Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Spinal Cord Injury Research Program

Investigator-Initiated Research Award

Funding Opportunity Number: W81XWH-10-SCIRP-IIRA

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I.   FUNDING OPPORTUNITY DESCRIPTION

A.   Program Description

The Spinal Cord Injury Research Program (SCIRP) was established in fiscal year 2009 (FY09) with a $35 million (M) congressional appropriation. The FY10 appropriation is $11.25M to promote research into regenerating damaged spinal cords, arthritis research, and improving rehabilitation therapies that offer real promise for enhancing long-term care of wounded soldiers. The SCIRP focuses its funding on innovative projects that have the potential to make a significant impact on improving the function, wellness, and overall quality of life for military Service Members as well as their caregivers, families, and the American public.

The FY10 SCIRP challenges the scientific community to design innovative research that will foster new directions for and address neglected issues in the fields of spinal cord injury (SCI)-focused research. Proposals from investigators within the military Services and proposals involving multidisciplinary collaborations among academia, industry, the military Services, the Department of Veterans Affairs (VA), and other Federal Government agencies are highly encouraged. Though the SCIRP supports groundbreaking research, all projects must demonstrate solid judgment and rationale.

B.   FY10 SCIRP Areas of Encouragement

The FY10 SCIRP encourages proposals that specifically address prevention, alleviation, or acute care of medical complications from SCI (e.g., autonomic dysreflexia, spasticity, sensory dysfunction or deficit, pain, skin care issues, bladder and bowel dysfunction, sexual dysfunction, and adjustment to disability).

The SCIRP seeks applications from the wide spectrum of basic, translational, and clinical research that are responsive to the Areas of Encouragement. Of particular interest to the program are projects focused on developing, testing, and translating novel interventions in SCI, and moving them into clinical practice. Since few advancements have impacted the standard of care in SCI, the SCIRP is giving special consideration to projects focused on implementation research (i.e. the development of methods or approaches that would enable the translation of research findings into SCI clinical practice) and/or the development of new clinical practice guidelines or the modification of current guidelines.

C. Encouraged DOD Collaboration and Alignment

Alignment with current Department of Defense (DOD) research and collaboration with military researchers and clinicians is encouraged. The following websites may be useful in identifying information about ongoing DOD areas of research interest within the FY10 SCIRP Areas of Encouragement:

Defense Technical Information Center
http://www.dtic.mil

Congressionally Directed Medical Research Programs
http://cdmrp.army.mil

U.S. Army Medical Research and Materiel Command
https://mrmc.amedd.army.mil

Air Force Research Laboratory
http://www.wpafb.af.mil/afrl

Navy and Marine Corps Public Health Center
http://www-nehc.med.navy.mil/

U.S. Department of Veterans Affairs, Office of Research and Development
www.research.va.gov

Office of Naval Research
http://www.onr.navy.mil/

U.S. Army Research Laboratory
http://www.arl.army.mil

U.S. Naval Research Laboratory
www.nrl.navy.mil

Defense Advanced Research Projects Agency
http://www.darpa.mil/

U.S. Army Medical Research Acquisition Activity
http://www.usamraa.army.mil

Naval Health Research Center
http://www.nhrc.navy.mil/

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics
http://www.acq.osd.mil/

D.   Award Description

The SCIRP Investigator-Initiated Research Award (IIRA) mechanism was first offered in FY09. Since then, 70 Investigator-Initiated Research Award applications have been received, and 13 have been recommended for funding.

The IIRA is intended to support studies that have the potential to make an important contribution to SCI research and/or patient care. Projects should be innovative, address an Area of Encouragement, and be applicable to the health care needs of the Armed Forces, their family members, and/or the U.S. veteran population. All applications must specifically and clearly address the military relevance of the proposed research. Collaboration with military researchers and clinicians is encouraged.

Research projects may focus on any phase of research from basic through translational, including preclinical studies in animal models or human subjects, as well as correlative studies associated with an existing clinical trial. Observations that drive a research idea may be derived from laboratory discovery, population-based studies, a clinician's first-hand knowledge of patients, or anecdotal data.

Proposals must include preliminary and/or published data originating from the PI, research team, or partners that is relevant to the topic area and the proposed project.

Clinical trials are not allowed under this mechanism. The SCIRP encourages clinical trials with a focus on rehabilitation through the Clinical Trial Award – Rehabilitation (for information about this award mechanism, see ***http://cdmrp.army.mil***). Principal Investigators (PIs) wishing

to apply for funding for a clinical trial focused on Rehabilitative Medicine should utilize this mechanism. A *clinical trial* is defined as a prospective accrual of patients where an intervention is tested on a human subject for a *measurable outcome* for safety and/or efficacy. Clinical trials require informed consent on the subject, and may include identifiable information.

Use of Human Subjects and Human Biological Substances: All DOD-funded research involving human subjects and human biological substances must be reviewed and approved by the USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to local IRBs. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed, and will require information in addition to that supplied to the local review board. Allow a minimum of 6 months for regulatory review and approval processes for studies involving human subjects.

Optional Qualified Collaborator(s): The FY10 SCIRP strongly supports collaborative research between basic scientists and clinical researchers, and between academic scientists and biotechnology/pharmaceutical industry scientists. Collaborations that bring new perspectives from other disciplines or bring new investigators into the SCI field are also strongly encouraged. Collaborations that meet the criteria below will qualify for a higher level of funding.

To utilize the Optional Qualified Collaborator:

1) The PI must submit a Statement of Collaboration that clearly identifies the collaborating investigator and addresses how each of the criteria below are met, and

2) The collaborator must provide a letter of collaboration describing his/her involvement in the proposed work.

It should be clear that the success of the project depends on the unique skills and contributions of each partner.

Optional Qualified Collaborator Criteria:

- The collaborator(s) must significantly contribute to the project such that the proposed work could not be accomplished without his/her involvement.
  - A proposed project in which the collaborator(s) merely supplies tissue samples or access to patients will not meet the intent and will not be qualified for the higher level of funding.
- Either the PI or the collaborator(s) must have SCI research experience as demonstrated through publications and/or funding history.
- The collaborator(s) must be *at or above* the level of Assistant Professor (or equivalent).
- At least a 10% level of effort is required of the collaborator(s). Contribution of the collaborator should be reflected in the application's budget.

E. Eligibility

Independent investigators at all academic levels (or equivalent) are eligible to submit applications. Optional Qualified Collaborator(s) must be at or above the level of Assistant Professor (or equivalent). Refer to General Application Instructions, Appendix 1, for general eligibility information.

F. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct cost for the entire period of performance is **$500,000**. If requesting an Optional Qualified Collaborator, the maximum allowable funding for the entire period of performance is **$750,000** in direct costs. More cost-effective studies that do not request the full available funding amount are encouraged.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum **3-**year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the organization's negotiated rate agreement.

Within the guidelines provided in the General Application Instructions, funds can cover:

- Salary
- Research Supplies
- Equipment
- Clinical costs (***clinical trials not allowed***)
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings
- Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification

An additional $1,800 in funding must be requested for the PI to travel to one DOD-sponsored scientific meeting in the Washington, DC/Baltimore, Maryland, area.

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $2.4M of the $11.25M FY10 SCIRP appropriation to fund approximately 3 Investigator-Initiated Research 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.

G. Award Administration

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2011. Refer to the General Application Instructions, Appendix 4, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

- **Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), August 5, 2010**
- **Invitation to Submit an Application: September 30, 2010**
- **Application Submission Deadline: 11:59 p.m. ET, December 1, 2010**
- **Scientific Peer Review: January 2011**
- **Programmatic Review: March 2011**

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline, and a proposal has been invited.

III. SUBMISSION PROCESS

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/). *Applications will be invited based on pre-application screening. Do not submit an application unless a letter of invitation has been received.*

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

PIs and organizations identified in the application should be the same as those identified in the pre-application. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

A. Step 1 – Pre-Application Components

All pre-application components must be submitted through the CDMRP eReceipt system by *5:00 p.m. ET on the deadline*. Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt system by separate tabs (Refer to the General Application Instructions for additional information on pre-application submission):

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

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

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

  The Preproposal Narrative should include the following:

  - **Research Idea:** State the ideas and reasoning on which the *proposed work* is based. Clearly state the type of study proposed (e.g., discovery, development, animal validation, human validation, etc.)

  - **Research Strategy:** Concisely state the project's objectives and specific aims.

  - **Impact:** State explicitly how the proposed work will have an impact on the understanding of SCI and/or amelioration of its consequences.

  - **Innovation:** State explicitly how the proposed work is innovative.

  - **Military Relevance:** Describe how the proposed work is applicable to the health care needs of military service members, their family members, and/or the U.S. veteran population.

  - **Alignment with Areas of Encouragement:** If applicable, explain how the proposed work addresses any of the FY10 SCIRP Areas of Encouragement.

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

- References Cited (one-page limit): List relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.

- Key Personnel Biographical Sketches (four-page limit per individual): Include biographical sketches for the PI and other key collaborators.

- **Submit Pre-application – Tab 5**

- **Other Documents Tab**

  Not applicable.

Pre-Application Screening: Pre-applications will be screened by the SCIRP Integration Panel (IP), composed of scientists, clinicians, and consumer advocates. The pre-application screening criteria are as follows:

- **Research Idea:** How well the described research demonstrates solid judgment and rationale for SCI research and clearly identifies the type of study to be performed (e.g., discovery, development, animal validation, human validation, etc.).

- **Research Strategy:** How well the specific aims support the research idea.

- **Impact:** How well the study addresses an important problem related to SCI. If successful, how the study will improve our understanding of SCI and/or amelioration of its consequences.

- **Innovation:** How the study is innovative in one or more ways including but not limited to concept or question, research methods or technologies, adaptations of existing methods or technologies.

- **Personnel:** Whether the PI and key collaborators have the necessary background and expertise to accomplish the proposed work.

- **Military Relevance**: How the proposed study may directly or indirectly benefit military service members, their family members, and/or the U.S. veteran population.

- **Alignment with Area of Encouragement:** If applicable, how the proposed study addresses any of the FY10 SCIRP Areas of Encouragement.

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

B.   Step 2 – Application Components

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

Applications are submitted by the Authorized Organizational Representative (AOR) through Grants.gov (http://www.grants.gov/). Applications must be submitted **by *11:59 p.m. ET on the deadline.***

Each application submission must include the completed application package of forms and attachments identified in Grants.gov for this Program Announcement/Funding Opportunity.

The Grants.gov application package consists of the following components (Refer to the General Application Instructions, Section II.B., for additional information on application submission):

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

2. **Attachments Form**

    - **Attachment 1: Project Narrative (10-page limit):** Upload as "ProjectNarrative.pdf."

      Describe the proposed project in detail using the outline below. *The Project Narrative must include preliminary data that is relevant to SCI and the proposed project.*

      ○ **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to this 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 funded by this application. If the proposed work is part of a larger study, present only tasks that the DOD award would fund.

- ○ **Research Strategy:** Describe the study design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Describe the statistical plan if appropriate for the research proposed. ***This award may not be used to conduct clinical trials.***

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***Each component has no page limit unless otherwise noted.***

  - ○ References Cited: List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.

  - ○ List of Acronyms and Symbols: Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).

  - ○ Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information.

  - ○ Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then they must be included. Extra items will not be reviewed.

  - ○ Letters of Organizational Support (two-page limit per letter): Provide a letter (or letters if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project. If the PI is a practicing clinician, the institution must clearly demonstrate a commitment to the clinician's research.

  - ○ Letters of Collaboration (if applicable) (two-page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.

  - ○ Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

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

  Technical abstracts should be written using the outline below.

  - Background: Present the ideas and reasoning behind the proposed work.

  - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

  - Specific Aims: State the specific aims of the study.

  - Study Design: Briefly describe the study design including appropriate controls.

  - Impact: Briefly describe how the proposed project will have an impact on SCI research and/or patient care.

  - Innovation: Briefly describe how the proposed project uses innovation to advance the understanding of SCI and amelioration of its consequences.

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

  Public abstracts should be written using the outline below.

  - Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed work.

    - Do not duplicate the technical abstract.

  - Describe the ultimate applicability of the research.

    - What types of 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?

  - If the research is too basic for clinical applicability, describe the interim outcomes.

  - What are the likely contributions of this study to advancing the field of SCI research?

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

- **Attachment 6: Detailed Budget and Justification (no page limit):** Upload as "Budget.pdf." Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Refer to the General Application Instructions, Section II.B., for detailed information.

- **Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as "SubBudgets.pdf." Refer to the General Application Instructions, Section II.B., for detailed information.

- **Attachment 8: Impact Statement (one-page limit):** Upload as "Impact.pdf." Describe the potential impact of this study on the field of research and/or patient care in SCI. Include an assessment of the likelihood that a successful outcome to the research project will lead to a practical application in patients. The following are examples of ways in which proposed studies, if successful, may have an impact. Although not all inclusive, these examples are intended to help PIs frame the impact of the proposed research:

  - Has the potential to advance the field of research in SCI.

  - Has the potential to change the standard of care.

  - Contributes to the development or validation of evidence-based policy or guidelines for patient evaluation and care.

- **Attachment 9: Innovation Statement (one-page limit):** Upload as "Innovation.pdf." Summarize how the proposed work is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative. ***Although not all-inclusive***, the following examples are ways in which the proposed work may be innovative and are intended to help PIs frame the innovative features:

  - Study concept: Investigation of a novel idea and/or research question.

  - Research method or technology: Use of novel research methods or new technologies, including technology development, to address a research question.

  - Novel method or technology: Development of a novel method or technology for preventing, detecting, diagnosing, or treatment.

  - Existing methods or technologies: Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

- **Attachment 10: Statement of Collaboration (required if requesting higher level of funding):** Upload as "Collaboration.pdf." If applying for the higher level of funding for the Optional Qualified Collaborator, the PI must submit a statement that identifies the collaborating investigator and addresses all criteria described in Section I.D. It should be clear that the success of the project depends on the unique skills and contributions of each partner.

- **Attachment 11: Military Relevance Statement (one-page limit):** Upload as "Military.pdf." Demonstrate how the proposed study is applicable to the health care needs and quality of life of military service members, their family members, and/or the U.S. veteran population. If active duty military, military families, or veteran population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e. Armed Forces, their family members, and/or the U.S. veteran population).

- **Attachment 12: Approval for Access to Military and VA Populations (if applicable, one-page limit):** Upload as "ApprovalAccess.pdf." A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving active duty military, military families, or veterans; military-controlled study materials; databases; and/or restricted facilities (e.g., biological or chemical containment facilities).

3. Research & Related Senior/Key Person Profile (Expanded) Form: Refer to the General Application Instructions, Section II.B., for detailed information.

- PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
- PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
- Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
- Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

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

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on scientific merit, the overall goals of the program, and specific intent of the award mechanism. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP may be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria, which are listed in decreasing order of importance:

- **Research Strategy and Feasibility (preliminary and/or published data are required)**
  - How well the preliminary data and scientific rationale support the research project.
  - How well the hypothesis or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
  - How well the PI acknowledges potential problems and addresses alternative approaches.
  - If the application includes the Optional Qualified Collaborator, how well the nature of the collaboration supports the research project.

- **Impact**
  - How the proposed study addresses a critical problem in SCI research or patient care.
  - How the proposed research will make original and important contributions towards the goal of advancing SCI research or patient care.

- **Innovation**
  - How the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies.
  - How the proposed research represents more than an incremental advance upon published data.

- **Personnel**
  - How the background and expertise of the PI and other key personnel are appropriate to accomplish the proposed work.
  - How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
  - How the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed work.
  - **Optional Qualified Collaborator(s) (if applicable)**
    - Whether the collaborator's experience, expertise, and involvement in the study significantly contribute to the project such that the proposed work could not be accomplished without his/her involvement.
    - Whether the collaborator(s) meets the criteria for an Optional Qualified Collaborator as verified by the Statement of Collaboration (i.e. the

collaborator[s] possesses appropriate SCI research experience if the PI does not; the collaborator[s] is at or above the level of Assistant Professor [or equivalent]; the collaborator[s] is contributing at least 10% level of effort).

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

- **Environment**
  - ○ How the scientific environment is appropriate for the proposed research.
  - ○ How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - ○ How the quality and extent of institutional support are appropriate for the proposed research.

- **Budget**
  - ○ Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**
  - ○ How the writing and components of the application influenced the review.

2. Programmatic Review: The following equally weighted criteria are used by programmatic reviewers to make funding recommendations.

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Program portfolio composition, with consideration of the Areas of Encouragement,
- Relative impact and innovation,
- Adherence to the intent of the award mechanism, and
- Military relevance.

V.   ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

A.   Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Submission of an application for which a letter of invitation was not received.

B.   Modifications

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section V-A, Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C.   Withdrawal

The following may result in administrative withdrawal of the application:

- FY10 SCIRP IP member(s) is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY10 SCIRP IP members may be found at http://cdmrp.army.mil/scirp/panels/panel10.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- The proposed research is or contains a clinical trial.
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.

D.   Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

VI.   CONTACT INFORMATION

A.   CDMRP Program Announcement Help Desk: Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. ET. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

> Phone: 301-619-7079
> Email: cdmrp.pa@amedd.army.mil

B.   CDMRP eReceipt System Help Desk: Questions related to the submission of the pre-application through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

> Phone: 301-682-5507
> Email: help@cdmrp.org

C.   Grants.gov Contact Center: Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week. Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance regarding Grants.gov submissions.

> Phone: 800-518-4726
> Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1	
	Upload Supporting Documentation (Support.pdf) as Attachment 2	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3	
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4	
	Upload Statement of Work (SOW.pdf) as Attachment 5	
	Upload Detailed Budget and Justification (Budget.pdf) as Attachment 6	
	Upload Subaward Detailed Budget and Justification (SubBudgets.pdf) as Attachment 7	
	Upload Impact Statement (Impact.pdf) as Attachment 8	
	Upload Innovation Statement (Innovation.pdf) as Attachment 9	
	Upload Statement of Collaboration (Collaboration.pdf), if requesting higher level of funding, as Attachment 10	
	Upload Military Relevance Statement (Military.pdf) as Attachment 11	
	Upload Approval for Access to Military and VA Populations (ApprovalAccess.pdf), if applicable, as Attachment 12	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field	
Project/Performance Site Location(s) Form	Complete form as instructed	