

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

**Defense Health Program
Autism Research Program**

Pilot Award

Funding Opportunity Number: W81XWH-11-ARP-PA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 20, 2011
- **Invitation to Submit an Application:** September 21, 2011
- **Application Submission Deadline:** 11:59 p.m. ET, November 9, 2011
- **Scientific Peer Review:** January 2012
- **Programmatic Review:** March 2012

New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Assistant Secretary of Defense for Health Affairs, Defense Health Program is soliciting applications for the Autism Research Program (ARP). The ARP was established in 2007 to provide support for innovative, high-impact research focused on autism spectrum disorders (ASD). Appropriations for the ARP from FY07 through FY10 totaled \$29.9 million (M). The FY11 appropriation is \$6.4M.

The ARP's vision is to improve the lives of individuals with ASD *now* by promoting innovative research that advances the understanding of ASD and leads to improved outcomes.

B. FY11 ARP Areas of Interest

The Pilot Award seeks applications from all areas of basic and preclinical research. The FY11 ARP Pilot Award encourages applications that address the critical needs of the ASD community in the following areas:

- Studies that lead to improved subgrouping of individuals with ASD to inform on the mechanisms, natural history, and response to treatment. For example:
 - Biomarkers
 - Risk factors including, but not limited to perinatal, infectious, environmental exposures, and gene-environment interactions
 - Co-morbid medical and behavioral conditions
 - Sex ratio (biological basis for male bias in ASD)
- Identification of therapeutic targets, excluding new gene discovery
- Studies that leverage existing biological samples, clinical populations, and databases to provide statistical power to test ideas

C. Award Information

The ARP Pilot Award mechanism is being offered for the first time in FY11. The ARP Pilot Award supports conceptually innovative, high-risk/high-reward research that could ultimately lead to critical discoveries or major advancements that will drive the field of ASD forward. Research projects should include a testable hypothesis based on a strong scientific rationale. This award is not intended to support the continuation of existing studies or the next logical extension and/or incremental step. The Pilot Award emphasizes untested, novel, innovative, and potentially groundbreaking concepts, theories, paradigms, and/or methods.

The award is designed to provide investigators with the opportunity to pursue serendipitous observations that may reveal entirely new avenues for investigation. The existence of preliminary data suggests that the proposed research does not meet the intent of this award mechanism. Therefore, ***preliminary data are not allowed. The strength of the application should be based on sound scientific rationale and logical reasoning.***

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 (CFR), 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 may be found at https://cdmrp.org/Program_Announcements_and_Forms/ and in the General Application Instructions, Appendix 5, for more information.

All Department of Defense (DOD)-funded research involving new and ongoing research with human subjects and human anatomical substances must be reviewed and approved by the US Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local IRB of record. Local IRB approval at the time of submission is NOT required. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DOD. These laws and directives are rigorous and detailed, and will require information in addition to that supplied to the local IRB. Allow a minimum of 4 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

Clinical trials will not be supported by this award mechanism. The ARP is offering a Clinical Trial award mechanism and any research proposing a clinical trial should apply to that funding opportunity.

D. Eligibility Information

- Investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **2** years.
- The maximum allowable direct costs for the entire period of performance is **\$100,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding for a project that may have a period of performance of less than the maximum **2** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget form. In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$1.6M of the \$6.4M FY11 ARP appropriation to fund approximately 10 Pilot 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.

II. SUBMISSION INFORMATION

Submission is a multi-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.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-11-ARP-PA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the Principal Investigator (PI) through the CDMRP eReceipt System (<https://cdmrp.org/>). 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.

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 CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

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, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**

- **Collaborators and Conflicts of Interest (COI) – Tab 3**
- **Required Files – Tab 4**

Preproposal Narrative: Provide responses in the appropriate data fields to the following:

- Describe the proposed research idea (1,000-character limit).
 - Describe the potential impact of the proposed research and how it is innovative (2,000-character limit).
 - State the FY11 ARP Pilot Award Area of Interest (if applicable).
- **Submit Pre-application – Tab 5**
 - **Other Documents Tab**
No additional documents are required.

Pre-Application Screening

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DOD and CDMRP, pre-applications will be screened based on the following criteria:

- Adherence to the intent of the award mechanism.
 - Potential impact of the proposed research for the ASD community.
 - Relative innovation in the ASD field.
- **Notification of Pre-Application Screening Results**
Following the pre-application screening, PIs will be notified whether or not they are invited to submit an application; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application.
Pre-application notification dates are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Form

Applications will not be accepted unless the PI has received an invitation.

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative (AOR) through the Grants.gov portal (<http://www.grants.gov/>).

Grants.gov application package components: For the Pilot Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

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

2. Attachments Form

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

The Project Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. PIs must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the application to be competitive. Throughout the Project Narrative, describe how the proposed research is innovative and detail its potential impact on ASD.

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations. *Preliminary data are not allowed.*
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be attained.
- **Specific Aims:** Concisely explain the project’s specific aims to be supported by this application. If this research project is part of a larger study, present only tasks that the DOD award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail. Address potential problem areas and present alternative methods and approaches. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Demonstrate the availability of tissue, data, or human subjects, if applicable. Describe a statistical plan where appropriate, including power analysis. *Clinical trials are not allowed.*
- **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 the references cited (including URLs if available) in the project narrative 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).
 - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

- 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.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publically available.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
The technical abstract should be written using the outline below.
 - Background: Present the ideas and reasoning behind the proposed research.
 - Objective/Hypothesis: State the objective/hypothesis to be tested.
 - Specific Aims: State the specific aims of the study.
 - Study Design: Briefly describe the methodology and statistical plan, if applicable.
 - Impact: Summarize how the proposed project is relevant and will have an impact on the outcomes of individuals with ASD and the understanding of ASD.
 - Innovation: Briefly describe how the proposed project uses innovation to yield critical discoveries, new avenues of investigation, and/or major advancements to improve the understanding of ASD and ultimately to improve outcomes of individuals with ASD.

- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”
Clearly describe, in a manner readily understood by lay persons, the central critical problem or question to be addressed, the innovative aspect of the research, the relevance of the project to ASD, and the potential impact of the proposed research on the understanding of ASD and/or ASD outcomes. Do not duplicate the technical abstract.
 - **Attachment 5: Statement of Work (SOW) (two-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information.
 - **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.” Describe how the proposed research is relevant to ASD. Detail the anticipated outcome(s)/product(s) (intellectual and/or tangible) that will be directly attributed to the results of the proposed research project. Compare the anticipated outcomes from the proposed project to ASD information/products currently available, if applicable. Describe the short-term and long-term impact of the expected results of the study on the field and on the outcomes of individuals with ASD.
 - **Attachment 7: Innovation Statement (one-page limit):** Upload as “Innovation.pdf.” Summarize how the proposed research is innovative and consistent with the ARP’s vision and mission. If the proposed research is successful, explain how it will provide new paradigms, technologies, evidence-based diagnoses, molecules, and/or applications.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., 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. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

D. Submission Dates and Times

All submission dates and times are indicated on the [title page](#) of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines shall result in application rejection.

E. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical 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 technical merit, the relevance to the mission of the DOD and CDMRP, and the 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 can be found at <http://cdmrp.army.mil/about/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 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. Application Review Criteria

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are listed in decreasing importance.

Note that innovation and impact do not compensate for deficiencies in scientific merit. A statistician will be included on the scientific review panels.

- **Scientific Merit**

- To what extent a clear hypothesis is stated and supported through scientific rationale and referenced literature.
- How well the hypothesis or objectives, specific aims, and experimental design are developed.
- How the application provides an appropriate statistical plan and power analysis of the proposed study, if applicable.
- How well the PI acknowledges potential problems and addresses alternative approaches.
- Whether the applicant demonstrates the availability of tissue, data, or human subjects, if applicable.

- **Innovation**

- How the proposed research, if successful, will challenge existing paradigms, or provide new paradigms, technologies, evidence-based diagnoses, molecules, and/or applications for ASD.
- To what degree the proposed research represents more than a logical extension and/or incremental advance upon published data.
- To what degree the proposed research emphasizes untested, novel, or potentially groundbreaking concepts.

- **Impact**

- How the proposed project is relevant to ASD.
- How the anticipated outcomes from the proposed project compare to information/products currently available, if applicable.
- How well the anticipated short-term outcome(s)/product(s) are described.
- How well the anticipated long-term gains from this research are described.
- How the proposed project, if successful, will ultimately improve the outcomes of individuals with ASD.

In addition, the following unscored criteria will also contribute to 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 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.
- 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**

- To what extent the writing, clarity, and presentation of the application components influenced the review.

2. Programmatic Review: To determine the application's relevance to the mission of the DOD and CDMRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

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

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

D. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. PIs will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

IV. 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 is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.

B. Modification

- 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 IV.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 pre-application or application:

- FY11 ARP Integration Panel (IP) member 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 FY11 ARP IP members may be found at <http://cdmrp.army.mil/arp/panels/panels11>.
- 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 Research and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Preliminary data are included.
- The proposed research is, or requests funding for, 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 required 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.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2012. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section C, for general information regarding administrative and national policy requirements.

C. Reporting

Refer to the General Application Instructions, Appendix 4, Section D, for general information on reporting requirements.

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section E, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements and questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 1-301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 1-800-518-4726

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 Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 7.	
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.	
Research & Related Budget	Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	