

Program Announcement

Defense Health Program
Defense Medical Research and Development Program

Department of Defense Congressionally Directed Medical Research Programs (CDMRP)

Military Infectious Diseases Applied Research Award

Funding Opportunity Number: W81XWH-11-DMRDP-MID-ARA

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), September 13, 2011
- **Invitation to Submit an Application:** October 2011
- **Application Submission Deadline:** 11:59 p.m. ET, December 7, 2011
- **Scientific Peer Review:** January 2012
- **Programmatic Review:** March 2012

New for 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 Defense Medical Research and Development Program (DMRDP) was established in fiscal year 2010 (FY10) by the Defense Health Program in the Office of the Assistant Secretary of Defense for Health Affairs. The primary purpose of the DMRDP is to invest in research outcomes that will expedite translation of health care solutions toward advancement of the health and welfare of military personnel, families, and communities, by executing innovative approaches to basic and applied research. 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 in multiple military-relevant areas.

B. Award Information

This Program Announcement/Funding Opportunity is focused on applied research. Applied research is defined as work that refines concepts and ideas into potential solutions with a view toward evaluating technical feasibility of emerging approaches, technologies, and promising new products. Efforts may include hypothesis-testing and/or proof-of-concept studies in in vitro and/or in vivo models. Applied research may evaluate, mature, and/or downselect potential product candidates (drugs, biologic/vaccine constructs, or devices/systems) in vitro and/or in vivo, and may consist of preclinical safety and/or toxicity studies sufficient to support Investigational New Drug/Investigational Device Exemption (IND/IDE) applications. The FY11 Military Infectious Diseases Applied Research Award (MID-ARA) seeks applications focused on reduction of morbidity and mortality of infections of trauma-induced wounds in Wounded Warriors (combat-related wound infections). These awards are expected to yield potential health products, approaches, or technologies positioned for human testing.

Awards may support studies with human subjects but may not be used to support clinical trials. Awards may not be used to support fundamental basic research. Proposals for basic research studies addressing microbes and wound infections are being solicited by a separate Program Announcement/Funding Opportunity at Grants.gov (FY11 Military Infectious Diseases Basic Research Award, MID-BRA).

Awards under this announcement will consist solely of assistance agreements (Cooperative Agreements and Grants).

Presentation of preliminary data is required. Investigators must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the application to be competitive. Research projects should include a well-formulated, testable hypothesis based on strong scientific rationale.

All applications must address at least one of the following focus areas related to combat-related wound infections:

- Development of new methods for rapid multi-pathogen/multi-phenotype detection of multidrug-resistant organisms (MDROs) and/or nosocomial pathogens, [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], and/or rapid multi-pathogen/multi-phenotype characterization of antimicrobial resistance patterns.
- Development of assays for host immune response biomarkers for diagnosis or prognosis (with associated outcomes) of infection to inform clinical wound management decisions (e.g., optimal wound closure time, optimal duration of antibiotics for osteomyelitis).
- Development and preclinical testing of novel chemotypes (chemical classes/materials) and/or biologics as potential therapeutics or prophylactics for wound infection and/or biofilm formation, maintenance, or propagation. Innovative treatment approaches (e.g., chelators, antibody, phage, antimicrobial peptides, quorum-sensing inhibitors, and host immunoaugmentation, etc.) are encouraged.

NOTES FOR ALL FOCUS AREAS:

- Preference will be given to approaches that address infections with one or more 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 wound infection.
- Applications incorporating high-throughput drug screening and/or in silico modeling will NOT be funded. Applications proposing these types of studies will be administratively withdrawn at the pre-application screening stage and not invited to submit full applications.

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 U.S. 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. The term “human subjects” is used in

this Program Announcement/Funding Opportunity to refer to individuals who will be recruited for or who will participate in the proposed research. Allow a minimum of 4 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

Research Involving Animal Use: Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding (these documents should not be submitted with the application). The Animal Care and Use Review Office (ACURO), a component of the USAMRMC ORP, must review and approve all animal use prior to the start of working with animals. Allow 2 to 4 months for regulatory review and approval processes for animal studies. Refer to the General Application Instructions, Appendix 5, for more information. Contact ACURO for additional information via the central email box, ACURO@amedd.army.mil.

DOD-Aligned Organizations: Relevance to the health care needs of the Armed Forces and/or the U.S. veteran population is a key feature of this award. Therefore, applications with collaborations partnering extramural academic industry and non-DOD federal investigators with intramural investigators (especially investigators at Military Treatment Facilities), are highly encouraged. For applications that include intramural collaborations, the extramural Principal Investigator (PI) must provide more than a nominal contribution to the research project. *Note: Intramural collaborators are not allowed to be subawardees to the extramural applicant, but must submit a separate budget that will be funded through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Details for funding of such collaborations can be found in Section I.D., Funding.* Other Federal applicants, including Department of Veterans Affairs (VA) or Health and Human Services/National Institutes of Health PIs may submit applications as PIs or be included as subawardees.

Use of Military and VA Populations or Resources: If applicable, access to target military or VA patient population(s) should be confirmed at the time of application submission. Studies involving active duty military, military-controlled study materials, and/or military databases must include a letter of support signed by the lowest ranking person with approval authority. Studies proposing to recruit subjects from VA Medical Centers or use VA-controlled materials or information from VA data systems must either include an investigator with a VA appointment as the primary PI or a collaborator, or include a letter from an appropriate authority providing access to veterans, VA-controlled study materials, or VA data (as applicable). Use Attachment 10 to provide this documentation (see Section II.C., Application Submission Content and Form, Letter(s) of Support for Use of Military and VA Populations or Resources).

The following websites may be useful in identifying information about ongoing DOD areas of research interest pertinent to the MID-ARA focus areas:

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

Clinical and Rehabilitative Medicine
Research Program
<https://crmrp.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 (MIDRP)
https://mrmc.amedd.army.mil/index.cfm?pageid=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
(USAISR)
<http://www.usaisr.amedd.army.mil/>

U.S. Army Medical Research
Acquisition Activity (USAMRAA)
<https://www.usamraa.army.mil/>

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

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

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

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

Walter Reed Army Institute of Research
(WRAIR)
<http://wrair-www.army.mil/>

Walter Reed Army Institute of Research,
Multidrug-resistant Organism Repository
and Surveillance Network (MRSN)
<http://wrair-www.army.mil/index.php?view=MRSN>

C. Eligibility Information

- This Program Announcement/Funding Opportunity is intended only for extramural investigators or extramural investigators with one or more intramural collaborator(s). An *intramural* investigator is defined as a **DOD employee** working within a DOD laboratory or medical treatment facility (MTF), or a DOD activity embedded within a civilian medical center. An *extramural* investigator is defined as all those not included in the definition of intramural investigator (including, for example, VA, other Federal investigators, industry, academia, non-profit organizations). Pre-applications submitted to this Program Announcement/Funding Opportunity by an intramural investigator will be administratively withdrawn. A separate Program Announcement/Funding Opportunity will be released exclusively for intramural applications.
- Independent investigators at any academic level (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.

D. Funding

- The maximum period of performance is **3** years.
- The maximum allowable total costs for the entire period of performance are **\$2,000,000** including direct and indirect costs.
- 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.
- All direct and indirect costs of any subaward (subgrant or subcontract) with a non-Federal collaborator must be included in the total direct costs of the primary award.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- Funding for intramural collaborators will not be executed as subawards, but will be executed through the MIPR or FAD process. This process may include incremental funding; therefore, intramural collaborators are required to coordinate this process with their respective resource manager. For applications that include one or more intramural collaborators, these collaborator(s) must submit a separate budget form (in addition to the PI's budget) for their work on the project. Budget submission steps for intramural collaborators are detailed in Section II.B., Pre-Application Submission Content and Form, Notification of Pre-Application Screening Results, and Section II.D., Budget Submission for Intramural Collaborators.
- Regardless of whether there is an intramural collaborator, total funding for the entire project, covering direct and indirect costs of extramural and intramural institutions, is \$2,000,000 for the entire period of performance.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research and Related Budget form. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel costs for the PI to attend one DOD-specified meeting per year during the award period of performance. For planning purposes, it may be assumed that such meetings will be held in the National Capital Region.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Clinical research costs (clinical trials will not be supported)
- Equipment
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

The DMRDP expects to fund five FY11 MID-ARA 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 \$9 million(M) in FY11 funds are available and \$2M in FY12 funds are expected to be available for this Program Announcement/Funding Opportunity. Additional funds may become available to fund additional awards. Intramural collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers.

II. SUBMISSION INFORMATION

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

Submission of the same research project to different funding opportunities within the same program and fiscal year is 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-DMRDP-MID-ARA.

B. Pre-Application Submission Content and Form

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

Changes in the PI or organization after the pre-application deadline are strongly discouraged. Requests for a change in PI or organization for a MID-ARA application will be reviewed on a case-by-case basis. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the 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**

The PI must enter the contact information for any intramural collaborator(s) and/or subawardees 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.

The Preproposal Narrative should address the following:

- **Research Plan:** State the ideas and reasoning on which the proposed work is based. 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 may ultimately impact research and patient care related to combat-related wound infection.
- **Military Relevance:** Describe how the proposed work is applicable to the health care needs of military service members and U.S. veterans recovering from combat-related wound infection.
- **Alignment with Focus Areas:** Explain how the proposed work addresses at least one of the FY11 DMRDP MID-ARA focus areas.

Quad Chart: This document *must* be submitted by the pre-application submission deadline. The Quad Chart is a PowerPoint file that must be downloaded from the CDMRP eReceipt System (https://cdmrp.org/Program_Announcements_and_Forms)

and saved using Adobe Acrobat Reader as a PDF file. The Quad Chart must include the following sections:

- Focus Area: Include the MID-ARA focus area(s) as a subtitle on the Quad Chart.
 - Problem and Military Relevance: Provide a bulleted summary of the problem to be studied and its military relevance.
 - Proposed Solution: Provide a bulleted summary of the objectives of the work based on the Preproposal Narrative.
 - Picture: Insert a picture or other graphic that is representative of the work to be performed; this may, for example, show some aspect of the research to be performed, the expected technology outcome of the work, or the military problem that is being addressed.
 - Timeline and Cost: Identify the major planned activities or phases of the work and their duration on the chart provided, and provide the estimated direct costs by year.
- **Pre-Application Supporting Documentation**
 - **Key Personnel Biographical Sketches** (four-page limit per individual)
 - **References Cited** (one-page limit)
 - **Submit Pre-application – Tab 5**
 - **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 its relevance to the mission of the DOD, fully complete and compliant pre-applications will be screened by the Joint Program Committee for Military Infectious Diseases based on the following criteria:

 - **Research Plan:** How well the rationale, objectives, and specific aims support the research idea.
 - **Personnel:** How the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research project.
 - **Impact:** How well the proposed project addresses an important problem relevant to combat-related wound infection prevention and management, and/or antimicrobial countermeasures. If successful, how the study will improve our capabilities to prevent and/or treat combat-related wound infections.

- **Military Relevance:** How the proposed study will directly or indirectly benefit military service members and/or the U.S. veteran population.
- **Alignment with Focus Areas:** How well the project addresses at least one FY11 DMRDP MID-ARA focus area.
- **Notification of Pre-Application Screening Results**
Following the pre-application screening:
 - PIs will be notified by email 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. Intramural collaborators, if applicable, will also be notified by email whether or not the PI was invited to submit an application.
 - Intramural collaborators whose PI is invited to submit a full application must register with the CDMRP eReceipt System (<http://cdmrp.org>).
 - 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 PI has received a letter of invitation.

- If the PI was invited to submit an application, the intramural collaborator is required to download a Research and Related Budget form from Grants.gov and upload his/her individual budget in the CDMRP eReceipt System, as described in Section II.D.
- Intramural collaborators are required to ensure their budget forms are in compliance with MIPR and FAD policies.
- The PI is responsible for ensuring that the total budget (including any intramural collaborators and/or subawardees, if applicable) does not exceed the maximum allowed costs.
- Budgets for subawardees will be included in the PI's Research and Related Budget form submitted through Grants.gov.

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/>).

Grants.gov application package components: For the MID-ARA Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

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

2. Attachments Form

- **Attachment 1: Project Narrative (20-page limit):** Upload as “ProjectNarrative.pdf.”

Presentation of preliminary data is required. Describe the proposed project in detail using the outline below.

- **Background:** Describe in detail the rationale for the study and include a literature review, preliminary studies, and/or preclinical data that led to the development of the proposed project. 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 study and explain the applicability of the proposed findings.
- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
- **Research Design and Method:** Describe the experimental design, methods, and analyses including appropriate controls and statistical power needed in sufficient detail for analysis.
- **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.
- **Quality Management:** Describe the Quality Management plan that will be employed to ensure that research is conducted and results are documented as required to support the development of a U.S. Food and Drug Administration (FDA)-regulated product(s). Minimally include the following:
 - Plan for Good Documentation practices (e.g., review of human sample labeling for accuracy).
 - Protocols and or Study Plans to support analytical processes/parameters and product development. Include the procedures that will be employed to monitor controls and calibration for equipment.
 - Training/Proficiency Requirements Determination to ensure that personnel have appropriate training/competency.
 - Development/Technical Reports to summarize results including deviations from established development protocol/plan, and identification of the path forward based upon the results obtained.
- **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 (two-page limit per letter): Provide a letter (or letters if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project.
- Letters of Collaboration (if applicable) (two-page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations. Disclose any patents, issued or pending, and/or licenses, granted and/or pending, with respect to the intervention/device. Discuss and document availability of and access to the intervention/device. Provide documentation of access to and permission to use all intellectual and material property, as applicable.
- 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.
- 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.
- **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.
- Clinical Impact: Briefly describe how the proposed project will have an impact on military infectious disease research or patient care.
- Military Relevance: Briefly describe how the proposed project impacts the military population.
- **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?
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information.
- **Attachment 6: Human Sample Acquisition and Safety Procedures (if applicable; no page limit):** Upload as “HumSubProc.pdf.” The Human Sample Acquisition and Safety Procedures attachment should include the components listed below.

a. Study Population and Design

- 1) 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 samples were obtained). *Use of military populations is preferable but not required.* Demonstrate that the research team has access to the proposed study population samples.
- 2) Device/diagnostics studies that are required to demonstrate substantial equivalence include the following (*Note: Most in vitro devices are exempt from the medical device IDE regulations*):
 - 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.*

- 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. Laboratory Evaluations

- **Specimens to be collected, schedule, and amount:** All specimens that will be evaluated for study purposes must be clearly stated. The amount of material collected to be utilized for the study 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.
- **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.
- e. **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.
 - 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. These 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:

- (1) 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
- (2) 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.

f. 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.
- **Attachment 7: Military Impact Statement (one-page limit).** Upload as “Impact.pdf.”
 - Describe the potential impact of the proposed research on treatment of combat-related wound infections.
 - Describe the short-term impact: Detail the anticipated outcomes that will be directly attributed to the results of the proposed research.
 - Describe the long-term impact: Explain the long-range vision for implementation of the intervention in the clinic or field and describe the anticipated long-term benefits for the targeted population.
 - Compare the proposed intervention to pharmacologic agents, devices, and/or clinical guidance currently available, if applicable.
 - **Attachment 8: Transition Plan (one-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 schedule 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 9: Military Relevance Statement (one-page limit):** Upload as "MilRel.pdf."

Describe how the proposed study is responsive to the treatment of combat-related 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 MID-ARA focus area(s) aligned with the proposed project. Show how the proposed study complements ongoing DOD and VA areas of research interest.

If active duty military 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).

- **Attachment 10: Letter(s) of Support for Use of Military and VA Populations or Resources (if applicable).** Upload as "Access.pdf."

If the study involves active duty military, military-controlled study materials, and/or military databases, include a letter of support signed by the lowest ranking person with approval authority. If the study proposes to recruit subjects from VA Medical Centers or use VA-controlled materials or information from VA data systems and an investigator with a VA appointment is *not* included as the primary PI or a collaborator, include a letter from an appropriate authority providing access to veterans, VA-controlled study materials, or VA data (as applicable).

- **Attachment 11: IND/IDE Documentation Form (if applicable).** Upload as "IND.IDE.pdf."

Complete the IND/IDE Application Status Form, which is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity on Grants.gov.

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

- PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."

- PI Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch_LastName.pdf.”
 - Key Personnel Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
 - The PI is responsible for ensuring that the total budget (including any intramural collaborators and/or subawardees, if applicable) does not exceed the maximum allowed costs. Further details about intramural and extramural collaborators can be found in Section I.D., Funding.
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

D. Budget Submission for Intramural Collaborators (via CDMRP eReceipt System):

Intramural collaborators are required to submit an independent Research and Related Budget form through the CDMRP eReceipt System (not Grants.gov). This budget form will include a Budget Justification statement, and detail only the intramural collaborator’s contribution to the project. Intramural collaborators are reminded that they must consult their respective resource manager to validate whether incremental funding is being utilized and the proper procedures for executing those funds. The Research and Related Budget form (OMB No. 4040-0001) is accessible through Grants.gov using the following steps:

- 1) From the Grants.gov Basic Search page, search this Funding Opportunity Number, W81XWH-11-DMRDP-MID-ARA.
- 2) Within the DOD Military Infectious Diseases Basic Research Award page, click on “Application” at the top, and then download the Instructions and Application Package from the bottom of the page.
- 3) Within the first page of the Grant Application Package is a block of Mandatory Documents. Highlight and select the Research and Related Budget form from this block and click the arrow in the center of the page to “Move Form to Complete.” This will move the form into the Mandatory Documents for Submission block. Select the Research and Related Budget form from this block and click “Open Form” to open the file. You can now fill out the Research and Related Budget form, *save it to your computer*, and then upload it into the [CDMRP eReceipt System](#) (this will require eReceipt registration), under the “Other Documents” tab.
- 4) When filling out the form, enter your own organization name and *the PI’s* CDMRP Log Number (e.g., DM117777) in the Organization block of the Research and

Related Budget form. Intramural collaborators should not enter an Organizational DUNS and should not indicate a Budget Type. Note: Intramural collaborators are also required to provide a Budget Justification (no page limit, block K in the Research and Related Budget form). Refer to the General Application Instructions, Section 4 for details on content and format.

E. 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.

F. 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 and clinicians 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 based on technical merit, the relevance to the mission of the DOD and DMRDP, and the specific intent of the award mechanism. Programmatic review recommendations for funding are forwarded to the Commanding General for concurrence, and then to the Office of the Assistance Secretary of Defense for Health Affairs for final approval. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

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

- **Impact**
 - How relevant the anticipated outcomes of the proposed project are to addressing one or more of the MID-ARA research focus areas described in this Program Announcement/Funding Opportunity.
 - How the potential incremental research progress or long-term benefits of the proposed project may impact patient care and/or quality of life.
- **Research Strategy**
 - How the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature and logical reasoning, and presentation of preliminary data.
 - 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 PI acknowledges potential problems and addresses alternative approaches.
- **Transition Plan**
 - Whether the funding strategy described to bring the outcome(s) to the next level of Research and Development and/or clinical trial/testing is appropriate.
 - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
 - How the schedule and milestones for bringing the outcome(s) to the next level of Research and Development and/or clinical trial/testing is appropriate.
 - 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 (if applicable).

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

- **Personnel**
 - To what degree the study team's background and expertise are appropriate to accomplish the proposed work.
 - How the levels of effort of the study team members are appropriate for successful conduct of the proposed research.

- **Environment**
 - To what degree the scientific environment and the accessibility of institutional resources support the proposed research project.
 - If applicable, whether there is evidence for appropriate institutional commitment from each collaborating institution.
 - If applicable, how the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed research project.
 - **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:** Scientifically sound applications that best fulfill the following criteria and most effectively address the projects and tasks listed in this Program Announcement/Funding Opportunity will be identified and forwarded to the Director of the DMRDP for approval. The review criteria listed below (a-d) are in order of descending importance with Criteria a and b of equal importance.
- a. Responsiveness MID-ARA research focus areas**
 - How well the proposed study advances scientific knowledge within one or more of the research focus areas identified in this Program Announcement/Funding Opportunity.
 - b. Programmatic Relevance in Terms of Military Impact**
 - The potential impact of the results of the proposed project, if successful, on understanding or solving a military problem.
 - c. Ratings and Evaluations of the Scientific Peer Reviewers**
 - Scientific merit of the proposed project will be considered in the context of the programmatic review and compared to all eligible applications under consideration.
 - d. Portfolio Balance**
 - How well the proposed study contributes to ensuring an overall balance of research and development efforts.
 - Whether the proposed research is a duplication of effort funded by DOD or other agencies.

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 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.
- Preproposal is submitted by an intramural investigator as defined in Section I.C.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Submission of an application for which a letter of invitation was not received.

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 pre-application or application deadline, the PI or intramural collaborator, if applicable, 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 and the missing content may result in administrative withdrawal of the pre-application or application.

C. Withdrawal

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

- FY11/12 MIDRP Joint Program Committee (JPC) 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 FY11/12 MIDRP JPC members may be found at http://cdmrp.army.mil/dmrdp/jpc/11jpc_2.shtml.
- 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.
- Total costs as shown on the Quad Chart and/or 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 PI does not meet the eligibility criteria. Refer to the General Application Instructions, Appendix 1, for general eligibility information.
- The application incorporates high-throughput drug screening and/or in silico modeling.
- The application includes a clinical trial.

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, 2013. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section 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.

Quarterly, annual, and final technical progress reports will be required.

D. Award Transfers

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

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 USAMRAA Contracting/Grants Officer.

E. Pre-Award Meeting

At the Government's discretion, the PI and Clinical Study Coordinator may be requested to participate in a pre-award meeting. PIs recommended for funding will be notified during the award negotiation process whether a pre-award meeting will be required. In the event a pre-award meeting is required, the PI will be required to budget for travel expenses at that time.

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. PI APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Human Sample Acquisition and Safety Procedures (Attachment 6) as HumSubProc.pdf, as appropriate.	
	Upload Military Impact Statement (Impact.pdf) as Attachment 7.	
	Upload Transition Plan (Transition.pdf) as Attachment 8.	
	Upload Military Relevance Statement (MilRel.pdf) as Attachment 9.	
	Upload Letters Confirming Access to Target Military or VA Patient Population(s) (Access.pdf) as Attachment 10, as applicable.	
	Upload IND/IDE Documentation Form, if applicable, (IND.IDE.pdf) as Attachment 11.	
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.	

VIII. INTRAMURAL COLLABORATOR CHECKLIST

Submission Requirements	Action	Completed
eReceipt Registration	Intramural collaborators must register with the CDMRP eReceipt System.	
Research & Related Budget	<p>Download the Research and related Budget form from Grants.gov. Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.</p> <p>Upload the form into the CDMRP eReceipt System, under the “Other Documents” tab.</p>	