Program Announcement

for the

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Congressionally Directed Medical Research Programs

Military Infectious Diseases Applied Research Award

Funding Opportunity Number: W81XWH-14-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), June 10, 2013
- **Invitation to Submit an Application:** August 2013
- **Application Submission Deadline:** 11:59 p.m. ET, October 17, 2013
- **Peer Review:** To be determined
- **Programmatic Review:** To be determined

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 Applied Research Award (MID-ARA) 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 (MHS), or in civilian health care facilities.

The DMRDP Military Infectious Diseases Research Program (MIDRP) Joint Program Committee 2 (JPC-2) expects to fund approximately five FY14 DMRDP 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, we anticipate that up to $2.6M in FY14 and $8.5M in FY15-FY16 funds may be available. The executing agent for this announcement is the Congressionally Directed Medical Research Programs (CDMRP).

B. FY14 MID-ARA Focus Areas

All applications ***MUST*** specifically address at least one of the MID-ARA Focus Areas related to combat-related or trauma-induced wound infections. Research projects incorporating high-throughput drug screening and/or *in silico* modeling, as well as applications focused on areas other than those listed below should ***NOT*** be submitted. The MID-ARA Focus Areas are:

- Development of new methods for rapid multi-pathogen/multi-phenotype detection of multidrug-resistant organisms (MDROs), nosocomial 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), 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 multi-drug 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 wound infection.

C. Award Information

Overview: The FY14 DMRDP MID-ARA seeks applied research applications focused on the reduction of combat-related or trauma-induced wound infection morbidity and mortality. These awards are expected to yield potential health products, approaches, or technologies positioned for human testing. The intent of the FY14 DMRDP MID-ARA is to support:

- Hypothesis-testing and/or proof-of-concept studies in in vitro and/or in vivo models;
- Refinement of concepts and ideas into potential solutions with a view toward evaluating technical feasibility of emerging approaches, technologies, and promising new products;
- Evaluation, maturation, and/or down-selection of potential product candidates (drugs, biologic/vaccine constructs, or devices/systems) in vitro and/or in vivo and;
- Completion of preclinical safety and/or toxicity studies sufficient to support Investigational New Drug/Investigational Device Exemption (IND/IDE) applications.

Awards may support studies with human subjects but may not be used to support clinical trials. A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction.

Awards may not be used to support fundamental basic research. Basic research is defined as research directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward process or products in mind.

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.

Partnering Principal Investigator (PI) Option: The FY14 DMRDP MID-ARA 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 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. 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.

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. This review is in addition to the local Institutional Animal Care and Use Committee (IACUC) review and approval processes. Allow 2 to 3 months for IACUC and ACURO 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, Usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil.

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 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://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
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
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

Defense Manpower Data Center
www.dmdc.osd.mil

Use of Military and Veteran Affairs (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, public, military, 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 **$2,000,000** 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 **$2,000,000** for direct and indirect costs for up to a **3**-year period of performance. A separate award will be made to each PI's organization. The PIs are expected to be equal partners in the research, and 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 and are so 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
- Equipment costs up to $10,000

- Research supplies
- Research-related subject costs (clinical trials are NOT allowed)
- Support for multidisciplinary collaborations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings in addition to the required meeting described above
- Travel between collaborating organizations

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.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural organizations will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a federal organization or agency is not allowed except under very limited circumstances. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers.

The DMRDP MIDRP JPC-2 expects to allot approximately $11.1M of the DMRDP FY14-FY16 appropriations to fund approximately five MID-ARA 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-ARA Award mechanism is structured to accommodate up to three 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-ARA.

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 application should be the same as those identified in the pre-application. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org 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 – 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 (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 is 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 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. State how this project meets the intent of the award mechanism and addresses an important problem relevant to combat-related or trauma-induced wound infections.
- **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 or trauma-induced wound infection.
- **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-ARA 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 MIDRP JPC-2, pre-applications will be screened based on the following criteria:

- **Research Plan:** How well the rationale, objectives, and specific aims support the research idea. To what degree the proposed project addresses the intent of the award mechanism and addresses an important problem relevant to combat-related or trauma-induced wound infections.
- **Personnel:** To what extent the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research project.
- **Impact:** If successful, to what extent the study could impact research and improve patient care related to combat related or trauma-induced wound infections.
- **Military Benefit:** How well 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 FY14 DMRDP MID-ARA Focus Area.

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

  Following the pre-application screening, the 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 Single PIs or for Initiating PIs under the Partnering PI Option:

Grants.gov application package components: For the FY14 Military Infectious Diseases Applied Research Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

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

2. **Attachments Form**

   - **Attachment 1: Project Narrative (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 may 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 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 to at least one of the FY14 MID-ARA Focus Areas 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. ***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.
    - Letters of Organizational Support (2-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.
    - 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.
    - 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 Collaboration (if applicable) (2-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. Provide documentation of access to and permission to use all intellectual and material property, as applicable.

- Letter(s) of Support for Use of Military and VA Populations or Resources (if applicable) (2-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-ARA Focus Area(s) to be addressed and briefly describe how the proposed research will impact those area(s). Briefly describe how the proposed study can potentially benefit the military and Veteran populations 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-ARA Focus Area(s) will be addressed?
    - How can the proposed research impact the Focus Area(s) 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-ARA 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.
  - Describe the long-term impact: Explain the long-range vision for implementation of the intervention, device, assay, or knowledge product in the clinic or field, and describe the anticipated long-term benefits for the targeted population.
  - Compare the proposed intervention, device, assay or knowledge product to pharmacologic agents, devices, and/or clinical guidance currently available, if applicable.

- **Attachment 7: Transition Plan (two-page limit).** Upload as "Transition.pdf." Provide information on the methods and strategies proposed to move the product, approach, or technology to the next phase of research and development. The transition plan should include the components listed below.
  - Provide details of the funding strategy that will be used to bring the research outcomes to the next logical phase of research (e.g., specific potential industry partners, specific funding opportunities to be pursued).
  - 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 development.
  - 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: 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

    - 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.*** 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 effort in recruiting human subjects from the target population from previous interventional or observational studies. Address any potential barriers to accrual and plan for addressing unanticipated delays. Include justification of any age, race, ethnicity or sex limitations provided.

- 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.*** 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 the 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 study.

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 a two-stage consent process. Informed 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. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the study.
- Include information regarding the timing and location of the consent process.
- 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), 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:

  - 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://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf). 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.

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 PIs' budgets cannot exceed $2M.

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 $2M.

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.

All CDMRP 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:

   - **Impact**
     - How the proposed study addresses the FY14 MID-ARA Focus Area(s).
     - How relevant the anticipated research outcomes are to the FY14 MID-ARA Focus Area(s).
     - How well the potential incremental research progress or long-term benefits of the proposed project may impact patient care and/or quality of life.
   - **Research Strategy**
     - To what degree the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, logical reasoning, and presentation of preliminary data.
     - How well the study aims, hypotheses, objectives, experimental design, methods, data collection procedures, and analyses are designed to clearly answer the clinical objective.

- 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.
- How well the quality management plan ensures that the research is conducted and results documented to support the development of an FDA-regulated product(s).
- The extent to which the inclusion and exclusion criteria are well justified and meet the needs of the proposed research, if applicable.

- **Accrual of Human Subjects or Samples (if applicable)**
  - How well the PI addresses the availability of human subjects or samples.
  - Whether the PI has demonstrated access to the proposed human subjects population or samples.
  - The degree to which recruitment, informed consent, screening, and retention processes for human subjects/samples will meet the needs of the proposed study.
  - 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 research will affect the daily lives of individual human subjects participating in the study and has developed mitigation plans for any negative effects related to participation.
- **Transition Plan**
  - How well the described funding strategy will be able to bring the research outcome(s) to the next level of Research and Development.
  - 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 the next level of Research and Development 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 (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:** 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:

- **Ratings and Evaluations of the Peer Reviewers**
  - Scientific merit of the proposed project will be considered and compared to all other applications for this Funding Opportunity.
- **Adherence to the Intent of the Award Mechanism**
  - To what extent the proposed research will yield products, approaches, or technologies positioned for human testing.
- **Program 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.
- **Military Relevance**
  - To what extent the proposed research is responsive to the health care needs of military Service Members and Veterans.
  - To what extent the proposed research is aligned with the objectives of DMRDP.

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.
- 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 MIDRP JPC-2 members can be found at http://cdmrp.army.mil/dmrdp/jpc/13jpc_2.
- 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-ARA Focus Areas.
- The proposed research includes high-throughput drug screening and/or *in silico* modeling.
- The proposed research includes a clinical trial.
- The proposed study includes only basic research.

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 final report will be required.

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

D. Award Transfers

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 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 negotiation 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 Sample Acquisition and Safety Procedures (HumSubProc.pdf) as Attachment 8, as appropriate		
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		