

# **Program Announcement**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Spinal Cord Injury Research Program Translational Research Award**

**Funding Opportunity Number: W81XWH-12-SCIRP-TRA**

**Catalog of Federal Domestic Assistance Number: 12.420**

### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 5, 2012
- **Invitation to Submit an Application:** August 2012
- **Application Submission Deadline:** 11:59 p.m. ET, October 1, 2012
- **Peer Review:** November 2012
- **Programmatic Review:** January 2013

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## **I. FUNDING OPPORTUNITY DESCRIPTION**

### **A. Program Description**

Applications for the Spinal Cord Injury Research Program (SCIRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The SCIRP was established in 2009 to fund innovative projects that have the potential to make a significant impact on improving the health and well-being of military Service members, Veterans, and other individuals living with SCI. Appropriations for the SCIRP from FY09 through FY11 totaled \$58.25 million (M). The FY12 appropriation is \$9.6M.

The FY12 SCIRP challenges the scientific community to design innovative research that will foster new directions for and address neglected issues in the field of SCI-focused research. Applications from investigators within the military Services, and applications 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 scientific rationale.

### **B. FY12 SCIRP Areas of Encouragement:**

The FY12 SCIRP encourages applications that specifically address the following areas related to acute SCI:

- Pre-hospital, en route care, and early hospital management of SCI
- Prevention of pressure ulcers

FY12 SCIRP also encourages applications that specifically address the following areas related to chronic SCI:

- Autonomic dysfunction
- Bowel dysfunction
- Neuropathic pain and sensory dysfunction
- Respiratory dysfunction, sleep disordered breathing, and ventilation management

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 ongoing areas of DoD research interest within the FY12 SCIRP Areas of Encouragement.

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

Clinical and Rehabilitative Medicine  
Research Program  
<https://crmp.amedd.army.mil>

Combat Casualty Care Research Program  
<https://ccc.amedd.army.mil>

Congressionally Directed Medical Research  
Programs

<http://cdmrp.army.mil>

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

Defense Medical Research and Development Program

<http://dmrdp.fhpr.osd.mil/home.aspx>

Defense Technical Information Center

<http://www.dtic.mil>

Military Infectious Disease Research Program

<https://midrp.amedd.army.mil>

Military Operational Medicine Research Program

<https://momrp.amedd.army.mil>

Naval Health Research Center

<http://www.med.navy.mil/sites/nhrc>

Navy and Marine Corps Public Health Center

<http://www-nmcpbc.med.navy.mil/>

Office of Naval Research

<http://www.med.navy.mil/>

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics

<http://www.acq.osd.mil/>

U.S. Army Medical Research Acquisition Activity

<https://www.usamraa.army.mil/>

U.S. Army Medical Research and Materiel Command

<https://mrmc.amedd.army.mil>

U.S. Army Research Laboratory

<http://www.arl.army.mil>

U.S. Naval Research Laboratory

<http://www.nrl.navy.mil>

U.S. Department of Defense Blast Injury Research Program

<https://blastinjuryresearch.amedd.army.mil/>

U.S. Department of Veterans Affairs, Office of Research and Development

<http://www.research.va.gov>

USUHS Center for Neuroscience and Regenerative Medicine

<http://www.usuhs.mil/cnrm/>

Walter Reed Army Institute of Research

<http://wrair-www.army.mil>

### C. Award Information

The Translational Research Award (TRA) mechanism was first offered as the Translational Research Partnership Award (TRPA) in FY09. Thirty-one TRPA applications were received, and 9 were recommended for funding. ***NEW for FY12:*** The award mechanism has been modified to support individual investigators, and is ***no longer limited to multi-institutional, multidisciplinary partnerships among clinicians and basic scientists.***

This award supports translational research that will accelerate the movement of promising ideas in spinal cord injury research into clinical applications. Observations that drive a research idea may be derived from a laboratory discovery, population-based studies, or a clinician's first-hand knowledge of patients and anecdotal data. While the ultimate goal of translational research is to move an observation forward into clinical application, PIs should not view translational research as a one-way continuum from bench to bedside. The research plan must involve a reciprocal flow of ideas and information between basic and clinical science. Developmental pathways for translational research that may be useful for designing translational research studies for support under this mechanism may be found at (<http://www.cancer.gov/aboutnci/trwg/Pathways-to-Clinical-Goals>).

***Applications must include preliminary data relevant to SCI and the proposed project.***

***Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity.*** A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested with a human subject for a measurable outcome with respect to exploratory information, safety,

effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information on clinical trials and clinical research, a Human Subject Resource Document is provided on the CDMRP eReceipt System at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/). Principal Investigators (PIs) wishing to apply for funding for a clinical trial should utilize the FY12 SCIRP Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-12-SCIRP-CTA).

**Use of Human Subjects and Human Anatomical Substances:** All DoD-funded research involving new and ongoing research with human subjects and human anatomical substances must be reviewed and approved by the US Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is NOT required. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DoD. Allow a minimum of 4 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

**Use of Military and VA Populations:** If applicable, access to target military or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving active duty military, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.

**Use of Common Data Elements (CDE):** The use of the spinal cord injury CDE standards developed through the collaboration of the International Spinal Cord Society, the American Spinal Injury Association, and the National Institute of Neurological Disorders and Stroke CDE team, as referenced at <http://www.commondataelements.ninds.nih.gov/SCI.aspx>, is encouraged. Additionally, the government reserves the right to identify repositories for submission of data for archive. Any costs associated with submission of data to such repositories will be addressed during award negotiations.

***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**

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

#### **E. Funding**

- The maximum period of performance is 3 years.
- The maximum allowable direct costs for the entire period of performance are \$750,000 plus indirect costs. More cost-effective studies that do not request the full available funding amount are encouraged.

- 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.

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:

Must be requested for:

- PI's travel to one DoD-sponsored scientific meeting in the Washington, DC, metropolitan area (\$1,800). Costs associated with travel to this meeting should be included in Year 1 of the budget.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs (clinical trials not allowed)
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

*The CDMRP expects to allot approximately \$2.4M of the \$9.6M FY12 SCIRP appropriation to fund approximately 2 Translational 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.*

## **II. SUBMISSION INFORMATION**

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

Submission of the same research project to different funding opportunities within the same program and fiscal year is 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-SCIRP-TRA.

## 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 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](mailto:help@cdmrp.org) or 301-682-5507.

A change in PI or organization after submission of the pre-application will be allowed only at the discretion of the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer.

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 SCIRP 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).

- **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 must adhere to the following outline:

- **Background/Readiness:** 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.), and demonstrate that there is sufficient scientific evidence to support moving into the proposed stage of research.
- **Hypothesis and Approach:** Concisely state the project's hypothesis and describe the scientific approach. Include appropriate controls, and demonstrate that the work is appropriately powered. Describe the translational aspect of this application, providing evidence for the reciprocal transfer of ideas between basic and clinical science.
- **Impact:** State explicitly how the proposed work will have an impact on advancing the treatment of SCI and its consequences and, if applicable, how it addresses one or more FY12 SCIRP Areas of Encouragement.
- **Military relevance:** Describe how the proposed work is applicable to the health care needs of military Service members, Veterans, and other individuals living with SCI.

**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 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.
- PI Biographical Sketch (two-page limit): Include a biographical sketch for the PI only.
- **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 SCIRP, pre-applications will be screened based on the following criteria:

  - **Background/ Readiness:** How well the described research demonstrates solid scientific rationale for SCI research and provides sufficient evidence that the research is ready to move into the proposed stage of research (e.g., discovery, development, animal validation, human validation, etc.).
  - **Hypothesis and Approach:** How well a clear hypothesis is stated and supported through scientific rationale and referenced literature, and how well the project’s approach will address the hypothesis. How the project will translate promising, well-founded research findings into clinical applications in spinal cord injury.
  - **Impact:** How well the study addresses an important problem related to SCI and, if applicable, how it addresses one or more FY12 Areas of Encouragement. If successful, how the study will impact clinical practice, and improve the treatment of SCI and its consequences.
  - **Military Relevance:** How well the proposed study directly or indirectly benefits military Service members, Veterans, and other individuals living with SCI.
- **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 applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application.

The invitation to submit an application date 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 Translational Research 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.”

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

- **Background/Readiness:** Present the ideas and reasoning behind the proposed work, and clearly demonstrate that there is sufficient scientific evidence to support moving into the proposed stage of research. Cite relevant literature. Describe previous experience most pertinent to this project.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective(s) 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 SCIRP award would fund.
- **Research Strategy and Feasibility:** Describe the research strategy, methods, and analyses, including appropriate controls, in sufficient detail for analysis of its appropriateness and feasibility. 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. *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/copies of the published manuscript(s) 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 (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.
- Data and Research Resources Sharing Plan (if applicable): Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publically available. Include plans for utilizing the spinal cord injury Common Data Element (CDE) standards developed through the collaboration of the International Spinal Cord Society, the American Spinal Injury Association, and the National Institute of Neurological Disorders and Stroke CDE team, as referenced at <http://www.commondataelements.ninds.nih.gov/SCI.aspx>. Additionally, the government reserves the right to identify repositories for submission of data for archive. Any costs associated with submission will be addressed during award negotiations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”  
 Technical abstracts should be written using the outline below. The technical abstract is used by all reviewers; however, programmatic reviewers do not typically have access to the full application and rely on the technical abstract for appropriate description of the project’s key aspects.
  - Background/Readiness: Present the ideas and reasoning behind the proposed work, including sufficient scientific evidence to support moving into the proposed stage of research.
  - Objective/Hypothesis: State the objective(s)/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

- Specific Aims: State the specific aims of the study.
- Research Strategy: Briefly describe the study design including appropriate controls.
- Impact: Briefly describe how the proposed project will have an impact on advancing the treatment of SCI and its consequences and, if applicable, how it addresses one or more FY12 SCIRP Areas of Encouragement.
- Translation: Briefly describe how the proposed project will translate promising, well-founded research findings into clinical applications in spinal cord injury.
- Military Relevance: Briefly describe the relevance of the proposed project to the health care needs of military Service members, Veterans, and other individuals living with SCI.

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

Lay abstracts should be written using the outline below. Do not duplicate the technical abstract. The lay abstract is used by consumer peer reviewers along with other components of the application package.

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

- **Attachment 6: 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. If applicable, address the impact on one or more of the FY12 SCIRP Areas of Encouragement. Include an assessment of the likelihood that a successful outcome to the research project will lead to a practical application in individuals living with SCI. 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 7: Translation Statement (one-page limit):** Upload as “Translation.pdf.” Describe the translational research that will be performed through this award. State explicitly how the proposed research is translational in nature, allowing for the reciprocal transfer of ideas between basic and clinical science.
  - **Attachment 8: 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, Veterans, and other individuals living with SCI. If the active duty military, Veteran, or military family member 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.
  - **Attachment 9: Approval for Access to Military and VA Populations (if applicable, one-page limit per site):** 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, Veterans, or military family members; military-controlled study materials; databases; and/or restricted facilities (e.g., biological or chemical containment facilities).
3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.
    - PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
    - PI Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
    - Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch\_LastName.pdf.”
    - Key Personnel Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
    - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
  5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
  6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

#### **D. Submission Dates and Times**

All submission dates and times are indicated on the title page of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines 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, U.S. Army Medical Research and Materiel Command (USAMRMC), based on technical merit, the relevance to the mission of the DoD and SCIRP 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, which are listed in decreasing order of importance:
  - **Translational Potential**
    - How well the project will translate promising, well-founded basic or clinical research findings into clinical applications for individuals living with, or populations at risk for, SCI.
  - **Research Strategy and Feasibility**
    - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, relevant preliminary data, and logical reasoning.

- How well the hypothesis or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
- How well the PI provides sufficient evidence that the research is ready to move into the proposed stage of research
- How well the PI acknowledges potential problem areas and addresses alternative approaches.
- **Impact**
  - If successful, how well the aims of the study will eventually move a clinical observation, a basic discovery, or population-based study into clinical application.
  - How well the proposed research will have an impact on the concepts or methods that drive the field of SCI research.
  - How well the proposed research will make original and important contributions toward the goal of advancing SCI research or patient care.
  - If applicable, how well the study addresses the impact on one or more of the FY12 SCIRP Areas of Encouragement.
- **Personnel**
  - How well the background and expertise of the PI and other key personnel are appropriate to accomplish the proposed work.
  - How well the levels of effort by the PI and other key personnel are appropriate to ensure the success of this project.
  - How well the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed work.

The following unscored criteria will also contribute to the overall evaluation of the application:

- **Environment**
  - How well the evidence indicates an appropriate scientific environment and the accessibility of institutional resources to support the proposed translational research at each participating organization.
  - How well the evidence supports appropriate institutional commitment from each participating organization.
  - If applicable, how the intellectual and material property plan that is agreed upon by each participating organization is appropriate for the proposed translational 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 SCIRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

- Adherence to the intent of the award mechanism
- Military relevance
- Program portfolio composition, with consideration of the FY12 Areas of Encouragement
- Programmatic relevance
- Ratings and evaluations of the peer reviewers
- Relative impact

**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:

- 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 Preproposal Narrative and the Project 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 SCIRP 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 SCIRP IP members can be found at <http://cdmrp.army.mil/scirp/panels/panel12.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.
- The PI does not meet the eligibility criteria.

## **D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the 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.

### **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](mailto: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](mailto: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**

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Completed</b>
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 Translation Statement (Translation.pdf) as Attachment 7.	
	Upload Military Relevance Statement (Military.pdf) as Attachment 8.	
	Upload Approval for Access to Military and VA Populations (ApprovalAccess.pdf) as Attachment 9.	
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 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.	