

Program Announcement

for the

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Congressionally Directed Medical Research Programs

Military Infectious Diseases Clinical Trial Award

Funding Opportunity Number: W81XWH-14-DMRDP-MID-CTA

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 3, 2013
- **Invitation to Submit an Application:** August 2013
- **Application Submission Deadline:** 11:59 p.m. ET, October 17, 2013
- **Peer Review:** December 2013
- **Programmatic Review:** January 2014

This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2014 (FY14) Defense Medical Research and Development Program (DMRDP) Military Infectious Diseases Clinical Trial Award (MID-CTA) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA).

The goal of the DMRDP is to advance the state of medical science in those areas of most pressing need and relevance to today's battlefield experience. The objectives of the DMRDP are to discover and explore innovative approaches to protect, support, and advance the health and welfare of military personnel, families, and communities; to accelerate the transition of medical technologies into deployed products; and to accelerate the translation of advances in knowledge into new standards of care for injury prevention, treatment of casualties, rehabilitation, and training systems that can be applied in theater, in the clinical facilities of the Military Health System, or in civilian health care facilities.

The DMRDP Military Infectious Diseases Research Program (MIDRP) Joint Program Committee 2 (JPC-2) expects to fund approximately four FY14 DMRDP MID-CTA applications, depending on the quality and number of applications received and the total cost of applications approved for funding. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this Program. Funding allotted for this Program Announcement/Funding Opportunity is approximate and subject to realignment. Currently, it is anticipated that up to \$3.1 million (M) in FY14 and \$8.3M in FY15-FY16 funds may be available. The executing agent for this announcement is the Congressionally Directed Medical Research Programs (CDMRP).

B. FY14 MID-CTA Focus Areas

All applications ***MUST*** contain only one clinical trial/testing with a distinct study design and address at least one of the Focus Areas listed below. Applications focused on areas other than those listed below should ***NOT*** be submitted.

- **Therapeutics.** Evaluation of optimum preventative or directive therapies for combat-related or trauma-induced wound infections using Food and Drug Administration (FDA) approved drugs, biologics, or devices either alone or in combination. Studies focusing on either new indications of FDA approved drugs/biologics/devices, or investigational new drugs/biologics/devices will be accepted.
- **Rapid detection of pathogens and/or microbial drug resistance markers.** Evaluation of a functional prototype device or assay for the rapid detection of pathogens and/or microbial drug resistance markers in combat-related or trauma-induced wounds. Research outcomes and documentation should support the development of an FDA-regulated device or assay.
- **Rapid detection of biomarkers.** Evaluation of a functional prototype device or assay for the rapid detection of novel and specific in vivo or in vitro biomarkers (from wound, serum, saliva, or urine) that predict development of infection or discriminate

between infection and colonization. Research outcomes and documentation should support the development of an FDA-regulated device or assay.

NOTES FOR ALL FOCUS AREAS:

- Studies involving carbapenem-resistant organisms are particularly sought.
- Preference will be given to approaches that address infections with one or more multidrug-resistant organisms (MDROs), particularly, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, extended-spectrum beta-lactamase producing *Enterobacteriaceae* (including *Escherichia coli* and *Klebsiella pneumoniae*), and methicillin-resistant *Staphylococcus aureus* (MRSA), and/or invasive fungal (mold) pathogens.
- Preference will be given to studies leading toward topical treatments for prevention and management of combat-related or trauma-induced wound infections.

C. Award Information

Overview: The FY14 DMRDP MID-CTA is intended to support early phase clinical trials/testing with the potential to have a major impact on treatment of combat-related or trauma-induced wound infections. These studies must be responsive to the health care needs of military Service Members and Veterans; however, the use of military populations in the clinical trial/testing is not a requirement. Proposed projects should be designed to demonstrate the safety and efficacy of novel therapies and diagnostics in human patients suffering from serious, debilitating combat-related or trauma-related wound infections. The purpose of such demonstrations is to accelerate translation of greater medical capabilities to patients; ***this can range from proof of concept (i.e., first in human or Phase 0) trials through Phase II clinical trials, as well as Class I, II, or III medical device trials/testing. Phase III trials for FDA licensure of drugs or definitive testing for device or assay clearance by the FDA will NOT be permitted under this Program Announcement/Funding Opportunity.*** Projects of interest are those focused on testing and translating investigational interventions or devices already proven in relevant definitive animal models and moving those interventions or devices into advanced clinical development.

Funding from this award mechanism must support a clinical trial/testing and cannot be used for preclinical research studies. A clinical trial/testing 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. ***For this Program Announcement/Funding Opportunity the term “device” includes diagnostics (e.g., in vivo, in vitro, and/or biomarkers).*** In vitro diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. For this Program Announcement/Funding Opportunity the term “human subjects” refer to individuals who will be recruited for or who will participate in the proposed clinical trial. For more information on

clinical trials and phase/class of study, a Human Subject Resource Document is provided at https://cdmrp.org/Program_Announcements_and_Forms/.

If the proposed trial involves the use of a drug that has not been approved by the FDA for its investigational use, then an Investigational New Drug (IND) application may be required. If the proposed study involves an investigational device that has not been approved or cleared by the FDA for its investigational clinical use, the study may be required to comply with the FDA Investigational Device Exemption (IDE) regulations. ***If the documented status of the IND or IDE has not been obtained within 6 months of the award date, the award may be terminated for failure to comply with a material provision of the award.***

All of the following are important aspects of FY14 DMRDP MID-CTA application submission. The application should:

- Include a clinical trial that begins no later than 12 months after the award date, if a clinical trial is proposed.
- Include preliminary data relevant to the proposed research project. Preliminary data relevant to the proposed research are required; any unpublished preliminary data originating from the laboratory of the Principal Investigator (PI), collaborator(s), or subawardee(s) named on this application should be included.
- Be based on sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature as documented in the application.
- Demonstrate and document availability of and access to the drug/compound, device, and/or other materials needed.
- Demonstrate availability of and access to a suitable human subject population that will support a meaningful outcome for the study.
- Include a discussion of how accrual goals will be achieved, and how standards of care may impact the study population.
- Describe appropriate and clearly defined endpoints for the proposed clinical trial/testing.
- Include a clearly articulated statistical analysis plan, as well as appropriate statistical expertise and a power analysis reflecting sample size projections that will clearly answer the objectives of the study.
- Discuss the potential impact of the study results on prevention and/or treatment of combat-related or trauma-induced wound infections.
- Include a study coordinator(s) who will guide the clinical trial protocol through the local Institutional Review Board (IRB) of record and other regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate human subject accrual.
- Demonstrate institutional support and access to institutional resources

- Include a Transition Plan that describes a clear path to further develop the trial product and how the project will continue to the next level of development after the end of the award period of performance.

Partnering Principal Investigator (PI) Option: The FY14 DMRDP MID-CTA mechanism supports applications that include meaningful and productive collaborations. The Partnering PI Option under this mechanism is structured to accommodate up to three PIs who will each receive a separate award. One partner is identified as the Initiating PI and the other partner(s) as the Partnering PI(s). *All investigators should collaborate in the development and submission of the proposed research project.* It should be clear that each investigator has a significant level of intellectual input and brings complementary strengths to the project. Multidisciplinary and multi-organizational projects are allowed. If multi-organizational, participating organizations must be willing to resolve potential intellectual and material property issues and remove any barriers that might interfere with successful completion of the research.

Use of Human Subjects and Human Anatomical Substances: All Department of Defense (DoD)-funded research involving new and ongoing research with human subjects and human anatomical substances must be reviewed and approved by the US Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local IRB of record. Local IRB approval at the time of submission is NOT required. Time and level of effort for local IRB approval(s) should be considered in planning. 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. In addition to time for local IRB approval(s), allow a minimum of 2 months for HRPO regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

DoD Collaboration and Alignment Encouraged: Relevance to the health care needs of the Armed Forces, their family members, and/or the U.S. Veteran population is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate, integrate, and/or align their research projects with military and/or Department of Veterans Affairs (VA) research laboratories and programs. The following websites may be useful in identifying information about ongoing DoD areas of research interest:

Air Force Research Laboratory
<http://www.wpafb.af.mil/afrl>
Clinical and Rehabilitative Medicine
Research Program
<https://crrmp.amedd.army.mil/>
Congressionally Directed Medical
Research Programs
<http://cdmrp.army.mil>
Defense Advanced Research Projects
Agency
<http://www.darpa.mil/>
Defense Technical Information Center
<http://www.dtic.mil>
Military Infectious Diseases Research
Program
[https://mrmc.amedd.army.mil/index.cfm?pa
geid=medical_r_and_d.midrp.overview](https://mrmc.amedd.army.mil/index.cfm?pa
geid=medical_r_and_d.midrp.overview)
Naval Health Research Center
<http://www.med.navy.mil/sites/nhrc>
Naval Medical Research Center
www.med.navy.mil/sites/nmrc
Navy and Marine Corps Public Health
Center
<http://www.nmcphc.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 Institute of Surgical Research
<http://www.usaisr.amedd.army.mil/>
U.S. Army Medical Research Acquisition
Activity
<http://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
www.nrl.navy.mil
U.S. Department of Veterans Affairs,
Office of Research and Development
www.research.va.gov
Walter Reed Army Institute of Research
<http://wrair-www.army.mil/>
Walter Reed Army Institute of Research,
Multidrug-resistant Organism Repository and
Surveillance Network (MRSN)
[http://wrair-www.army.mil/
OtherServices_MRSN.aspx](http://wrair-www.army.mil/
OtherServices_MRSN.aspx)
Defense Manpower Data Center
www.dmdc.osd.mil

Use of Military and VA Populations or Resources: If the proposed research plan involves access to military and/or VA population(s) and/or resource(s), the PI is responsible for establishing access. If possible, access to target military and/or VA population(s) and/or resource(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 military Service Members, Veterans, military and/or VA-controlled study materials and military and/or VA databases. Use Attachment 2 to provide this documentation (see Section II.C., Application Submission Content and Form, Supporting Documentation).

D. Eligibility Information

- Independent Investigators at any academic level (or equivalent) are eligible to submit applications.
- Both intramural and extramural Investigators are encouraged to apply to this Program Announcement/Funding Opportunity.
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, military, civilian, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

Applications with a single (non-partnering) PI:

- The maximum period of performance is **3** years.
- The maximum allowable total costs for the entire period of performance are **\$2,500,000** including direct and indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable total costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Applications with the Partnering PI Option:

- The combined total funding for the Initiating PI and the Partnering PI(s) may not exceed **\$2,500,000** for total costs for up to a **3**-year period of performance, plus indirect costs as appropriate. A separate award will be made to each PI's organization. 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.4., for budget regulations and instructions for the Research & Related Budget. *For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.*

In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel costs for the PI(s) to disseminate project results at one DoD-related meeting to be determined at the discretion of the Government during the award performance

period. Costs associated with travel to this meeting, up to \$1,800, should be included in Year 2 of the budget. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Research-related subject costs
- Clinical research/trials costs
- Equipment costs up to \$10,000
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$3,600 per year to attend scientific/technical meetings in addition to the required meeting described above

Both intramural and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. However, all applicants to this Program Announcement must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for System for Award Management (SAM) and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

The DMRDP MIDRP JPC-2 expects to allot approximately \$3.1M of the FY14 and \$8.3M of the FY15-FY16 appropriations to fund approximately four FY14 MID-CTA Award applications, depending on the quality and number of applications received. Dollar amounts in this Program Announcement/Funding Opportunity are approximate and subject to realignment. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.

II. SUBMISSION INFORMATION

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

The FY14 DMRDP MID-CTA mechanism is structured to accommodate up to three collaborating PIs (one initiating PI and up to two partners). One partner will be identified as the Initiating PI and the other PI(s) will be identified as Partnering PI(s). Initiating and Partnering PI(s) 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 of the pre-application submission separately by email. Each Partnering PI must follow the link in this email and register with the CDMRP eReceipt System in order to associate his/her grant application package with that of the Initiating PI. If an application is invited, only the Initiating PI will receive notification of invitation via email from CDMRP.

Submission of multiple applications that are essentially identical or propose essentially the same research project to this Funding Opportunity or other Funding Opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

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-14-DMRDP-MID-CTA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the Single (non-partnering) or 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. The title should be detailed enough to accurately reflect the work that will be done in the study.

Partnering PI Option: *The Initiating PI is responsible for submission of all pre-application components.*

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY13 MIDRP JPC-2 members should not be involved in any pre-application or application. For questions related to JPC-2 members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP [Help Desk](mailto:help@cdmrp.org) at help@cdmrp.org or 301-682-5507.

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

- **Required Files – Tab 4**

Preproposal Narrative (three-page limit): The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage are prohibited and will result in administrative withdrawal of the pre-application.

Note: *At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.*

The Preproposal Narrative should include the following:

- **Research Plan:** State the ideas and reasoning on which the clinical trial/testing is based. Clearly specify which type (e.g., drug, device, behavioral) of clinical trial/testing is being proposed, and indicate the phase of trial and/or class of device and regulatory status as appropriate. Concisely state the project's objectives and specific aims.
- **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research project.
- **Impact:** State explicitly how the proposed work will have an impact on research and patient care related to combat-related or trauma-induced wound infection. Describe how the study will accelerate promising treatments/devices/assays into clinical practice.
- **Military Benefit:** Describe how the proposed work will directly or indirectly benefit military Service Members and U.S. Veterans recovering from combat-related or trauma-induced wound infections.
- **Alignment with Focus Areas:** Explain how the proposed work addresses at least one of the FY14 DMRDP MID-CTA Focus Areas.

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

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- **Key Personnel Biographical Sketches (four-page limit per individual)**
- **Quad Chart:** The Quad Chart template is a one-page PowerPoint file that must be downloaded from the CDMRP eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms/, completed, and saved using Adobe Acrobat Reader as a PDF file.

- **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 DMRDP and the MIDRP JPC-2, pre-applications will be screened based on the following criteria:

- **Research Plan:** How well the proposed project addresses the intent of the award mechanism and the program. To what degree the rationale, objectives, and specific aims support the research idea.
- **Personnel:** How well the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research project.
- **Impact:** How well the study addresses an important problem relevant to combat-related or trauma-induced wound infection prevention and/or management, and antimicrobial countermeasures. If successful, how the study will improve our capabilities to prevent and/or treat combat-related or trauma-induced wound infections. To what degree the study will accelerate promising treatments/devices/assays into clinical practice.
- **Military Benefit:** To what degree the proposed study will directly or indirectly benefit military Service Members and/or the U.S. Veteran population recovering from combat-related or trauma-induced wound infections.
- **Alignment with Focus Areas:** How well the project addresses at least one of the FY14 DMRDP MID-CTA Focus Areas. Preference will be given to studies leading toward topical treatments for prevention and management of combat-related or trauma-induced wound infections.

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

Following the pre-application screening, Single (non-partnering) or Initiating PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Form

Applications will not be accepted unless the Single (non-partnered) or Initiating PI has received notification of invitation.

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

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

Application Components for the Single (non-partnered) or Initiating PI under the Partnering PI Option:

Grants.gov application package components: For the FY14 MID-CTA, 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**

If a clinical trial is proposed, the Project Narrative is NOT the formal clinical trial protocol. Instead, all essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 8-10 described below. Failure to submit these attachments as part of the application package will result in rejection of the entire application.

- **Attachment 1: Project Narrative (20-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Describe in detail the rationale for the clinical trial/study and include a literature review, preliminary studies, and/or preclinical data that led to the development of the proposed clinical trial/testing. The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should

establish the relevance of the clinical trial/study to at least one of the FY14 MID-CTA Focus Areas and explain the applicability of the proposed findings.

- If the proposed clinical trial/study was initiated using other funding prior to this application, explain the history and background of the clinical trial/study and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.
- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
- **Study Design:** Describe the type of study to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action.
 - Identify the intervention or device to be tested and describe the projected outcomes.
 - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
 - If a clinical trial that will recruit human subjects is proposed:
 - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).
 - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
 - Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. Specify the approximate number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Describe the data analysis plan in a manner that is consistent with the study objectives.
- **Technical Risks:** Identify and describe potential problem areas in the proposed approach and alternative methods and approaches that will be employed to mitigate any risks that are identified.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.***

- References Cited: List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government 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.
- Data and Research Resources Sharing Plan: 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 publicly available.
- Intellectual Property
 - Background and Proprietary Information (if applicable): All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project. Identify any proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the federal purpose license.
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
 - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to market, competitors and management team. Discuss the significance of this development effort, when it can be anticipated and the potential commercial use for the technology being developed.
- Current Quad Chart: Provide a current Quad Chart in the same format as in the pre-application. If no changes have been made to the project, the same Quad Chart submitted with the pre-application may be used.

- Letters of Organizational Support (two-page limit per letter): Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project.
- Letters of Collaboration (if applicable) (two-page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Letter(s) of Support for Use of Military and VA Populations or Resources (if applicable) (two-page limit per letter): Provide a letter(s) signed by the lowest ranking person with approval authority for studies involving military Service Members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
 Technical abstracts should be written using the outline below. (Proprietary or confidential information should *not* be included.)
 - 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.
 - Military Benefit: Identify the FY14 MID-CTA Focus Area(s) to be addressed and briefly describe how the proposed project benefits the military and Veteran population with trauma-induced or combat related wound infections.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”
 Lay 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.
 - Which FY14 MID-CTA Focus Area(s) will be addressed?
 - What are the potential clinical applications, benefits, and risks?
 - What types of military, VA, and/or civilian patients will it help, and how will it help them?
 - What is the projected time it may take to achieve a patient-related outcome?
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.

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

- **Attachment 6: Military Benefit Statement (two-page limit).** Upload as “Benefit.pdf.”
 - Describe how the proposed study is responsive to the treatment of combat-related or trauma-induced wound infections. Provide information about the incidence and/or prevalence of the disease or condition in military Service Members and/or Veterans, if appropriate and available. Identify the FY14 MID-CTA Focus Area(s) aligned with the proposed project. Show how the proposed study complements ongoing DoD and VA areas of research interest.
 - If military Service Members and/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 accessing 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., military Service Members or Veterans).
 - Describe the short-term impact: Detail the anticipated outcomes that will be directly attributed to the results of the proposed research. Outcomes should be specific, measurable, and should include a definition of the end user.
 - Describe the long-term impact: Explain the long-range vision for implementation of the intervention or device in the clinic or field and describe the anticipated long-term benefits for the targeted population.
 - Compare the proposed intervention or device to pharmacologic agents, devices, and/or clinical guidance currently available, as applicable.
- **Attachment 7: Transition Plan (two-page limit).** Upload as “Transition.pdf.” Provide information on the methods and strategies proposed to move the product to the next phase of clinical trials/testing and/or delivery to the military or civilian market after successful completion of the award. The transition plan should include the components listed below.
 - Provide details of the funding strategy that will be used to bring the outcomes to the next level of clinical trials/testing and/or delivery to the military or civilian market (e.g., specific potential industry partners, specific funding opportunities to be applied for)
 - A description of collaborations and other resources that will be used to provide continuity of development. For any industry partner(s), include a description of their product development and/or marketing experience.
 - A brief timeline and milestones for bringing the outcome(s) to the next phase of clinical trials/testing and/or delivery to the military or civilian market.

- A risk analysis for cost, schedule, manufacturability, and sustainability.
- A description of relevant product patents and intellectual property ownership, and their potential impact on product development and the Government's ability to access any technology or products supported with this award.
- **Attachment 8:** One of the documents below *MUST* be submitted with a FY14 MID-CTA application. Complete either **Human Subject Recruitment and Safety Procedures** if the proposed study will be recruiting human subjects for a drug/therapeutic device clinical trial **OR** complete **Human Sample Acquisition and Safety Procedures** if the proposed study will be collecting human anatomical substances (fluids, tissues, cells) for in vitro device/diagnostic assay evaluation.
 - **Attachment 8: Human Subject Recruitment and Safety Procedures (no page limit).** Upload as "HumSubProc.pdf". The Human Subject Recruitment and Safety Procedures attachments should include the components listed below.
 - a. **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from which the sample will be recruited/drawn). *Use of military populations is preferable but not required.* If a military population is not used, describe how the identified population serves as a surrogate to the military experience. Demonstrate that the research team has access to the proposed study population.

If applicable, discuss past efforts in recruiting human subjects from the target population for previous interventional or observational studies. Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.
 - b. **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

Inclusion of Women and Minorities in Study. Consistent with the Belmont Report and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical trial.
 - c. **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification).

- Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
 - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
 - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements, and should accurately reflect the study.
- d. Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.
- Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
 - Include information regarding the timing and location of the consent process.
 - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
 - Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
 - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
 - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+10USC980). If applicable, please refer to the General Application Instructions, Appendix 5, for more information.
 - Provide a draft in English of the proposed Informed Consent Form. A plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial should be included.

- **Assent.** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- e. **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Please note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.
- f. **Risks/Benefits Assessment:**
- **Foreseeable risks:** Clearly identify all study risks. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
 - **Risk management and emergency response:**
 - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel, or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
 - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
 - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
 - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
 - **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.

- **Attachment 8: Human Sample Acquisition and Safety Procedures (no page limit).** Upload as “HumSubProc.pdf”. The Human Sample Acquisition and Safety Procedures attachments should include the components listed below.
 - a. **Study Design:** Most in vitro devices are exempt from medical device IDE regulations. Studies required to demonstrate substantial equivalence include the following:
 - In the majority of cases, analytical studies using clinical samples (sometimes supplemented by carefully selected artificial samples) will suffice.
 - For some in vitro diagnostics, the link between analytical performance and clinical performance is not well defined. In these circumstances, clinical information may be required.
 - The FDA rarely requires prospective clinical studies for in vitro diagnostics, but regularly requests clinical samples with sufficient laboratory and/or clinical characterization to allow an assessment of the clinical validity of a new device. This is usually expressed in terms of clinical sensitivity and clinical specificity or agreement.
 - Note that the study design may include identification of surrogate endpoints to establish the device performance (clinical sensitivity and specificity or agreement) with relation to the identified endpoints in corollary studies using randomly collected clinical studies. *Use of laboratory samples from military populations is preferable but not required.* If a military population is not used, describe how the identified population serves as a surrogate to the military experience. Demonstrate that the research team has access to the proposed study population samples.
 - b. **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria evaluation of samples for the proposed research. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

Inclusion of Women and Minorities in Study. Consistent with the Belmont Report and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if samples from women and/or minorities will be excluded from the clinical trial.
 - c. **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study inclusion and the diagnostic criteria for entry. Please note that some screening procedures may require a separate consent or waivers of consent. Informed consent or appropriate waivers of consent

must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

- d. Description of the Informed Consent Process:** In certain cases, federal regulations allow the IRB to approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or to waive the requirement to obtain any informed consent. Most complete waivers of consent involve studies in which there are minimal risks to subjects. Specifically describe the plan for obtaining informed consent or appropriate waivers of informed consent for clinical samples from human subjects.
- Identify who is responsible for explaining the study, answering questions, and obtaining informed consent or appropriate informed consent waivers. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial/testing.
 - Describe the biological origin of the samples to be tested (e.g., primary fibroblast cells from adults with and without disease).
 - The narrative should also describe the sample source(s), such as purchased human samples obtained from a clinical repository, or previously collected as part of a research effort. If samples will be or have been collected as part of a research activity, the application should state whether donors provided consent for use of their samples in future research consistent with this proposed effort.
 - Describe the plan, if appropriate, for obtaining waivers of informed consent or the informed consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study.
 - **Waiver of Informed Consent**, described in Federal regulation 45 CFR 46.116(d) Federal regulations at 45 CFR 46.116(d), establishes four criteria for waiving consent or altering the elements of consent in minimal risk studies. All four criteria must be addressed.
 - **Waiver of Documentation of Consent**, described in Federal regulation 45 CFR 46.117(c), allows the IRB to waive the requirement for obtaining signed consent if it finds that either:
 - The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (these criteria cannot be used for FDA-regulated studies), or
 - The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. This paragraph only also applies to FDA-regulated studies per 21 CFR 56.109(c)(1).

- **State** law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed research to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+10USC980). If applicable, please refer to the General Application Instructions, Appendix 5, for more information.

e. Risks/Benefits Assessment:

- **Foreseeable risks:** Clearly identify all study risks. Study risks include any risks that the human subject is subjected to (including retroactively, as identified by the ORP and IRB) as a result of participation in the research. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
- **Risk management and emergency response:** Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel, or to manage unpreventable risks.
- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.

f. Quality Control: Quality control (QC) is a material or mechanism that, when used with or as part of a test system, monitors the analytical performance of that test system. It may monitor the entire test system or only one aspect of it. Note that the FDA regulates the *material or mechanism as a medical device*; it does not monitor how a QC component is used within a laboratory (i.e., how often other QC types should be run or whether the QC replaces other, more traditional external types of QC).

Describe the QC to be employed for the study and/or device and, as appropriate, include:

- Procedures that will be employed to monitor QC (i.e., how often other QC types should be run or whether the QC replaces other, more traditional external types of QC).
 - Review of sample labeling for accuracy,
 - Determination/inclusion of manufacture protocols and protocols to ensure stability.
- **Attachment 9: Intervention or Device (no page limit):** Upload as “Intervention.pdf.” The Intervention attachment should include the components listed below.
 - a. Description of the Intervention or Device:** As applicable, the description of the intervention/device should include the following components: source, dose, schedule, administration route, washout period, duration of the intervention, and

concomitant medications allowed. Description of devices should include general concept of design, detailed operational instructions, any potential risks to users, and intended benefits. Description of diagnostic assays should include: target(s) to be measured/assessed, type of assay (end point, kinetic, quantitative, semi-quantitative, qualitative, PCR, multiplex, immuno, direct, indirect, etc), time required, reagents [sample, equipment] needed, protocol overview, and detailed protocol. Other types of interventions or devices should be fully described.

- b. Study Procedures:** Describe the interaction with the human subject to include the study intervention or device that he/she will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Discuss how compliance with Good Clinical Practices, Good Manufacturing Practices, and other regulatory considerations will be established, monitored, and maintained, as applicable.
- **Attachment 10: Data Management (no page limit):** Upload as “Data_Manage.pdf.” The Data Management attachment should include the components listed below.
 - a. Data Management:** Describe all methods used for data collection to include the following:
 - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
 - **Confidentiality:**
 - Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
 - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
 - Address requirements for reporting sensitive information to state or local authorities.
 - **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored.
 - **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.

b. Laboratory Evaluations

- **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
- **Evaluations:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
- **Storage:** Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
- **Laboratories performing evaluations and special precautions:** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.
- **Attachment 11: Study Personnel and Organization (no page limit):** Upload as “Personnel.pdf.” The Study Personnel and Organization attachment should include the components listed below.
 - a. **Principal Investigator/Study Staff:** Provide an organizational chart identifying key members of the study team including institution/center/department. Briefly describe their roles on the project. A medical monitor (external to the study and not reimbursed by the study) and study coordinator(s) should be included.
 - b. **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial/testing is multi-institutional, plans for communication and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, should be included. Provide a plan for real-time communication among collaborating institutions (if applicable).
- **Attachment 12: IND/IDE Documentation Form:** Upload as “IND_IDE.pdf.”
 - a. Complete the IND/IDE Documentation Form, which is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity on Grants.gov
 - b. If an IND/IDE is required, an explanation of the status of the IND/IDE submission should be provided (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold). Inclusion of a copy of the FDA meeting minutes is encouraged but not required. Provide the date of

the IND/IDE submission. If an IND/IDE is not required for the proposed study, provide evidence in the form of official communication from the FDA or the IRB of record to that effect.

- **Attachment 13: Surveys, Questionnaires, and Other Data Collection Instruments (if applicable, no page limit):** Upload as “Surveys.pdf.” The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instruments will be administered. Describe how the survey is adapted to the subject population.
- 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.”
 - Include biographical sketches for both the Initiating and Partnering PI(s).
 - Key Personnel Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Include current/pending support for both the Initiating and Partnering PI(s).
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
- For the Partnering PI Option: Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PI(s), even if they are located within the same organization. The combined total costs for the Initiating and Partnering PI(s)’ budgets cannot exceed \$2.5M.*
- 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), if applying under the Partnering PI Option:

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

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

1. SF 424 (R&R) Application for Federal Assistance Form

2. Attachments Form

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.*

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

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

Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Partnering PI(s) should not include budget information for the Initiating PI, even if they are at the same organization. The combined total costs for the Initiating and Partnering PIs’ budgets cannot exceed \$2.5M.

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

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

D. Submission Dates and Times

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

E. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Office of the Assistant Secretary of Defense, Health Affairs), based on technical merit, the relevance to the mission of the DHP, DMRDP and MIDRP JPC-2 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 review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization’s application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Criteria

1. Peer Review: To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

- **Clinical Impact**

- How the proposed clinical trial/testing addresses at least one of the FY14 MID-CTA Focus Areas.
- How relevant the anticipated outcomes of the proposed clinical trial/testing are to at least one of the FY14 MID-CTA Focus Areas.
- How well the sample population represents the targeted patient population that might benefit from the proposed intervention or device.

- How the potential outcomes of the proposed clinical trial/testing will provide or improve short-term benefits for individuals.
- How significantly the long-term benefits for implementation of the intervention or device may impact patient care and/or quality of life.
- **Ethical Considerations**
 - How well the level of risk to human subjects is minimized and whether there is sufficient evidence of a monitoring plan that is appropriate for the level of risk.
 - To what extent the evidence shows that the procedures are consistent with sound study design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.
 - To what extent privacy issues are appropriately considered.
 - To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
- **Intervention or Device Trial/Testing**
 - Whether there is evidence to support availability of the intervention or device, if applicable, for the proposed clinical trial/testing.
 - To what degree the intervention or device addresses the clinical need(s) described.
 - To what extent the intervention or device advances patient care beyond what is currently available (e.g., standard of care).
 - Whether a member of the study team holds the IND/IDE and whether the timeline proposed for IND/IDE application is appropriate (if applicable).
 - For investigator-sponsored IND/IDEs, whether there is institutional support to serve as a sponsor and whether they are equipped to assume the monitoring required by the FDA.
 - To what degree the data collection instruments (e.g., surveys, questionnaires, etc.), if applicable, are appropriate to the proposed study.
 - How the intervention or device compares with currently available interventions, devices, and/or standards of care.
- **Recruitment, Accrual, and Feasibility**
 - How well the PI addresses the availability of human subjects for the clinical trial/testing and the prospect of their participation and/or samples for clinical study.
 - Whether the PI has demonstrated access to the proposed clinical samples or human subject population.
 - The degree to which recruitment, informed consent, screening, and retention processes for human subjects/samples will meet the needs of the proposed clinical trial/testing.

- How well the application identifies possible delays and evidence of an adequate contingency plan to resolve potential delays (e.g., slow accrual, attrition).
- To what extent the PI has adequately considered how the proposed clinical trial/testing will affect the daily lives of individual human subjects participating in the study and has developed mitigation plans for any effects of the intervention or device (e.g., Will human subjects still be able to take their regular medications while participating in the clinical trial/testing? Are human subjects required to stay overnight in a hospital?).
- **Research Strategy**
 - How well the scientific rationale for testing the intervention or device is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory and/or preclinical evidence.
 - How well the study aims, hypotheses or objectives, experimental design, methods, data collection procedures, and analyses are designed to clearly answer the clinical objective.
 - How well the inclusion and exclusion criteria are justified and meet the needs of the testing phase or proposed clinical trial.
 - How well the potential problem and risk areas in the experimental approach were identified and the extent the proposed alternative methods and approaches address those areas
- **Statistical Plan (as appropriate for the proposed clinical trial/testing)**
 - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
- **Transition Plan**
 - How well the described funding strategy will be able to bring the research outcome(s) to the next level of clinical trial/testing and/or delivery to the military or civilian market.
 - To what extent the collaborations and other resources for providing continuity of development are feasible, established and/or well described.
 - How the schedule and milestones for bringing the outcome(s) to clinical trial/testing and/or delivery to the military and/or civilian market is appropriate.
 - How well the risk analysis for cost, schedule, manufacturability, and sustainability is developed.
 - How well the application identifies intellectual property ownership and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this Program Announcement/Funding Opportunity.

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

- **Personnel and Communication**
 - How the composition of the study team (e.g., study coordinator, statistician) is appropriate for the proposed work.
 - To what degree the study team’s background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the disease, and clinical studies).
 - How the levels of effort of the study team members are appropriate for successful conduct of the proposed trial/testing.
 - To what degree the logistical aspects of the proposed clinical trial/testing (e.g., communication plan, data transfer, standardization of procedures) are adequate.
 - **Environment**
 - To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical trial/testing at each participating center or institution (including collaborative arrangements).
 - Whether there is evidence for appropriate institutional commitment from each participating institution.
 - If applicable, how the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed clinical trial/testing.
 - **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, DMRDP, and MIDRP JPC-2, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:
- a. **Ratings and evaluations of the peer reviewers**
 - b. **Relevance to the mission of the DHP and DMRDP, as evidenced by the following:**
 - Adherence to the intent of the award mechanism
 - Program portfolio balance
 - Military relevance

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

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

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- Human Subject Recruitment and Safety Procedures or Human Sample Acquisition and Safety Procedures (Attachment 8), as appropriate, is missing.
- Intervention or Device description (Attachment 9) is missing.
- Data Management (Attachment 10) is missing.
- All associated (Initiating and Partnering PI) applications are not submitted by the deadline.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.

- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- A FY13 MIDRP JPC-2 member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY13/14 MIDRP JPC members can be found at http://cdmrp.army.mil/dmrpd/jpc/13jpc_2.shtml.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Total costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research is not relevant to any of the FY14 MID-CTA Focus Areas.
- The proposed research does not include a clinical trial or includes more than one trial.
- The proposed research includes a Phase III clinical trial for FDA licensure of drugs or definitive testing for device or assay clearance by the FDA. An IND/IDE is required and an application was not submitted to the FDA prior to FY14 DMRDP MID-CTA application submission.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section D, for general information regarding administrative and national policy requirements.

C. Reporting

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

Quarterly technical progress reports and annual reports will be required.

In addition to written progress reports, oral presentations may be requested.

D. Award Transfers

The transfer of an award to another institution is strongly discouraged. A transfer will not be allowed for any institution that includes a study site/clinical trial at its location. Approval of a transfer request from an institution that does not include a study site at its location will be at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

E. Pre-Award Meeting

At the Government's discretion, the PI and Clinical Study Coordinator or other personnel may be requested to participate in a pre-award meeting at the Government's expense. PIs recommended for funding will be notified during the award negotiations process whether a pre-award meeting will be required.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

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

Phone: 800-518-4726

Email: support@grants.gov

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

VII. APPLICATION SUBMISSION CHECKLIST:

Grants.gov Application Components	Action	Single or Initiating PI Completed	Partnering PI(s) Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.		
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.		
	Upload Supporting Documentation (Support.pdf) as Attachment 2.		
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.		
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.		
	Upload Statement of Work (SOW.pdf) as Attachment 5.		
	Upload Military Benefit Statement (Benefit.pdf) as Attachment 6.		
	Upload Transition Plan (Transition.pdf) as Attachment 7.		
	Upload Human Subject Recruitment and Safety Procedures (HumSubProc.pdf) OR Human Sample Acquisition and Safety Procedures (HumSubProc.pdf) as Attachment 8.		
	Upload Intervention or Device (Intervention.pdf) as Attachment 9.		
	Upload Data Management (Data_Manage.pdf) as Attachment 10.		
	Upload Study Personnel and Organization (Personnel.pdf) as Attachment 11.		
	Upload IND/IDE Documentation Form (IND_IDE.pdf) as Attachment 12.		
Upload Surveys, Questionnaires, and Other Data Collection Instruments (Surveys.pdf) as Attachment 13, if applicable.			
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		