

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Autism Research Program

Idea Award

Funding Opportunity Number: W81XWH-09-ARP-IDEA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Autism Research Program (ARP) was established in fiscal year 2007 (FY07) to promote innovative, high-impact research focused on autism spectrum disorders (ASD). Appropriations for the ARP from FY07 through FY08 totaled \$13.9 million (M). The FY09 appropriation is \$8.0M.

The goal of the FY09 ARP is to improve the lives of individuals living with autism spectrum disorders now. The ARP challenges the scientific community to design high-impact, innovative research that will foster new directions for and address neglected issues in the field of ASD research. The ARP focuses its funding on innovative projects that have the potential to make a significant impact on the lives of individuals with ASD.

B. Award Description

The ARP Idea Award mechanism is being offered for the first time in FY09.

The ARP Idea Award supports high-impact, innovative research that advances the understanding of ASD and leads to improved quality of life for individuals with ASD.

The Idea Award is designed to promote new ideas; therefore, proposals need not include preliminary data.

Areas of Interest (Revised for FY09): While this award mechanism seeks applications from all areas of basic, translational, clinical, behavioral, and epidemiological ASD research, the FY09 ARP encourages applications that address critical needs of the autism community in the following areas:

- Co-morbidity: (e.g., manifestations such as disorders [gastrointestinal, sleep, behavioral, speech/language], psychiatric, seizures, immune dysfunction, motor and sensory deficits, metabolic dysfunction, and effects of ASD on intellectual ability)
- Predictors for Treatment Outcome: Identification of biomarkers, clinical characteristics, or other phenotypic markers that predict outcomes of a treatment (traditional or complementary and alternative), or populations that will or will not respond to a treatment

Clinical trials are not allowed under this award mechanism. Principal Investigators (PIs) wishing to apply for funding for a clinical trial should utilize the Clinical Trial Award mechanism. Refer to the Application Instructions and General Information, Appendix 6, for helpful information about distinguishing clinical trials and clinical research.

Important aspects of the Idea Award are as follows:

- 1. Impact:** The proposed research should have a significant potential impact on the concepts or methods that drive the field of ASD research. The proposed research is

expected to make an important and original contribution to advancing the understanding of ASD and lead to improved quality of life for individuals with ASD.

2. Innovation: Research that is deemed innovative may represent a new paradigm or look at existing problems from new perspectives. Research may be innovative in study concept, research methods or technology, clinical interventions, or adaptations of existing methods or technologies. Research that represents an incremental advance on previously published work is not considered innovative.

It is the responsibility of the PI to clearly and explicitly articulate the project's innovation and the potential impact on ASD.

C. Eligibility

Investigators at all academic levels (or equivalent) are eligible to submit applications. Refer to the 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 **\$375,000** 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 your institution's negotiated rate agreement.

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

- Salary
- Research supplies
- Equipment
- Clinical costs (No clinical trials allowed)
- Travel between collaborating institutions
- Travel to scientific/technical meetings

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$3.9M of the \$8M FY09 ARP appropriation to fund approximately seven Idea Award applications, depending on the quality and number of applications received.

Funding received in response to this Program Announcement/Funding Opportunity is contingent on 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.

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|---|-----------------------|
| Pre-application Submission Deadline: | March 17, 2009 |
| Invitation to Submit an Application: | April 23, 2009 |
| Application Submission Deadline: | July 22, 2009 |
| Scientific Peer Review: | September 2009 |
| Programmatic Review: | November 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 \(https://cdmrp.org/\)](https://cdmrp.org/), and (2) an application submission through [Grants.gov \(http://www.grants.gov/\)](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, Submission, and Screening

Pre-application submission is the required first step. 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. ET on the pre-application deadline**. Refer to the Application Instructions and General Information for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)

- **Preproposal Narrative:** The Preproposal Narrative has a *two-page limit* inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the preapplication. The preproposal narrative should address the following:
 - **Research Idea:** State the ideas and reasoning on which the proposed work is based, and how the application addresses a central problem in ASD. State the ARP area of interest (if applicable).
 - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
 - **Research Strategy:** Concisely state the project's objective and specific aims. *This award may not be used to conduct clinical trials.*
 - **Impact:** Briefly state how the proposed research will significantly impact the lives of individuals with ASD, and the concepts and methods that drive the field of ASD research and/or ASD treatment.
 - **Innovation:** Describe how the research represents more than an incremental advance on published data.
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are:
 - **References Cited:** List up to five relevant journal references.
 - **Biographical Sketches:** Include biographical sketches for the PI and key collaborators.

Pre-Application Screening: Pre-applications will be screened by the ARP Integration Panel (IP), which is composed of scientists, clinicians, and consumer advocates. The pre-application screening criteria are as follows:

- **Research Idea:** How the application addresses the intent of the award mechanism and the Program's objectives.
- **Research Strategy:** How the specific aims support the research idea and objective.
- **Impact:** What impact these studies will have on the lives of individuals with ASD, and the concepts and methods that drive the field of ASD research and/or ASD treatment.
- **Innovation:** How the research represents more than an incremental advance on published data.

B. Step 2 – Application Components and Submission

Applications will be invited based on pre-application screening. Do not submit an application to Grants.gov unless a letter of invitation has been received. Applications submitted by an applicant who has not received a letter of invitation will be administratively withdrawn.

Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov). No paper copies will be accepted.

Each application submission must include the completed Grants.gov application package of forms and attachments identified in www.grants.gov for the 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 (6-page limit)

Describe the proposed project in detail using the outline below. The presentation of preliminary data is not required. However, PIs must demonstrate logical reasoning and sound scientific rationale established through a critical review and analysis of the literature for the proposal to be competitive. Throughout the Project Narrative describe how the proposed research is innovative and the potential impact it will have on ASD.

- **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature.
- **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 supported by this application. If the proposed work is part of a larger study, present only tasks that the Department of Defense 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. Describe the statistical plan if appropriate for the research proposed. 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
- Publication URLs and/or Patent Abstracts (five-document limit)
- Letters of Institutional Support (two-page limit per letter)

If the PI is a practicing clinician, 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 impact of this study on the lives of individuals with ASD, ASD research, and/or treatment outcomes. Describe how the expected results of the proposed work will contribute to the goals of decreasing the clinical impact of ASD and advancing methods, concepts, diagnosis, or treatment of ASD.

- Attachment 8: Innovation Statement (one-page limit)

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

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

- 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 research method or technology to address a research question.
- 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: Federal Agency Financial Plan (if applicable)
- Attachments 10-15: 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 proposals for funding based on scientific merit, the overall goals of the program, and the 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.htm>.

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., Innovation Statement or Impact Statement).

B. Review Criteria

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

- **Impact**
 - How the proposed project, if successful, will impact the lives of those affected by ASD.
 - How the project addresses a critical problem in ASD research or treatment.
 - How the proposed project, if successful, will advance the research methods, detection, diagnosis, understanding of, and/or treatment of ASD.
- **Innovation**
 - How the project proposes new paradigms or challenges existing paradigms.

- How the proposed research is innovative in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, clinical interventions, or other ways.
- How the proposed research represents more than an incremental advance upon published data.
- **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 and/or logical reasoning.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and support completion of the aims.
 - How well the PI acknowledges potential problems and addresses alternative approaches.

The following criteria 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.
 - The appropriateness of the levels of effort by the PI and other key personnel to ensure success of the project.
- **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 the award mechanism.
- **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 that maintain the program's broad portfolio:

- Adherence to the intent of the award mechanism,
- Program portfolio balance with consideration of the Program's Areas of Interest,

- Programmatic relevance,
- Ratings and evaluations of the peer reviewers, and
- Relative impact and innovation.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by IP members and recommended for funding to the Commanding General, US Army Medical Research and Materiel Command. 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 proposals that best fulfill the goals, objectives, and areas of encouragement of the program.

V. ADMINISTRATIVE ACTIONS

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

A. Rejection

The following will result in administrative rejection of the pre-application:

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

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 Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.
- **NEW for FY09:** Following the application deadline, you may be contacted by email from CDMRP 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 without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- Submission of an application for which a letter of invitation was not received.
- FY09 IP 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 IP members may be found at <http://cdmrp.army.mil/arp/panel09.htm>.
- 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 description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed the maximum allowed by the 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. ET.

Phone: 301-682-5507

Website: <https://cdmrp.org>

Email: help@cdmrp.org

C. Grants.gov contacts: Questions related to application submission through the [Grants.gov](http://www.grants.gov) ([http://www.grants.gov/](http://www.grants.gov)) portal should be directed to the Grants.gov help desk, which is available Monday through Friday, 7:00 a.m. to 9:00 p.m. ET. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Please note the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726

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.