

# Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Autism Research Program

Concept Award

Funding Opportunity Number: W81XWH-09-ARP-CA

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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 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. Within this context, the encouragement of established scientists in the field and the attraction of new scientific expertise from other fields are essential to the ARP community. 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 Concept Award mechanism was first offered in FY07. Since that time, 219 Concept Award applications have been received, and 16 have been recommended for funding.

The ARP Concept Award supports the exploration of a highly innovative new concept or untested theory that addresses an important problem relevant to ASD. The Concept Award is not intended to support a logical progression of an already established research project but, instead, allows Principal Investigators (PIs) the opportunity to pursue serendipitous observations. This award mechanism supports high-risk studies that have the potential to reveal entirely new avenues for investigation. Proposals must describe how the new idea will enhance existing knowledge of ASD or create an entirely new avenue for investigation. Research completed through a Concept Award may provide sufficient preliminary data to enable the PI to prepare a proposal for future research.

***Presentation of preliminary data is not consistent with the intent of this award mechanism and therefore is not allowed.***

**Areas of Interest (Revised for FY09):** 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 Outcomes: Identification of biomarkers, clinical characteristics, or other phenotypic markers that predict outcomes of a treatment, or populations that will or will not respond to a treatment (traditional or complementary and alternative)

***Clinical trials are NOT allowed under this award mechanism.*** 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.

Use of human subjects and human biological substances: Because these awards are designed for preliminary investigations, projects involving human subjects or specimens will not be supported unless they are exempt under Title 32, Code of Federal Regulations, Part 219, Section 101(b) (32 CFR 219.101[b]). ***Studies that do not qualify for exempt status during review at any level will be administratively withdrawn and will not be funded.*** For studies using only commercially available or de-identified specimens, a Claim of Exemption Form will be requested. Additional information regarding exempt status may be found on the US Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office website (<https://mrmc.amedd.army.mil/rodorphrpo.asp>).

### **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 **1** year.
- The maximum allowable funding for the entire period of performance is **\$75,000** in direct costs.
- The applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the negotiated rate agreement of the applicant's institution.

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

- Salary
- Research supplies
- Travel to scientific/technical meetings
- Travel between collaborating institutions

***The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$0.8M of the \$8.0M FY09 ARP appropriation to fund approximately seven Concept Award applications, depending on the quality and number of proposals 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 is a required first step.*

<b>Pre-application Submission Deadline:</b>	<b>June 24, 2009</b>
<b>Application Submission Deadline:</b>	<b>July 15, 2009</b>
<b>Scientific Peer Review:</b>	<b>September 2009</b>
<b>Programmatic Review:</b>	<b>November 2009</b>

Awards will be made approximately 4 to 6 months after receiving the 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) a proposal submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/).

PIs and organizations identified in the proposal 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](mailto: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

*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](https://cdmrp.org/) by **5:00 p.m. Eastern time (ET) 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](http://www.grants.gov)).

Each application submission must include the completed application package of forms and attachments identified in [www.grants.gov](http://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**

*Reviewers will be blinded to the identity of the PI and the PI's institution. Due to the blinded nature of the review process, references to the PI or the institution in the project narrative are prohibited and will result in administrative withdrawal of the proposal. In addition, the use of "I," "our," "this institution," or similar phrases that make it possible to identify the PI and/or institution through the references listed will result in administrative withdrawal of the proposal.*

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

Describe the proposed project in detail using the outline below. ***Presentation of preliminary data is not consistent with the intent of this award mechanism and therefore is not allowed.*** However, PIs must demonstrate logical reasoning and a rationale for the work must be provided. Proposals must describe how the new concept could create an entirely new avenue for investigation and how it is relevant to ASD.

**Innovation:** Innovation should be the primary feature of the proposed study.

**Hypothesis and Rationale:** State the hypothesis to be tested and rationale for the proposed research. Do not include preliminary data.

**Objectives:** State concisely the specific aims and research strategy of the study. Do not request funding as part of a larger study.

**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.

**Impact:** Provide a brief statement in nontechnical terms regarding the potential impact of this work on ASD. Describe how the project will lead to an original and important contribution to the goal of advancing basic, translational or clinical ASD research, or on the quality of life of individuals with ASD.

**References:** Cite relevant literature references using Attachment 2.

The one-page limit of the Project Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal.

- Attachment 2: Supporting Documentation
  - References Cited
  - Acronyms and Symbol Definitions
- Attachment 3: Statement of Work (SOW) (Two-page limit)
- Attachment 4: Detailed Budget and Justification
- Attachment 5: Federal Agency Financial Plan (if applicable)
- Attachments 6-15: Subaward Detailed Budget and Justification (if applicable)

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

- PI Biographical Sketch

Although requested, the Biographical Sketch will not be forwarded for review due to the blinded nature of each level of review for this award. The biographical sketch will be used for administrative purposes only.

### **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 proposals based on one or more of the required attachments or supporting documentation.

*Reviewers will be blinded to the identity of the PI and the PI's institution. Due to the blinded nature of the review process, identifying or making references to the PI or the institution within the project narrative is prohibited and will result in administrative withdrawal of the proposal. In addition, the use of "I," "our," "this institution," or similar phrases that make it possible to identify the PI and/or institution through the references listed, will result in administrative withdrawal of the proposal.*

## **B. Review Criteria**

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

- **Innovation**

- How the research 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.
- Whether the concept is untested (no preliminary data allowed).
- How the proposed research represents more than an incremental advance upon published data.

- **Impact**

- How the study addresses a critical problem in ASD research or care.
- How the project will lead to an original and important contribution to the goal of advancing basic, translational, or clinical ASD research, or on the quality of life of individuals with ASD.
- What impact this study will have on the concepts or methods that drive the field.

- **Research Strategy**

- How the rationale supports the project.
- How the concept will give rise to a testable hypothesis if successful.

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

- **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 innovation and impact.

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 the ARP Integration Panel (IP) and recommended for funding to the Commanding General, US 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 proposals that best fulfill the goals, objectives, and areas of encouragement 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.
- PI's name or institution is included in the Project Narrative.
- Use of "I," "our," "this institution," or similar phrases in the Project Narrative that make it possible to identify the PI and/or institution through the references listed.
- 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 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:

- 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 Program Announcement/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.
- Inclusion of preliminary data in the Project Narrative.
- Inclusion of studies that do not qualify for exempt status under Title 32, Code of Federal Regulations, Part 219, Section 101(b) (32 CFR 219.101[b]).

## 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](mailto: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](mailto:help@cdmrp.org)

**C. Grants.gov contacts:** Questions related to application submission through the [Grants.gov](https://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](mailto: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.***