Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Autism Research Program

Resource Development Award

Funding Opportunity Number: W81XWH-10-ARP-RDA

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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 make a significant impact on the lives of individuals with ASD.

B. Award Description

The ARP Resource Development Award mechanism is being offered for the first time in FY10.

The ARP recognizes the critical need for improved resources to advance the field of ASD research and diagnosis, and to improve outcomes for individuals with ASD. The Resource Development Award supports product-driven research aimed at developing tools for use by the ASD research and/or clinical communities. These resources may include, but are not limited to, high-throughput assays, non-invasive imaging techniques, diagnostic tests, databases, devices, clinical tools, and model systems. Applicants should clearly articulate how the proposed product addresses an unmet need in the ASD research or clinical communities.

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 where an intervention (e.g., device, drug, behavioral, surgical procedure, or other) is tested on human subjects for a measurable outcome. Principal Investigators (PIs) wishing to apply for funding for a clinical trial should utilize the Clinical Trial Award mechanism. Refer to the General Application Instructions, Appendix 5, for additional information about studies involving human subjects, human subjects data, or human anatomical substances.

Preliminary data relevant to the proposed product development is allowed, but not required. Preliminary data, unpublished results from the laboratory of the PI, research team, or collaborators named on this application, may be from outside of the ASD research field. Proposals should be based on a sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature.

Resource Distribution Plan: A plan describing the means by which the fully developed resource will be made available to the scientific and/or clinical community at reasonable or appropriate administrative costs, such as costs required for packaging and shipping the resource, should be addressed in the application.

C. Eligibility

Investigators at all academic levels (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 **2** years.
- The maximum allowable funding for the entire period of performance is $**150,000** 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
- Equipment
- Clinical research costs (clinical trials are not supported)
- Development of software, databases, inventory systems, websites, and/or other information technology
- Publication 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 2 Resource 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.

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), March 31, 2010**
- **Invitation to Submit an Application: May 2010**
- **Application Submission Deadline: 11:59 p.m. ET, July 28, 2010**
- **Scientific Peer Review: September 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/). ***Applications will be invited based on pre-application screening.***

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***. ***Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.***

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**

  Preproposal Narrative (one-page limit): The Preproposal Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

The Preproposal Narrative should include the following:

- **Resource Description:** Describe the product to be developed and rationale that supports the need for this resource. Describe how the resource addresses a critical need in ASD basic or clinical research, or the clinic.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Strategy:** Briefly describe the proposed project's specific aims. *This award may not be used to conduct clinical trials.*
- **Impact:** Describe the potential impact of the proposed resource on the ASD field.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application are limited to:

- References Cited (one-page limit): List 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.
- Key Personnel Biographical Sketches (four-page limit per individual)

- **Submit Pre-application – Tab 5**
- **Other documents – Not applicable**

Pre-Application Screening: Pre-applications will be screened by the ARP Integration Panel (IP) based on the following criteria:

- **Resource:** Does the proposed product address a critical need in the ASD research or clinical community? Does the rationale provided support the need to develop the proposed resource?
- **Research Strategy:** How well do the rationale and specific aims support the project's objective?
- **Impact:** What potential impact will the proposed resource have on the ASD field?
- **Personnel:** How the personnel's background and expertise are appropriate to develop the proposed product (i.e., statistical expertise, expertise in ASD, or expertise in clinical studies).

Following the pre-application screening, PIs will be notified of whether or not they are invited to submit an application; however, they will not receive feedback (e.g., strengths and weaknesses) on their pre-application.

B. Step 2 – Application Components

Applications will not be accepted unless the PI has received a letter of invitation.

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 date.***

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 (4-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 resource, and the rationale that supports the need for this resource. Include relevant literature citations. Preliminary data originating from the PI, research team, or collaborator(s) that is relevant to the proposed project is allowed but not required, and does not have to be from the ASD research field. Describe previous experience most pertinent to this proposal.
  - **Resource Description:** Describe the product to be developed and its utility in the field. Compare the anticipated product(s) (intellectual and/or tangible) to ASD information/products currently available, if applicable. Describe how the resource addresses a critical need in the ASD field.
  - **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. If the proposed research is part of a larger study, present only tasks that this award would fund.

- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a 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 (two-page limit per letter): 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.
  - Letters of Collaboration (if applicable) (two-page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
  - 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."
  - Describe the proposed research project including the following elements: background, resource description, hypothesis or objective, study design, and potential impact of the proposed resource.

- **Attachment 4: Public Abstract (one-page limit):** Upload as "PublicAbs.pdf."
    - The public abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community. Clearly describe, in a manner readily understood by lay persons, the product to be developed, rationale for the resource, and the relevance of the proposed resource to individuals with ASD.
- **Attachment 5: Statement of Work (SOW) (two-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: Impact Statement (one-page limit).** Upload as "Impact.pdf."

  Describe how the proposed resource is relevant to ASD. Describe the short-term and long-term impact of the potential resource on the field and on the outcomes of individuals with ASD.
- **Attachment 9: Resource Distribution Plan (one-page limit):** Upload as "DistribPlan.pdf."

  State concisely how the resource, once fully developed, will be made available to the scientific and/or clinical community at reasonable or appropriate administrative costs, such as costs required for packaging and shipping the resource.
- **Attachment 10: Data Reporting Plan (if applicable) (one-page limit):** Upload as "DataReporting.pdf."

  The Data/Research Resources Sharing Plan will not be reviewed during the peer or programmatic review processes. It will be used for administrative purposes only. Describe how unique and/or final research data and resources will be shared with the research community and general public, including cases where pre-existing data or research resources will be utilized and/or modified during the proposed study. Clearly explain any limitations associated with a pre-existing agreement that preclude subsequent data/research resources sharing.

  The content of the data/research resource sharing plan may depend on the data being collected or the resources being developed. PIs should describe briefly the expected schedule for sharing, format of the final dataset, documentation to be provided, analytic tools to be provided, data sharing or material transfer agreement (or other documentation) including criteria for deciding who can receive the data/research resource and whether or not any conditions will be placed on their

use, and mode of data/research resource sharing (e.g., posting data on an institutional or personal website). If research involves human subjects and the data and/or research resource(s) are intended to be shared, the application should discuss how the rights and confidentiality of participants would be protected. PIs should follow their institution's technology transfer policies and provide links to model technology transfer agreement used by institution, as appropriate. Refer to the General Application Instructions, Appendix 4, for more information on Data and Research Resources Sharing.

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:

- **Resource**
  - How well a clear product is identified.
  - How well the rationale provided supports the need to develop the proposed resource.
  - How well the proposed resource compares to ASD resources/products currently available, if applicable.
  - How well the plan for distribution of the resource following its development is described, feasible, and appropriate.
- **Impact**
  - How well the proposed resource addresses a critical need in the ASD research or clinical community.

- How well the proposed resource, if developed successfully, will advance ASD research, understanding, evaluation, diagnosis, treatment, and/or improve the outcomes of individuals with ASD.
- How well the proposed resource, if developed successfully, will advance the concepts or methods that drive the field.

- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, logical reasoning, and if applicable, by the presentation of preliminary data relevant to the project.
  - How well the hypotheses or objectives, aims, specific 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.
  - How well the proposal describes access to and the availability of human subjects and human biological samples, if applicable.

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

- **Personnel**
  - How the research team's background and expertise are appropriate to accomplish the proposed research.
  - To what degree the levels of effort are appropriate for successful conduct and completion of the proposed research.
- **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 impact
- Relevance to program objectives

V. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP 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).
- Submission of an application for which a letter of invitation was not received.

B. Modifications

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal 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 preapplication 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.
- The proposed research project includes a clinical trial.

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 Impact Statement (Impact.pdf) as Attachment 8	
	Upload Resource Distribution Plan (DistribPlan.pdf) Attachment 9	
	Upload Data Reporting Plan (DataReporting.pdf) as Attachment 10	
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	