Statement (one-page limit):** Upload as “Impact.pdf.”

Describe why the proposed research project is important to the genetic research of food allergies. Explain the potential short- and long-term impact of this study on the field of research. Detail the anticipated outcome(s)/product(s) (intellectual and/or tangible) that will be directly attributed to the results of the proposed research project (short-term impact). Describe the anticipated long-term gains from this research course, and compare these to food allergies information/products currently available, if applicable.

3. Research & Related Senior/Key Person Profile (Expanded) Form: Refer to the General Application Instructions, Section II.B., for detailed information.

- PI Biographical Sketch (four-page limit): Upload as “Biosketch_LastName.pdf.”
- PI Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch_LastName.pdf.”
- Key Personnel Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

4. Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.B., for detailed information.

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 applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on scientific merit, the overall goals of the program, and specific intent of the award mechanism. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess>

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a nondisclosure 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. Organizational personnel and PIs are prohibited from contacting persons involved in the 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 organization’s application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations 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).

B. Review Criteria

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

- **Impact**
 - How the short-term outcome(s)/product(s) (intellectual and/or tangible) of the research, if successful, will make an important contribution that significantly advances the field of genetic research of food allergies.
 - How the long-term gains from this research course, if successful, will make an important contribution that significantly advances the field of genetic research of food allergies.
- **Innovation**
 - How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
 - How the proposed research project is a new research idea and not the next logical step or continuation of a previous research project.
- **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, food allergies-relevant preliminary data, and/or logical reasoning.
 - How well the hypotheses or objectives, specific aims, experimental design, methods, and analyses are developed and integrated into the project.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - Whether the application includes an appropriate statistical plan with power analysis, if applicable.

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

- **Personnel**
 - Whether the applicant meets the eligibility requirements.
 - How the research team's background and expertise are appropriate to accomplish the proposed work.
 - To what degree the levels of effort are appropriate for successful conduct of the proposed work.

- **Environment**
 - How the scientific environment is appropriate for the proposed research.
 - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
 - How the quality and extent of institutional support are appropriate for the proposed research.
- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
 - How the writing and components of the application influenced the review.

2. Programmatic Review: The following criteria are used by programmatic reviewers to make funding recommendations.

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Ratings and evaluations of the peer reviewers
- Relative innovation and impact

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).
- Pre-application is not submitted

B. Modifications

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

- Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section V-A, Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- Funding recommendations for the FY10 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 FY10 PRMRP 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 FY10 PRMRP JPRP members may be found at <http://cdmrp.army.mil/prmrp/panel>
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- The proposed research is a clinical trial.
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.

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 US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. CDMRP Program Announcement Help Desk: Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. ET. 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
Email: cdmrp.pa@amedd.army.mil

B. CDMRP eReceipt System Help Desk: Questions related to the submission of the pre-application through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

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

C. Grants.gov Contact Center: Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week. Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance regarding Grants.gov submissions.

Phone: 800-518-4726
Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1	
	Upload Supporting Documentation (Support.pdf) as Attachment 2	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3	
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4	
	Upload Statement of Work (SOW.pdf) as Attachment 5	
	Upload Detailed Budget and Justification (Budget.pdf) as Attachment 6	
	Upload Subaward Detailed Budget and Justification (SubBudgets.pdf) as Attachment 7	
	Upload Innovation Statement (Innovation.pdf) as Attachment 8	
	Upload Impact Statement (Impact.pdf) as Attachment 9	
	Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field
Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field		
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field		
Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field		
Project/Performance Site Location(s) Form	Complete form as instructed	