Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Autism Research Program

Exploration – Hypothesis Development Award

Funding Opportunity Number: W81XWH-10-ARP-EHDA

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I.   FUNDING OPPORTUNITY DESCRIPTION

A.   Program Description

The Autism Research Program (ARP) was established in 2007 to provide support for innovative, high-impact research focused on autism spectrum disorders (ASD). Appropriations for the ARP from fiscal year 2007 (FY07) through FY09 totaled $21.9 million (M). The FY10 appropriation is $8M.

The vision of the FY10 ARP is to improve the lives of individuals with autism spectrum disorders now. The ARP challenges the scientific community to design high-impact, innovative research that advances the understanding of ASD and leads to improved outcomes for individuals with autism. The ARP focuses its funding on projects that have the potential to ultimately make a significant impact on the lives of individuals with ASD.

B.   FY10 ARP Areas of Interest

While this award mechanism/funding opportunity seeks applications from all areas of basic, preclinical, translational, and clinical research, the FY10 ARP encourages applications that address critical needs of the autism community in the following areas:

- Biological, infectious, or environmental risk factors
- Identifying therapeutic targets, excluding new gene discovery

C.   Award Description

The Exploration – Hypothesis Development Award mechanism is being offered for the first time in FY10.

The Exploration – Hypothesis Development Award supports the initial exploration of untested, novel, innovative, and potentially groundbreaking concepts, theories, paradigms, and/or methods that address an important issue in autism research. Results of studies conducted through this award may provide the scientific rationale upon which a new hypothesis can be based, or initial proof-of-principle of an innovative hypothesis. This award mechanism is not intended to support the continuation of existing studies.

This award is designed to provide investigators with the opportunity to pursue serendipitous observations that may reveal entirely new avenues for investigation. The existence of substantial preliminary data suggests that the proposed research does not meet the intent of this award mechanism. Therefore, *the inclusion of preliminary data is not allowed.*

Use of human subjects and human biological substances: Projects involving human subjects or human biological substances 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)) or eligible for expedited review under 32 CFR 219.110 or 21 CFR 56.110. Additional information regarding exempt status may be found on the following web sites https://mrmc.amedd.army.mil/rodorphrpo.asp,

and https://www.bids.tswg.gov/TSWG/bids.nsf/5DD5E2BA50F02C18852572B1005F5B8B/$file/Title_32_CFR_Part_219.pdf.

D. Eligibility

Investigators at all academic levels are eligible to submit applications. Refer to General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **2** years.

- The maximum allowable funding for the entire period of performance is **$100,000** in direct costs.

- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 2-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

- Clinical research costs

- 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 $480,000 of the $8M FY10 ARP appropriation to fund approximately 3 Exploration – Hypothesis Development 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.

F. Award Administration

Changes in organization are discouraged and will be allowed only at the discretion of the US Army Medical Research Acquisition Activity (USAMRAA) Grants Officer. 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 10, 2010**
- **Application Submission Deadline:** **11:59 p.m. ET, July 1, 2010**
- **Scientific Peer Review:** **August 2010**
- **Programmatic Review:** **November 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.

Principal Investigators (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 – 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 will not be accepted unless the pre-application process is completed by the pre-application deadline.

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**

    Reviewers will be blinded to the identity of the PI, collaborators, and their organizations. Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or their organizations in the Project Narrative or List of Acronyms and Symbols is prohibited and will result in administrative rejection of the application. In addition, the use of "I," "our," "this organization," or similar phrases that refer to the PI, collaborators, and/or organization through the references listed will result in administrative rejection of the application.

    - **Attachment 1: Project Narrative (one-page limit):** Upload as "ProjectNarrative.pdf."

      Describe the proposed project in detail using the outline below. *The presentation of preliminary data is not allowed.* The existence of substantial preliminary data suggests that the proposed research does not meet the intent of this award mechanism. However, logical reasoning and a sound scientific rationale for the proposed work must be provided. The one-page limit of the Project Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, or cartoons to support the proposed study. *The Project Narrative will be available for both peer and programmatic review.*

      ○ **Hypothesis and Rationale**: State the hypothesis to be tested and rationale for the proposed research. State the ARP Area of Interest (if applicable).

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

      ○ **Methods:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for evaluation. If the methodology is

new or unusual, describe it in sufficient detail for evaluation. Address potential problem areas and present alternative methods and approaches. This award may not be used to conduct studies involving human subjects or specimens that are not exempt under 32 CFR 219.101(b) or eligible for expedited review under 32 CFR 219.110 or 21 CFR 56.110.

○ **Innovation:** Innovation should be the primary feature of the proposed study. Concisely state how the proposed project represents the exploration of a shift in paradigms, a new line of questioning, or an innovative methodological approach to an important issue in autism. 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:

- 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.

- Novel applications of 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.

○ **Significance/Relevance:** Briefly state, in nontechnical terms, how the proposed project will potentially lead to an original and important contribution toward the goal of advancing basic, translational or clinical ASD research and ultimately improve the outcomes of individuals with ASD.

• **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 (five-citation limit): 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).

• **Attachment 3: Technical Abstract (one-page limit):** A technical abstract is not required for applications to the ARP Exploration – Hypothesis Development Award. Leave Attachment 3 blank in the Grants.gov Attachments Form.

- **Attachment 4: Public Abstract (one-page limit):** A public abstract is not required for applications to the ARP Exploration – Hypothesis Development Award. Leave Attachment 4 blank in the Grants.gov Attachments Form.

- **Attachment 5: Statement of Work (SOW) (one-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.

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."
- Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."

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

Although requested, the Statement of Work, Detailed Budget and Justification, Subaward Detailed Budget and Justification (if applicable), Biographical Sketches, and Project/ Performance Site Location(s) Form will not be forwarded for peer or programmatic review. These documents will be used for administrative purposes only.

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, US Army Medical Research and Materiel Command, 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 *Reviewers will be blinded to the identity of the PI, collaborators, and their organizations.*

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 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. 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:

- **Innovation**
  - How well the research proposes new paradigms, challenges existing paradigms, or is otherwise uniquely creative in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
  - To what degree the proposed research represents more than an incremental advance upon published data.

- **Significance/Relevance**
  - To what degree the proposed project is relevant to ASD.
  - How the proposed project, if successful, will ultimately improve the lives of individuals with ASD.

- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project and its feasibility, as demonstrated by the presentation of logical reasoning.
  - To what degree the experimental design and methodology are appropriate to address the stated objectives.

The following will not be individually scored, but 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.

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

Approximately 4 weeks after programmatic review, each PI will receive notification of the status of his/her application. However, PIs will not receive access to a scientific peer review Summary Statement or other feedback on the strengths and weaknesses of the application.

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.
- Name(s) or organization(s) of the PI or collaborator are included in the Project Narrative or List of Acronyms and Symbols.
- Identifying or making references to the PI, collaborators, or their organizations in the Project Narrative or List of Acronyms and Symbols.
- The use of "I," "our," "this institution," or similar phrases that refer to the PI, collaborators, and/or organization through the references listed.

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:

- FY10 ARP Integration Panel (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 FY10 ARP IP members may be found at http://cdmrp.army.mil/arp/panel10
- 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.
- Inclusion of studies that are not exempt under 32 CFR 219.101(b) or eligible for expedited review under 32 CFR 219.110 or 21 CFR 56.110.

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. 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	Not applicable (N/A)
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4	N/A
	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	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
Project/Performance Site Location(s) Form	Complete form as instructed	