

Program Announcement

**Defense Health Program
Defense Medical Research and Development Program**

Department of Defense Congressionally Directed Medical Research Programs (CDMRP)

Spinal Cord Injury Research Program

Translational Research Partnership Award

Funding Opportunity Number: W81XWH-11-SCIRP-TRPA

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 15, 2011
- **Invitation to Submit an Application:** September 2011
- **Application Submission Deadline:** 11:59 p.m. ET, December 1, 2011
- **Scientific Peer Review:** January 2012
- **Programmatic Review:** March 2012

New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Assistant Secretary of Defense for Health Affairs, Defense Health Program is soliciting applications for the Spinal Cord Injury Research Program (SCIRP) which was established in fiscal year 2009 (FY09). 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 spinal cord injured military Service members and veterans, their caregivers and family members, and the American public. Appropriations for the SCIRP through FY10 totaled \$46.25 million (M). The FY11 appropriation is \$12M.

The FY11 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. FY11 SCIRP Areas of Encouragement

The FY11 SCIRP encourages applications that specifically address the prevention, alleviation, or care of medical complications from SCI, including adjustment to disability, autonomic dysreflexia, bladder and bowel dysfunction, pain, pressure ulcers, psychological disorders, sensory dysfunction or deficit, sexual dysfunction, and spasticity. ***New for FY11: Applications that do not address at least one of these areas are required to justify the relevance of the project to the spinal cord injured military and/or veteran population.***

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 and 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.

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 research interest within the FY11 SCIRP Areas of Encouragement.

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

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

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

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

Navy and Marine Corps Public
Health Center
<http://www.nmcphc.med.navy.mil/>

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

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

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

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

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

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

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

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

USUHS Center for Neuroscience
and Regenerative Medicine
<http://www.usuhs.mil/cnrm/>

C. Award Information

The SCIRP Translational Research Partnership Award (TRPA) mechanism was first offered in FY09. Since then, 22 TRPA applications have been received, and 8 have been recommended for funding.

The intent of the TRPA is to promote *multi-institutional, multidisciplinary* partnerships among clinicians and basic scientists that accelerate the movement of promising ideas in spinal cord injury research into clinical applications. This award is intended to support both new and established scientists across a broad spectrum of disciplines in research projects that are likely to have a major impact on spinal cord injury research.

The TRPA supports the development of translational research partnerships among **two or three** independent investigators (known as partners). Applications should address one or more of the FY11 SCIRP Areas of Encouragement or justify the applicability of the research to the spinal cord injured military and/or veteran population. *At least one partner must be a clinician, and at least one partner must have experience in spinal cord injury basic research.* A clinician is defined as an individual who is credentialed (possesses the necessary degrees, licenses, and other certifications) as a care provider in any relevant capacity at the institution of record. Biosketches should include appropriate documentation of credentials. It should be clear that all partners have substantial intellectual input into the design of the research project. A proposed project in which one of the partners merely provides tissue samples or access to patients will not meet the intent of this mechanism.

Observations that drive a research idea may be derived from a basic discovery, population-based studies, or a clinician's firsthand knowledge of patients and preliminary data. While the ultimate goal of translational research is to move an observation forward into clinical application, members of the partnership should view translational research as a two-way continuum between

bench and bedside. Developing the research plan must involve a reciprocal flow of ideas and information within the partnership. 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.

Important aspects of the TRPA are as follows:

- 1. Translational:** The application should provide evidence for the reciprocal transfer of ideas between basic and clinical science in developing and implementing the research plan.
- 2. Partnership:** The success of the project depends on the unique disciplines, skills, and contributions of each partner. Of the two to three partners, at least one must be a clinician, and at least one must have experience in SCI basic research.
- 3. Multi-institutional:** At least two distinct institutions must be involved.
- 4. Impact:** The proposed research should have a significant impact on the concepts or methods that are likely to accelerate the movement of promising ideas in spinal cord injury research into clinical applications.

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 on 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. The SCIRP encourages clinical trials with a focus on rehabilitation through the FY11 SCIRP Clinical Trial Award – Rehabilitation mechanism (Funding Opportunity Number: W81XWH-11-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. These laws and directives are rigorous and detailed, and will require information in addition to that supplied to the local IRB. Allow a minimum of 4 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

D. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.

- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance is **\$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.
- Each partner will be a Principal Investigator (PI), and a separate award will be made to each PI's organization.
- The PIs are expected to be equal partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget form. 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/Baltimore, Maryland, area (\$1,800)
- Each PI must also request travel funds to attend one program review meeting every other year starting with the first year of the award period of performance. For planning purposes, it may be assumed that program reviews will be held in the Washington, DC/ Baltimore, Maryland, metropolitan area.

May be requested for (not all-inclusive):

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

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$2.4M of the \$12M FY11 SCIRP appropriation to fund approximately 2 Translational Research Partnership Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

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

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

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to 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-11-SCIRP-TRPA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the Initiating PI through the CDMRP eReceipt System (<https://cdmrp.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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

Changes 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**

The Initiating PI must enter the contact information for the Partnering PI(s) in the Partnering PI section.

- **Required Files – Tab 4**

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

The Preproposal Narrative should include the following:

- **Research Idea:** State the ideas and reasoning on which the proposed work is based. Show how the perspective of each team member contributes to the development of the idea. Clearly state the type of study proposed (e.g., animal validation, human validation, etc.).
- **Research Strategy:** Concisely state the project's objectives and specific aims.
- **Translational:** Describe the translational aspect of this application, providing evidence for the reciprocal transfer of ideas between basic and clinical science in developing and implementing the research plan.
- **Partnership:** Describe how the project incorporates multiple institutions and disciplines, and how it depends on the unique skills of each partner. Provide the time commitment for each partner. Describe how the proposed partnership involves a substantial contribution by each partner and the reciprocal flow of ideas and information.
- **Impact:** State explicitly how the proposed work will have an impact on the understanding of SCI, clinical practice and/or amelioration of its consequences.
- **Military Relevance:** Describe how the proposed project is applicable to the health care needs of spinal cord injured military Service members and veterans, and/or their caregivers and family members.
- **Alignment with Areas of Encouragement:** If applicable, explain how the proposed work addresses an SCIRP FY11 Area of Encouragement. Alternatively, if the application does not address at least one Area of Encouragement, the PI must justify the relevance of the project to the spinal cord injured military and/or veteran population.

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 Sketches (two-page limit each): Include biographical sketches for the Initiating and Partnering PIs.

- **Submit Pre-application – Tab 5**

- **Other Documents Tab**

No additional documents are required.

Pre-Application Screening

- **Pre-Application Screening Criteria**

Pre-applications will be screened by the SCIRP Integration Panel (IP), composed of scientists, clinicians, and consumer advocates, based on the following criteria:

- **Research Idea:** How well the described research demonstrates solid scientific rationale for SCI research.
- **Research Strategy:** How the specific aims support the research idea.
- **Translational:** How the project will translate promising, well-founded research findings into clinical applications in spinal cord injury.
- **Partnership:** Whether the partnership is multi-institutional and multidisciplinary, and includes at least one clinician and one experienced SCI basic researcher. How the partners' backgrounds and expertise are appropriate to accomplish the proposed research that could not be accomplished by either a single investigator or through separate efforts. How the disciplines and the levels of effort are appropriate for the proposed research.
- **Impact:** How well the study addresses an important problem related to SCI. If successful, how the study will impact clinical practice, and improve our understanding of SCI and/or amelioration of its consequences.
- **Military Relevance:** How well the proposed project directly or indirectly benefits spinal cord injured military Service members and veterans, and/or their caregivers and family members.
- **Alignment with Area of Encouragement:** How the proposed study addresses at least one of the FY11 SCIRP Areas of Encouragement, or justifies the relevance of the project to the spinal cord injured military and/or veteran population.

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

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., a critique of strengths and weaknesses) on their pre-application.

Pre-application notification dates are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Form

Applications will not be accepted unless the Initiating PI has received a letter 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 (AOR) through the Grants.gov portal (<http://www.grants.gov/>). For the Translational Research Partnership Award, additional application components are also required and should be submitted as directed below.

The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI. Initiating and Partnering PIs will each be assigned unique and separate log numbers by the CDMRP eReceipt System. Each Grants.gov application package must be submitted using the unique log number.

Application Components for the Initiating PI:

Grants.gov application package components: For the Translational Research Partnership 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:** 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 SCIRP 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.***

- **Partnership:** Describe how the proposed project incorporates the unique skills of each partner. Provide the time commitment for each partner. Describe how the proposed partnership involves a substantial contribution by each partner and the reciprocal flow of ideas and information. Demonstrate how the translational research partnership will maximize the use of existing resources and minimize unnecessary duplication. Describe the communication plan and provide the evidence of institutional support for resolving potential intellectual and material property issues, and removing institutional barriers to achieving high levels of cooperation.
- **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 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 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:** 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 clinician, the institution must clearly demonstrate a commitment to the clinician’s research.
 - **Letters of Collaboration:** 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:** 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.
 - 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.
 - 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 spinal cord injured military Service members and veterans, and/or their caregivers and family members.
- **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?
 - 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.

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

- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.” Describe 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 FY11 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 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 7: 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 spinal cord injured military Service members, veterans, and/or their caregivers and family members. 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 8: Translation Statement (one-page limit):** Upload as “Translation.pdf.” Describe the translational research that will be performed through this award, and articulate why it could not be achieved through separate efforts. State explicitly how the proposed research is translational in nature, allowing for the reciprocal transfer of ideas between basic and clinical science.
- **Attachment 9: 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, 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) Form: 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.”
- Initiating and Partnering PIs must each submit a budget and justification specific to their effort as part of their separate Grants.gov application packages. The Research & Related Budget form for the Initiating PI should not include budget information for the Partnering PIs, even if they are at the same organization.*
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

Application Components for the Partnering PI(s):

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

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

- 1. SF 424 (R&R) Application for Federal Assistance Form**
- 2. Attachments Form**
 - **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI (s) should be noted for each task.*
- 3. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
 - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”

Initiating and Partnering PIs must each submit a budget and justification as part of their separate Grants.gov application packages. The Research & Related Budget form for the Initiating PI should not include budget information for the Partnering PIs, even if they are at the same organization.

4. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
5. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

D. Submission Dates and Times

All submission dates and times are indicated on the [title page](#) of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines shall 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 Number System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

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

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. 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 the project will translate promising, well-founded basic or clinical research findings into clinical applications for patients 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 partners acknowledge potential problem areas and consider alternative approaches.

- **Partnership**

- How the partnership between the clinician(s) and SCI basic researcher(s) is likely to result in a level of productivity greater than that achievable by each PI working independently.
- How well the evidence supports that all partners contribute substantially to the development and implementation of the research plan, and to the reciprocal flow of ideas.
- How the multiple disciplines and multiple institutions within the partnership support the proposed project.
- How the partners' background, expertise, and levels of effort support the proposed project.

- **Impact**

- If successful, how the partnership and the aims of the study will eventually move a clinical observation, a basic discovery, or population-based study into clinical application.
- How the proposed research will have an impact on the concepts or methods that drive the field of SCI research.
- How the proposed research will make original and important contributions toward the goal of advancing SCI research or patient care.
- If applicable, address the impact on one or more of the FY11 SCIRP Areas of Encouragement.

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

- **Application Presentation**

- To what extent the writing, clarity, and presentation of the application components influenced the review.

- **Budget**

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

- **Environment**

- How 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.

2. Programmatic Review: To determine the application's relevance to the mission of the DOD and CDMRP, as well as to make funding recommendations, the 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 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. PIs will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.
- All associated (Initiating and Partnering PI) applications are not submitted by the deadline.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, you 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:

- FY11 SCIRP IP member 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 FY11 SCIRP IP members may be found at <http://cdmrp.army.mil/scirp/panels/panels11>.

- 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 Research and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- The proposed research involves less than two distinct organizations.
- At least one partner is not a clinician, or at least one partner does not have experience in SCI basic research or SCI patient care.
- The proposed research is, or requests funding for, a clinical trial.
- The PI(s) does not meet the eligibility criteria.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the USAMRAA 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, 2012. 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 C, for general information regarding administrative and national policy requirements.

C. Reporting

Refer to the General Application Instructions, Appendix 4, Section D, for general information on reporting requirements.

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section E, 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 and questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 1-301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 1-800-518-4726

Email: support@grants.gov

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

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Initiating PI Completed	Partnering PI Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.		
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.		
	Upload Supporting Documentation (Support.pdf) as Attachment 2.		
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.		
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4.		
	Upload Statement of Work (SOW.pdf) as Attachment 5.		
	Upload Impact Statement (Impact.pdf) as Attachment 6.		
	Upload Military Relevance Statement (Military.pdf) as Attachment 7.		
	Upload Translation Statement (Translation.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 form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Project/Performance Site Location(s) Form	Complete form as instructed.		
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.		