Program Announcement

for the

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Congressionally Directed Medical Research Programs

Amyotrophic Lateral Sclerosis Research Program

Therapeutic Development Award

Funding Opportunity Number: W81XWH-13-ALSRP-TDA

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 5, 2013
- **Invitation to Submit an Application:** July 2013
- **Application Submission Deadline:** 11:59 p.m. ET, September 18, 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) Amyotrophic Lateral Sclerosis Research Program (ALSRP) 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 ALSRP was established in 2007 to provide support for research of exceptional scientific merit aimed at preclinical assessment of therapeutics for amyotrophic lateral sclerosis (ALS). Appropriations for the ALSRP from FY07 through FY12 totaled $31.9 million (M). The FY13 appropriation is $7.5M.

The goal of the ALSRP is to contribute to a cure for ALS by funding innovative preclinical research to develop new treatments for ALS.

B. Award Information

The ALSRP Therapeutic Development Award (TDA) mechanism was first offered in FY07. Since then, 128 Therapeutic Development Award applications have been received, and 12 have been recommended for funding**.**

The TDA supports the preclinical assessment of therapeutics for ALS. The proposed studies are expected to be empirical in nature and product-driven but may have a hypothesis-driven approach, provided the focus is on therapeutics. It is anticipated that the agents and/or data generated from these awards will lead to the advancement of new therapies for ALS.

The TDA mechanism is designed to support ***preclinical*** testing and development of therapeutics for ALS. Applications must include ***preliminary data*** relevant to the phase(s) of the preclinical development process covered by the proposed research. The application should include a clear statistical plan of analysis, if appropriate. Applicants must clearly and explicitly articulate what impact the project may have on therapeutic development for ALS. **Clinical trials will not be supported with this Program Announcement/Funding Opportunity**.

Therapeutic Development Award applications are limited to the areas of programmatic interest listed below. Applications must focus on one or more of these areas to be considered for funding. Applications that do not focus on at least one of the following areas will be administratively withdrawn.

- Development and/or validation of high-throughput screens to define targets with therapeutic potential or to identify lead agent candidates for ALS treatment and be an asset for the ALS research community;
- Development, modification, and/or validation of preclinical model systems in order to assess lead compounds and potential therapeutics by pharmacological and/or pharmacokinetic testing. Such models would also serve as improved tools for the ALS research community;

- Development and optimization of pharmacologic agents through Adsorption, Distribution, Metabolism, Excretion (ADME) studies, and toxicology testing, including Investigational New Drug (IND)-enabling pharmacology/toxicology testing;
- Formulation and stability studies, design and implementation of full-scale, pilot current Good Manufacturing Practice (cGMP) production of therapeutics and/or delivery systems for use in advanced preclinical and initial clinical trials;
- Development of pharmacologic agents up to IND submission to initiate Phase I clinical trials after the award's completion.

In contrast, investigators interested in more basic research focused on ALS therapeutics should consider the FY13 ALSRP Therapeutic Idea Award, which does not require preliminary data (***http://cdmrp.army.mil/funding/alsrp***).

If a therapeutic agent(s) that is the subject of a Therapeutic Development Award application was initially developed under an ALSRP Therapeutic Idea Award (TIA), the applicant should describe the role of the TIA in that development.

The preclinical drug development process may require resources beyond those available at a single organization. Therefore, ***Therapeutic Development Awards are open to investigators participating in collaborations focused on identifying and/or testing lead agents for the treatment of ALS***. Collaborations should be dedicated to a single, preclinical development project rather than an additive set of subprojects. If a collaboration is proposed, letters confirming/supporting the collaboration are required**.** If the collaboration is multiorganizational, participating organizations should ensure the success of the collaboration by resolving potential intellectual and material property issues and by removing organizational barriers that might interfere with achieving high levels of cooperation. A proposed means to resolve these issues must be delineated in an Intellectual and Material Property Plan to be included with the application. Due to the nature of the work involved in the development process, biotechnology and pharmaceutical companies are invited to apply. Whether a biotechnology or pharmaceutical company applies for this mechanism as an individual applicant or as part of a collaboration, the company is expected to leverage its own resources to complement the funding provided by this award.

Use of human subjects and human anatomical substances: Because these awards are designed for preclinical studies, projects involving human subjects or specimens will not be supported unless they are exempt under Title 32, Code of Federal Regulations, Part 219, Section 101(b) (32 CFR 219.101[b]). ***Applications for studies involving human subjects or human anatomical substances that do not qualify for exempt status will be administratively withdrawn and will not be funded.*** For studies using only commercially available or de-identified specimens, a Claim of Exemption Form will be requested if the application is recommended for funding. Additional information regarding exempt status may be found on the U.S. Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office website (https://mrmc.amedd.army.mil/rodorphrpo.asp) and the General Application Instructions, Appendix 5, for this award mechanism.

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.

C. Eligibility Information

- Independent investigators at all academic levels (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.

D. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **$1,500,000** 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.
- More cost-effective studies that do not request the full available funding amount are encouraged. 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.

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
- Equipment (Note: Cost sharing is encouraged for large equipment purchases)
- Consultation with scientific and/or technical experts (e.g., statisticians, editors)

- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings in addition to the required meeting described below.

Must be requested for:

- Travel costs of up to $1,800 for the PI to attend one DoD military research-related meeting to be determined by the CDMRP during the award performance period. These costs are independent of travel costs between the above-mentioned collaborating organizations.

The CDMRP expects to allot approximately $4.8M of the $7.5M FY13 ALSRP appropriation to fund approximately 1-2 Therapeutic 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/).

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 application.

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-ALSRP-TDA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the 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 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**

  FY13 ALSRP 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 help@cdmrp.org (301-682-5507).

- **Required Files – Tab 4**

  Preproposal Narrative (three-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 Strategy and Objectives:** State the rationale on which the proposed work is based. Concisely state the project's objectives and specific aims.
  - **Impact:** Describe how the project will make an important contribution to ALS therapeutic development. Describe in general terms how the outcomes of the project, if successful, will be translated to the clinic and made available to ALS patients.
  - **Personnel:** Briefly state the qualifications of the PI, collaborators (if applicable) and key personnel to perform the described research project.

  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, this document only) 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 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 ALSRP, pre-applications will be screened based on the following criteria:

  - **Research Strategy and Objectives:** How the scientific rationale supports the project objectives and feasibility.
  - **Impact:** How the project will make an important contribution to ALS research and/or therapeutic development. Whether general steps for clinical translation of the projected outcomes of the project were adequately described.
  - **Personnel:** How the qualifications of the PI and key personnel are appropriate to perform the proposed research project.

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

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

Grants.gov application package components: For the Therapeutic 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 (20-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.

Describe the proposed project in detail using the outline below. The project narrative must include preliminary data relevant to the phase(s) of the preclinical development process addressed by the proposed research.

- **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to this project.
- **Objectives and Specific Aims:** Concisely explain the project's objectives and specific aims and their rationale. Show how the specific aims will support the proposed outcome(s) of the study/project. If the research is hypothesis-driven, state the hypothesis(es) to be tested.
- **Research Strategy:** Describe the study design, methods, and analyses, including statistical analyses, where applicable, in sufficient detail for assessment of the application. Address potential problem areas and present alternative methods and approaches**.**
- **Collaborations:** If a collaborative project is proposed, describe the expected working relationship between collaborators and how the expertise and resources of each collaborator will be brought to bear on the proposed project.

- **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 if Government-owned facilities or equipment are proposed for use. If so, 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/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.

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

  The technical abstract is used by all reviewers. Of particular importance, 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.

  Use the outline below:

  - Background: Present the ideas and reasoning behind the proposed work.
  - Objective/Hypothesis: State the objectives/hypothesis(es) to be tested. Provide evidence or rationale that supports the objectives/hypothesis(es).
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design including appropriate controls.
  - Impact: Summarize briefly how the proposed project will impact the development of therapeutics for ALS.

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

  Do not duplicate the technical abstract. The lay abstract is used by consumer peer and programmatic reviewers along with other components of the application package. Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without scientific or medical backgrounds.

  Describe the ultimate applicability of the research.

  - What type of ALS patients will it help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a patient-related outcome?

- What are the likely contributions of this study in advancing the development of therapeutics for ALS?

- **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.
- **Attachment 6: Impact Statement (one-page limit):** Upload as "Impact.pdf."

  Explain how the expected results of the study will make an important contribution to ALS therapeutic development. For projects involving product-driven research, describe the potential impact of the product on patients' lives. For projects involving hypothesis-driven research, describe the potential impact of the concepts or methods to drive therapeutic development.
- **Attachment 7: Transition Plan (one-page limit):** Upload as "Transition.pdf."

  Describe potential methods and strategies to move the product to the next phase of clinical trials/development after successful completion of the award. The transition plan should include the following components:

  - Outline a funding strategy that could be used to bring the therapy to the next phase of clinical trials/development.
  - Describe collaborations and other resources that could be used to provide continuity of development.
  - Provide a brief schedule and milestones for bringing the therapy to the next phase of clinical trials/development.

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

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

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

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

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

D. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines 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 ALSRP 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, which are of equal importance.

   - **Research Strategy (preliminary data are required)**
     - How well the scientific rationale supports the feasibility and development of the proposed product as demonstrated by a critical review and analysis of the literature, preliminary data, and logical reasoning;
     - How well the hypotheses or objectives and aims are developed;
     - How well the experimental design, methods, and analyses support the study outcomes;
     - If the research is product-driven, whether the study has clearly identified endpoints;
     - How well the applicant identifies potential problems and addresses alternative approaches;

     And, as appropriate:

     - The suitability of the screening assays and preclinical models to be developed, modified, and/or validated for identification and/or assessment of therapeutic agents;
     - How well the applicant clearly demonstrates the intent to use the proposed tools or models for preclinical therapeutic testing, not for basic research;
     - How well the outlined chemical synthetic pathways for modification of lead compounds or the formulation of potential delivery systems are feasible and based in rational design.
   - **Impact and Translational Potential**
     - How the study will make an impact on the development of therapeutics for ALS;
     - For projects involving product-driven research, the potential impact on patients' lives, and the quality and feasibility of the Transition Plan;
     - For projects involving hypothesis-driven research, the potential impact of the concepts or methods to drive therapeutic development.
   - **Adherence to the Award Intent**
     - How well the project addresses one or more of the areas of programmatic interests stated in the program announcement.
   - **Personnel**
     - How the research team's background and expertise are appropriate to develop the proposed product or, for hypothesis-driven projects, to conduct the proposed research;

- How the levels of effort are appropriate for the successful development of the proposed product;
- If multiple investigators are participating in the project, whether the letters of collaboration adequately describe all aspects of the collaborative effort.

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

- **Environment**
  - The appropriateness of the scientific environment for the proposed research;
  - How the research requirements are supported adequately by the availability of and accessibility to facilities and resources (including collaborative arrangements);
  - The quality and extent of organizational support, including the ability to support the therapy for the next level of clinical trials/development;
  - If multi-organizational, the quality and completeness of the Intellectual and Material Property Plan.
- **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 equally considered 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 ALSRP, as evidenced by the following:**
      - Program portfolio composition
      - Adherence to the intent of the award mechanism
      - Programmatic relevance

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.

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 ALSRP 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 ALSRP IP members can be found at http://cdmrp.army.mil/alsrp/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 PI does not meet the eligibility criteria.
- The application is or includes a clinical trial or non-exempt clinical research.
- The application does not address any of the topic areas of programmatic interest described under Section I.B., Award Information.

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.

D. Award Transfers

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.

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: 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	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 Transition Plan (Transition.pdf) as Attachment 7.	
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 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.	