Program Announcement

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Autism Research Program

Idea Development Award

Funding Opportunity Number: W81XWH-12-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), June 20, 2012
- **Invitation to Submit an Application:** July 2012
- **Application Submission Deadline:** 11:59 p.m. ET, September 20, 2012
- **Peer Review:** November 2012
- **Programmatic Review:** January 2013

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I.   FUNDING OPPORTUNITY DESCRIPTION

A.   Program Description

Applications for the Autism Research Program (ARP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. 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 FY11 totaled $36.3 million (M). The FY12 appropriation is $5.12M.

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.   FY12 ARP Areas of Interest

The Idea Development Award seeks applications from all areas of basic and preclinical research. The FY12 ARP Idea Development Award encourages applications that address the critical needs of the ASD community in the following areas:

- Improved sub-grouping of individuals with ASD to provide information on the mechanisms, natural history, and response to treatment (e.g., biomarkers, risk factors, and sex ratio)

- Identification of therapeutic targets, excluding new gene discovery

- Psychosocial research across the lifespan, including influences on brain function/structure

- Co-morbid conditions across the lifespan, especially sleep disorders and gastrointestinal issues

C.   Award Information

The ARP Idea Development Award mechanism was first offered in FY07. Since then, 237 Idea Development Award applications have been received, and 18 have been recommended for funding.

The ARP Idea Development Award supports the development of innovative, high-impact ideas that advance the understanding of ASD and that ultimately will lead to improved outcomes for individuals with autism. Through the Idea Development Award, the ARP seeks to promote multidisciplinary collaborations (e.g., special education, biomedical science, preclinical research); to develop and validate biologically relevant animal models of autism (with appropriate justification for its relevance to a given subgroup); to investigate the implications of immunological response and ASD; and to leverage existing biological samples, clinical populations, and databases to provide power to test ideas.

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.

- **Innovation:** Research deemed innovative may represent a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other uniquely 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 typically considered innovative.

It is the responsibility of the PI to clearly and explicitly articulate the project's innovation and the potential impact on 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 FY12 ARP supports collaborative research to bring a new perspective to ASD research and/or facilitate progress in the field by combined effort. Therefore, up to three investigators, each of whom will be recognized as a PI and receive a separate award, may work 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 application addressing a central problem or question in ASD research. 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. 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 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 (found at https://cdmrp.org/Program_Announcements_and_Forms/), for more information.

Clinical trials 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 by CDMRP-funded research activities 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 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

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 **$400,000** 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 **$400,000** for direct costs for up to a **3**-year period of performance, plus indirect costs as appropriate. A separate award will be made to each PI's organization.

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

May be requested for (not all-inclusive):

- Salary

- Research supplies

- Publication costs

- Equipment

- 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 $3.2M of the $5.12M FY12 ARP 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 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/).

The Idea Development Award mechanism is structured to accommodate up to three PIs (one Initiating PI plus up to two Partnering 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 separately by email. Please note that each Partnering PI must follow the link in this email and register with CDMRP eReceipt 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. The letter will provide the information necessary to begin application submission through Grants.gov.

Submission of the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will 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-12-ARP-IDA.

B.   Pre-Application Submission Content and Form

All pre-application components must be submitted by the Initiating 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 any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 1-301-682-5507.

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**

    FY12 ARP Integration Panel (IP) members should not be involved in any pre-application 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 (1-301-682-5507).

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

- **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. 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 project's objective and specific aims. State the FY12 ARP Idea Development Award Area of Interest (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)

- ○ 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 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 DoD and the ARP, pre-applications will be screened based on the following criteria:

  - ○ **Research Idea:** How the proposed project addresses the intent of the award mechanism and the program. How the rationale and specific aims support the project's objective.

  - ○ **Impact:** What potential impact these studies will have on the outcomes of individuals with ASD and/or the understanding of ASD.

  - ○ **Innovation:** How the research represents more than an incremental advance on published data.

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

  Following the pre-application screening, Initiating PIs 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.

  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 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 with Multiple PI Option, 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. 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 Project Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

     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. Throughout the Project Narrative, describe how the proposed research is innovative and the potential impact it will have on ASD.

     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.

     - **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. Describe the statistical plan with appropriate power analysis where appropriate. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects, or the acquisition of samples. ***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. ***There are no page limits for any component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection 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 if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present 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 of each published manuscript must be included in Attachment 2. Extra items will not be reviewed.

  - ○ Letters of Organizational Support: 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 (two-page limit each, if applicable): 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."

  The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects. 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 understanding of ASD.
  - ○ 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."

  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) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information.

  **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). Describe the anticipated long-term gains from this research trajectory. 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.

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."

     ○ **Multiple PI Option:** Include biographical sketches for both the Initiating and Partnering PI(s).

   - Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

     ○ **Multiple PI Option:** Include 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 at the same organization. The combined total direct costs for the Initiating and Partnering PI(s)' budgets cannot exceed $400,000.*

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 CDMRP eReceipt 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 $400,000.

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. Organizations are required to provide a Data Universal Numbering 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.shtml.

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, 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.

   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 is the most important criterion, followed by Impact and Innovation, which are of equal importance:

- **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 well the statistical plan and power analysis for the proposed study (if applicable) adequately represent 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.

- **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.

  - How well the anticipated short-term outcome(s)/product(s) are described.

  - How well the anticipated long-term gains from this research course are described.

  - To what extent the proposed project, if successful, will ultimately improve the outcomes of individuals with ASD.

- **Innovation**

  - How well the proposed research, if successful, will challenge existing paradigms, or provide new paradigms, technologies, evidenced-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.

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 highest scoring applications from the first tier of review are not automatically recommended for funding. The Integration Panel balances the needs of the program by using the following equally considered criteria:

- Adherence to the intent of the award mechanism

- Programmatic relevance

- Program portfolio balance or 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. Each PI 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 exceeds page limit.

- 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 the same research project to different funding opportunities within the same program and fiscal year.

- Submission of an application for which a letter of invitation was not received.

- **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 FY12 ARP Integration Panel (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 FY12 ARP IP members can be found at http://cdmrp.army.mil/arp/panels/panels12.shtml.

- 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.

- 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 U.S. 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, 2013. 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.

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: 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	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.		
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.		