Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Autism Research Program

Idea Development Award

Funding Opportunity Number: W81XWH-13-ARP-IDA

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 2, 2013
- **Invitation to Submit an Application:** August 2013
- **Application Submission Deadline:** 11:59 p.m. ET, October 15, 2013
- **Peer Review:** December 2013
- **Programmatic Review:** February 2014

This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) Autism Research Program (ARP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The ARP was established in 2007 to provide support for innovative, high-impact research focused on autism spectrum disorder (ASD). Appropriations for the ARP from FY07 through FY12 totaled $41.42 million (M). The FY13 appropriation is $6M.

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. FY13 ARP Areas of Interest

The Idea Development Award seeks applications from all areas of basic and preclinical research. The FY13 ARP Idea Development Award ***encourages*** applications that address the critical needs of the ASD community in the following areas:

- Understanding factors underlying the heterogeneity of clinical expression or response to treatment of ASD, excluding new gene discovery
- Conditions co-occurring with ASD
- Validation of new or existing therapeutic targets, excluding new gene discovery
- Psychosocial factors promoting success in key transitions to independence for individuals living with ASD
- Factors promoting success in family/caregiver well-being

C. Award Information

The ARP Idea Development Award mechanism was first offered in FY07. Since then, 225 Idea Development Award project applications have been received, and 24 have been recommended for funding.

The ARP Idea Development Award supports the development of innovative, high-risk/high-reward research that could lead to critical discoveries or major advancements that will accelerate progress in improving outcomes for individuals with autism. This award mechanism is designed to support innovative ideas with the potential to yield impactful data and new avenues of investigation. Through the Idea Development Award, the ARP seeks to promote multidisciplinary collaborations (e.g., special education, biomedical science, preclinical research). Past experimental research in the ASD research field or in other developmental disorders is crucial to the Idea Development Award and will be evaluated.

Important aspects of the Idea Development Award are as follows:

- **Impact:** The proposed research is expected to make an important and original contribution to advancing the understanding of ASD and lead ultimately to improved outcomes for individuals with ASD. The project's impact on both ASD research and patient care should be articulated, even if clinical impact is not an immediate outcome.

- **Innovation:** Research deemed innovative may represent a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other highly creative qualities. Research may be innovative in study concept, research methods or technology, or adaptations of existing methods or technologies. Research that represents an incremental advance on previously published work is not considered innovative.

It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate the project's innovation and the potential impact on outcomes in ASD.

Preliminary data relevant to the proposed research project are required. Preliminary data, which may include unpublished results from the laboratory of the PI, research team, or collaborators named on this application, may be from outside the ASD research field. However, the proposed research must have direct relevance to ASD. Applications should also be based on a sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature.

Multiple PI Option: The FY13 ARP supports collaborative research to bring a new perspective to ASD research and/or facilitate progress in the field by combined effort. Therefore, the FY13 ARP is offering a Multiple PI Option for this award mechanism. The Multiple PI Option is structured so that up to three investigators, each of whom will be designated as a PI and receive a separate award, will work synergistically on a single project. One member of the team will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with the application. The other member(s) will be referred to as the Partnering PI(s). ***All the investigators must collaborate to submit a single project addressing a central problem in ASD or one or more of the FY13 ARP Areas of Interest. Applications submitted by a mentor and trainee as Initiating and Partnering PI(s) do not meet the intent of the Multiple PI Option.*** It should be clear that all investigators have an equal level of intellectual input and effort. Multidisciplinary and multi-organizational projects are allowed. ***A separate Grants.gov submission is required for each PI, even if the PIs are at the same organization.*** If the project is multi-organizational, PIs should include plans for communication between investigators at each organization. Additionally, participating organizations must be willing to resolve potential intellectual and material property issues and to remove any barriers that might interfere with achieving high levels of cooperation to ensure successful completion of this award.

Use of Human Subjects and Human Anatomical Substances: 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 U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (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 by the local IRB. Allow a minimum of 2-3 months for regulatory review and approval processes. Additional information may be found at https://cdmrp.org/files/forms/generic/Human_Subject_Research.pdf and in the General Application Instructions, Appendix 5.

Behavioral Research: A behavioral clinical trial with a prospective accrual of patients where a behavioral intervention (i.e., cohort or case-controlled study) has been designed to determine the outcome (testing instrument, study tool, hazard, etc.) with respect to exploratory information, safety, or effectiveness ***may be allowed*** if it is ***no greater than minimal risk*** as determined by the local IRB of record and HRPO.

Clinical trials involving prospective accrual of patients to test a device, drug, biologic, or surgical procedure for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy ***will not*** be supported by this award mechanism.

Correlative Studies: Correlative studies associated with a clinical trial testing a device, drug, biologic, or surgical procedure are permitted if it is determined to be ***no greater than minimal risk*** by the local IRB of record and HRPO. A correlative study is defined as a prospective or retrospective collection of human anatomical substances (e.g., tissue, blood, nail clippings, bone marrow, behavioral documentation, other) to be used in research to answer a question regarding the disease, injury or condition, and/or intervention. It does ***not*** include the direct assessment of the ***outcome*** of ***any intervention*** for the prevention, diagnosis, treatment, or evaluation of the quality of life of the patient.

Human subject research qualifying as greater than minimal risk will not be supported by this award mechanism.

Investigators are encouraged to submit their data to the National Database for Autism Research (NDAR), a secure bioinformatics platform for data sharing of ASD-related information, supported by the National Institutes of Health. For more information, please consult the NDAR at http://ndar.nih.gov.

The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

D. Eligibility Information

- Investigators at or above the level of Assistant Professor (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.

- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

Applications with a single Principal Investigator (PI) or with the Multiple PI Option:

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **$350,000** 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 amount for a project that may have a period of performance less than the maximum **3** 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.
- **Multiple PI Option:** The combined total funding for the Initiating PI and the Partnering PI(s) may not exceed **$350,000** for direct costs for up to a **3**-year period of performance, plus indirect costs as appropriate. The PIs are expected to be equal partners in the research, and direct cost funding should be divided accordingly, unless otherwise warranted and clearly justified.
- A separate award will be made to each PI's organization.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4 of the General Application Instructions.***

In addition, for this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Research supplies
- Publication costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings

The CDMRP expects to allot approximately $2.8M of the $6M FY13 appropriation to fund approximately five Idea 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.

II. SUBMISSION INFORMATION

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/).

The Idea Development Award mechanism is structured to accommodate up to three PIs. One partner will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will then be notified of the pre-application submission separately by email. Each Partnering PI must follow the link in this email and register with the CDMRP eReceipt System in order to associate his/her grant application package with that of the Initiating PI. If an application is invited, only the Initiating PI will receive notification of invitation via email from CDMRP.

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the 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-13-ARP-IDA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI (for single PI applicants) or the Initiating PI (for applicants submitting under the Multiple PI Option) 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 pre-application should be the same as those intended for the subsequent application submission. If any changes are 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**

  Multiple PI Option: The Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section.

  FY13 ARP Integration Panel (IP) members (http://cdmrp.army.mil/arp/panels/panels13) should not be involved in any preapplication or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

- **Required Files – Tab 4**

  Preproposal Narrative (two-page limit): The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

  Note: At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.

  The Preproposal Narrative should include the following:

  - **Research Idea:** State the hypothesis to be tested or the objective to be reached. State the ideas and reasoning on which the proposed project is based and how the research addresses a central problem in ASD. Concisely state the specific aims. State the FY13 Idea Development Award Area(s) of Interest (if applicable). Detail access to the study population, if applicable.
  - **Impact:** Describe the potential impact of this study on the outcomes of individuals with ASD and/or the understanding of ASD.
  - **Innovation:** Describe how the proposed project is innovative and how the research represents more than an incremental advance on published data.

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

  - References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal 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 used in the Preproposal Narrative.
- Key Personnel Biographical Sketches (four-page limit per individual)

- **Submit Pre-Application – Tab 5**

  This tab must be completed for the pre-application to be accepted and processed by the CDMRP.

- **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 DHP and the ARP, pre-applications will be screened based on the following criteria:

  - **Research Idea:** How well the proposed project addresses the intent of the award mechanism and the program. How well the rationale and specific aims support the project's objective. To what extent the research can be accomplished with the defined study population, if applicable.
  - **Impact:** What potential impact these studies will have on the outcomes of individuals with ASD and/or the understanding of ASD.
  - **Innovation:** To what extent the research is creative and represents more than an incremental advance on published data.

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, PIs (or Initiating PIs, if applying under the Multiple PI Option) will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application.

  The estimated timeframe for notification of invitation to submit an application is 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 or Initiating PI has received notification of 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 through the Grants.gov portal (http://www.grants.gov/). For the Idea Development Award, additional application components are also required and should be submitted as directed below.

Multiple PI Option: The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned unique log numbers by the CDMRP eReceipt System. Each Grants.gov application package must be submitted using the unique log number.

Application Components for Single PIs or for the Initiating PI:

Grants.gov application package components: For the Idea Development 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 (10-page limit):** Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

     The Project Narrative must include preliminary data originating from the PI research team or collaborator that are relevant to the proposed project, but do not have to be from the ASD research field. The research strategy should be based on sound scientific rationale, outlined in detail, and fully supported by preliminary data and published reports.

     Describe the proposed project in detail using the outline below.

     - **Background:** Present the ideas and reasoning behind the proposed research and include relevant literature citations. Describe and show the preliminary data to justify the rationale for the proposed project.
     - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
     - **Specific Aims:** Concisely explain the project's specific aims to be supported by this application. If the proposed 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 limitations and present alternative methods and approaches. Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, if applicable. If a behavioral clinical trial is proposed, describe the type of study to be performed (e.g., prospective,

randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action.

- **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. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.***
    - 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 award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award 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 a copy/copies of the published manuscript(s) must be included in Attachment 2. 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, confirming 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 Property
        - Background and Proprietary Information (if applicable): All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project. Identify any proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the federal purpose license.

- 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 publicly available.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

  The technical abstract is used by all reviewers. The technical abstract should be written using the outline below.

  - Background: Present the ideas and reasoning behind the proposed research.
  - Hypothesis/Objective: State the hypothesis/objective to be tested.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design including appropriate controls.
  - Impact: Summarize how the proposed project is relevant to and will have an impact on the outcomes of individuals with ASD and/or an understanding of ASD. Describe the impact on the specified population, if applicable.
  - Innovation: Briefly describe how the proposed project uses innovation to yield critical discoveries, new avenues of investigation, or major advancements to improve the understanding of ASD and ultimately to improve outcomes of individuals with ASD.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf."

  The lay abstract is used by all reviewers. Do not duplicate the technical abstract. Include an overview of the proposed research project that can be readily understood by lay persons. Avoid over use of acronyms and abbreviations, if possible. Describe the proposed research project by including the following elements in plain language.

  - The critical problem or question to be addressed by the proposed research project. Identify the FY13 ARP Area(s) of Interest addressed in the proposed research, if applicable.
  - Innovative aspect of the proposed research project.
  - The impact that the proposed research project results might have on the field of ASD research. Describe the impact in the short or long term on individuals with ASD and how the research is relevant now.

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.

Multiple PI Option: ***Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.***

- **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 (short-term impact). 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. State how the research challenges existing paradigms or presents new paradigms in the field of ASD research. Investigating the next logical step or an incremental advancement on published data is not considered innovative.

- **Attachment 8: Performance History (four-page limit):** Upload as "Performance.pdf"

  Please write the performance history based on the outline below:

  - Current ASD support from both federal and non-federal sources from the past 5 years. Researchers new to the ASD field should describe related support from both federal and non-federal sources.
  - Any honorariums, awards, or other distinctions received for work in ASD or other developmental disorders from the past 5 years.
  - Any patents or ASD related research accomplishments from the past 5 years.

- **Attachment 9: Human Subject Prospective Recruitment and Safety Procedures, *if applicable* (no page limit):** Upload as "HumSubProc.pdf." The Human Subject Recruitment and Safety Procedures attachment should include the components listed below. This plan should be attached if using a prospectively recruited population.

  a. Study Population: Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and demographic characteristics of the accessible population at the study site. Demonstrate that the research team has access to the proposed study population. Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.

  b. Inclusion/Exclusion Criteria: List the inclusion and exclusion criteria. Provide detailed justification for exclusions.

  Inclusion of Women and Minorities in Study. Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human

Subjects," and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical trial.

c. Description of the Recruitment Process: Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification).

- Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
- Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
- Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

d. Description of the Informed Consent Process: Specifically describe the plan for obtaining informed consent from human subjects.

- Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
- Include information regarding the timing and location of the consent process.
- Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
- Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf). If applicable, please refer to the General Application Instructions, Appendix 5, for more information.
- ***Assent.*** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.

e. Screening Procedures: List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Please note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

f. Risks/Benefits Assessment:

- **Foreseeable risks:** Clearly identify all study risks. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
- **Risk management and emergency response:**
  - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
  - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
  - Address any special precautions to be taken by the human subjects before, during, and after the study.
- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information. ***Note: Some of the items in this attachment may be made available for programmatic review.***

- PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
- Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
  - **Multiple PI Option*:*** Include biographical sketches for both the Initiating and Partnering PI(s).
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
  - **Multiple PI Option*:*** Include previous/current/pending support for both the Initiating and Partnering PI(s).

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."

   Multiple PI Option: ***Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PI(s), even if they are located within the same organization. The combined total direct costs for the Initiating and Partnering PI(s)' budgets cannot exceed $350,000.***

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.

Application Components for the Partnering PI(s) Applying Under the Multiple PI Option:

Each Partnering PI must follow the link in the email from the CDMRP eReceipt System and complete the registration process prior to the application submission deadline in order to associate his/her grant application package with that of the Initiating PI.

The application submission process for Partnering PI(s) uses an abbreviated application package of forms and attachments from Grants.gov that includes:

1. **SF 424 (R&R) Application for Federal Assistance Form**

2. **Attachments Form**

   - **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information on completing the SOW. ***Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.***

3. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.

   - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

   Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Partnering PI(s) should not include budget information for the Initiating PI, even if they are at the same organization. The combined total direct costs for the Initiating and Partnering PIs' budgets cannot exceed $350,000.

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

5. **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 will 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. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an "Active" status 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 makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DHP and ARP 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. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations 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 panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 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, of which Scientific Merit is significantly more than the remaining criteria, which are of equal importance.

   Note that innovation and impact do not compensate for deficiencies in scientific merit. A statistician will be included on all 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.
     - If the application includes the Multiple PI Option, how well the research project is supported by the nature of the collaboration.
     - If applicable, to what extent the human subject population is described as being appropriate for the study and there is clear access to the designated population.
     - If applicable, to what degree the statistical plan is appropriate for the experimental methodology being used.
       - How well the proposed statistical analysis demonstrates the relevance of any research outcomes to the central problem or FY13 ARP Area(s) of Interest identified.
       - Whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed.
     - 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.
     - The degree to which the informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical trial, if applicable.
     - If applicable, how well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate contingency plans to resolve them. To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study.
   - **Impact**
     - To what degree the proposed project is relevant to ASD.
     - How the anticipated outcomes from the proposed project compare to information/products currently available, if applicable.
     - To what extent the anticipated short-term outcome(s)/product(s) may impact the ASD community.

- To what degree the anticipated long-term gains from this research course may impact the ASD community.
- To what extent the proposed project, if successful, will ultimately improve the outcomes of individuals with ASD and well-being of families/caregivers.

- **Innovation**
  - To what extent 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.
- **Personnel**
  - To what extent the research team's background and expertise are appropriate to accomplish the proposed research.
  - If applicable, how inclusion of a biostatistician will improve the overall analysis and course of the study.
  - To what extent the levels of effort by the PI and other key personnel are appropriate for successful conduct of the proposed research.
  - To what extent the PI has demonstrated expertise and skill in the research areas of ASD or developmental disorders as evidenced by funding, distinctions, awards, and/or patents.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **Environment**
  - Whether the scientific environment is appropriate for the proposed research.
  - Whether the research requirements are supported by the availability of and accessibility to facilities and resources.
  - To what extent 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 make funding recommendations, the following criteria are used by the programmatic reviewers:

   a. **Ratings and evaluations of the peer reviewers**

   b. **Relevance to the mission of the DHP and FY13 ARP, as evidenced by the following:**

      - Adherence to the intent of the award mechanism
      - Program portfolio balance
      - Programmatic relevance
      - If applicable, past research accomplishments and performance
      - Relative impact and innovation

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

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. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from the CDMRP eReceipt System 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.

The following will result in administrative rejection of the application:

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

- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- **Multiple PI Option:** All associated (Initiating and Partnering PI) applications are not submitted by the deadline.

B. Modification

- 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, the PI 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:

- A FY13 ARP IP member is named as being involved in the research proposed or is found to have assisted 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 FY13 ARP IP members can be found at http://cdmrp.army.mil/arp/panels/panels13.
- 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 & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed human subject research qualifies as greater than minimal risk by the local IRB of record or by HRPO.
- The proposed research is a clinical trial other than a behavioral intervention trial.
- The PI does not meet the eligibility criteria.

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 USAMRAA 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, 2014. 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 D, for general information regarding administrative and national policy requirements.

C. Reporting

Refer to the General Application Instructions, Appendix 4, Section E, for general information on reporting requirements. Quarterly technical progress reports may be required.

D. Award Transfers

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

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as 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: 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: 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 or by responding to the prompt provided by Grants.gov when first downloading the application package. 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	Initiating PI Completed	Partnering PI 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 Lay Abstract (LayAbs.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.		
	Upload Performance History (Performance.pdf) as Attachment 8.		
	Human Subject Prospective Recruitment and Safety Procedures (HumSubProc.pdf), if applicable, as Attachment 9.		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
	Attach PI Previous/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 Previous/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.		