Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Defense Medical Research and Development Program

Joint Program Committee-2/ Military Infectious Diseases Research Program

Applied Research Award

Funding Opportunity Number: W81XWH-17-DMRDP-MID-ARA

Catalog of Federal Domestic Assistance Number: 12.420

Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), January 26, 2016
- **Invitation to Submit an Application:** March 7, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, May 9, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, May 12, 2016
- **Peer Review:** July 2016
- **Programmatic Review:** August 2016

The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

This Program Announcement/Funding Opportunity 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 2017 (FY17) Joint Program Committee-2/Military Infectious Diseases Research Program (JPC-2/MIDRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs [OASD(HA)], the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) provides Defense Medical Research and Development Program (DMRDP) execution management support for DHP core research program areas, including JPC-2/MIDRP. This Program Announcement and subsequent awards will be managed and executed by CDMRP with strategic oversight from JPC-2/MIDRP.

The JPC-2/MIDRP is one of six major DHP core research program areas within the DHA RDA Directorate and is administered with oversight from JPC-2, which consists of Department of Defense (DoD) and non-DoD medical and military technical experts relevant to the program area. The JPC-2/MIDRP supports research and development leading to the fielding of effective, improved means of bacterial, parasitic and viral infection prevention, screening, diagnosis, and treatment to maintain maximal global operational capability with minimal morbidity and mortality. JPC-2/MIDRP's DHA-aligned mission is focused on polytrauma and blast injury, with a DHP core research program emphasizing wound infection prevention and management, as well as antimicrobial countermeasures.

B. FY17 JPC-2/MIDRP Applied Research Award Focus Areas

To meet the intent of the FY17 JPC-2/MIDRP Applied Research Award (ARA) mechanism, applications ***MUST*** specifically address at least one of the FY17 JPC-2/MIDRP ARA Focus Areas related to combat-related or trauma-induced wound infections listed below. Research projects incorporating high-throughput drug screening and/or *in silico* modeling, as well as applications focused on areas other than those listed below will not be considered for funding.

FOCUS AREAS:

- 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 infection management decisions (e.g., optimal wound closure time, optimal duration of antibiotic administration 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.

APPLICABLE TO ALL FOCUS AREAS:

- Studies involving carbapenem-resistant organisms are particularly sought.
- 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.

C. Award Information

The FY17 JPC-2/MIDRP ARA seeks to fund applied research applications focused on the reduction of combat-related or trauma-induced wound infection morbidity and mortality. These projects are expected to inform and identify which potential health products, approaches, or technologies are best positioned for human testing. The intent of the FY17 JPC-2/MIDRP ARA is to support the following:

- 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 involving human subjects but not 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. Principal Investigators (PIs) seeking support for a clinical trial should apply to the FY17 JPC-2/MIDRP Clinical Studies Award (Funding Opportunity Number: W81XWH-17-DMRDP-MID-CSA).

Awards may not be used to support early-stage, 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.

Applications must include preliminary and/or published data that is relevant to the award and the proposed research project. 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 PI Option: The FY17 JPC-2/MIDRP 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, all 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.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the 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 requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. The HRPO reviews and approves the participation of each site in the clinical trial. Refer to the General Application Instructions, Appendix 5, and the Human Subject Resource Document available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

Reporting Guidelines: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical/animal studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies and should be applied to those projects as well.

Research Involving Animals: Projects that include research on animal models are required to submit Attachment 9, Animal Research Plan, as part of the application package. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at http://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf.

All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO must review and approve all animal use prior to the start of working with animals. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." ***Allow at least 3 to 4 months for regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 5, for additional information.

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

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

Armed Forces Institute of Regenerative Medicine http://www.afirm.mil

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

Clinical and Rehabilitative Medicine Research Program
https://crmrp.amedd.army.mil

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

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

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

Defense Health Agency Research, Development, and Acquisition Directorate
http://www.health.mil/About-MHS/Defense-Health-Agency/Research-Development-Acquisition

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

Military Infectious Diseases Research Program https://midrp.amedd.army.mil

Military Operational Medicine Research Program https:/momrp.amedd.army.mil

National Center for Telehealth and Technology http://t2health.org/

National Museum of Health and Medicine
http://www.medicalmuseum.mil/index.cfm

Naval Health Research Center
http://www.med.navy.mil/sites/nhrc

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

Office of Naval Research
http://www.med.navy.mil

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

U.S. Army Medical Research Acquisition Activity https://www.usamraa.army.mil/

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

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

U.S. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.amedd.army.mil/

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

U.S. Naval Research Laboratory
https://www.nrl.navy.mil

Walter Reed Army Institute of Research
http://wrair-www.army.mil

Use of Military and VA Populations or Resources: If the proposed research plan involves access to military and/or VA population(s) and/or resource(s), the PI is responsible for establishing access. If possible, access to target military and/or VA population(s) and/or resource(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving military Service members, Veterans, military- and/or VA-controlled study materials and military and/or VA databases. Use Attachment 2 to provide this documentation (see Section II.C., Full Application Submission Content, Supporting Documentation). If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for an access to the relevant population(s) and/or resources.

The MIDRP and CDMRP intend that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 3, Section L.

D. Eligibility Information

- Independent investigators at any academic level (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

Applications submitted with a single PI or under the Partnering PI Option have the same funding limits:

- The maximum period of performance is **3** years.
- The anticipated total costs budgeted for the entire period of performance will not exceed **$2 million (M)**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$2M** total costs or using an indirect rate exceeding the organization's negotiated rate.

- 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) must be included in the total direct costs of the primary award.
- **Partnering PI Option:** The anticipated combined total costs (direct plus indirect) budgeted for the entire period of performance for the Initiating PI and the Partnering PI(s) applications will not exceed **$2M**. If the Initiating PI's or a Partnering PI's budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget indirect costs in accordance with each organization's negotiated rate. The combined budgeted total costs approved by the Government will not exceed **$2M** and will not use an indirect rate exceeding each organization's negotiated rate. A separate award will be made to each PI's organization.

Refer to the General Application Instructions, Section II.C.5., for budget regulations and instructions for the Research & Related Budget. ***For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.5. of the General Application Instructions***.

For this award mechanism, direct costs must be requested for:

- Travel costs for the PI(s) to disseminate project status at one DoD JPC-2/MIDRP In-Progress Review meeting to be held at the discretion of the Government during the award performance period. Costs associated with travel to this meeting should be included in Year 2 of the budget. For planning purposes, it should be assumed that the meeting will be a 1-day meeting 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
- Clinical research costs (clinical trials are NOT allowed)
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings in addition to the required DoD meeting described above

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such***

cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Section II.A. 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 agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The JPC-2/MIDRP expects to allot approximately $20.5M of the anticipated FY17-FY19 DHP RDT&E appropriations to fund approximately ten Applied Research Award applications, depending on the quality and number of applications received. Of the total amount, approximately $6.4M will be available in FY17, with the remaining years being incrementally funded. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program. As of the release date of this Program Announcement/Funding Opportunity, the FY17 Defense Appropriations Bill has not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this Program Announcement/Funding Opportunity is 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 of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative applications.

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (https://eBRAP.org/) and (2) application submission through Grants.gov (http://www.grants.gov/). Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation

during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

Partnering PI Option: The ARA is structured to accommodate up to three PIs (one initiating PI and up to two partners). One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as the Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-17-DMRDP-MID-ARA in Grants.gov (http://www.grants.gov/).

B. Pre-Application Submission Content

All pre-application components must be submitted by the PI (for single PI applications) or Initiating PI (for Partnering PI Option applications) through eBRAP (https://eBRAP.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.

Partnering PI Option: ***The Initiating PI is responsible for submission of all pre-application 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 eBRAP in order to associate his/her Grants.gov application package with that of the Initiating PI.*** Do not delay completing these steps. If they are not completed, the Partnering PI will not be able to view and modify his/her application submission in eBRAP.

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

The pre-application consists of the following components, which are organized in eBRAP 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**
  - Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF-424 Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
  - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Collaborators and Key Personnel – Tab 3**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
  - FY16 JPC-2 members will serve as the FY17 JPC-2/MIDRP ARA programmatic panel and should not be involved in any pre-application or application. For questions related to the FY17 JPC-2/MIDRP ARA programmatic panel members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.
  - **Partnering PI Option:** The Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section.
- **Conflicts of Interest (COIs) – Tab 4**
  - List all individuals other than collaborators and key personnel who may have a COI in the review of the pre-application or application (including those with whom the PI(s) has a personal or professional relationship).
- **Pre-Application Files – Tab 5**

  Note: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

  Preproposal Narrative (three-page limit): The Preproposal Narrative page limit 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 Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include 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(s) 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, Veterans, and/or other Military Health System beneficiaries affected by combat-related or trauma-induced wound infections.
- **Alignment with Focus Areas:** Explain how the proposed work addresses at least one of the FY17 JPC-2/MIDRP ARA Focus Areas.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application ***must be uploaded as individual PDF documents*** and 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** (five-page limit per individual).
- **Quad Chart:** Complete the Quad Chart as instructed. The Quad Chart template and instructions are available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm).

- **Submit Pre-Application – Tab 6**
  - This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the DHP and JPC-2/MIDRP, 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(s) 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, Veterans, and/or other Military Health System beneficiaries affected by combat-related or trauma-induced wound infections.
- **Alignment with Focus Areas:** How well the project addresses at least one of the FY17 JPC-2/MIDRP ARA Focus Areas.

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

  Following the pre-application screening, the PI or Initiating PI 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. Full Application Submission Content

Applications will not be accepted unless the PI or Initiating PI has received notification of invitation.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

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

Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to the application submission deadline***.

Partnering PI Option: 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 eBRAP. Each Grants.gov application package must be submitted using the unique log number. ***Note: All associated applications (Initiating and each Partnering PI) must be submitted by the Grants.gov deadline.***

Application Components for a Single PI or for the Initiating PI under the Partnering PI Option:

Grants.gov application package components: For the 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**

   Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

   - **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 and/or preliminary data, published or unpublished, 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 FY17 JPC-2/MIDRP 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 research strategy, methods, and analyses, including appropriate controls, in sufficient detail for evaluation of its appropriateness and feasibility. Describe the statistical plan as appropriate for the proposed research. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***This award may not be used to conduct clinical trials.***

- **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:** As applicable, 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 will result in the removal of those items or may result in 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 a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Letter(s) Confirming Access to Military and VA Populations or Resources (if applicable): 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.
- Quad Chart: Provide an updated 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.
- Intellectual Property
  - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- 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 3, Section L for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf."** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Technical abstracts should be written using the outline below. Abstracts of all funded research projects will be posted on the CDMRP website (http://cdmrp.army.mil); therefore, 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.
- Impact and Military Benefit: Identify the FY17 JPC-2/MIDRP 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 Service members, Veterans, and/or other Military Health System beneficiaries affected by trauma-induced or combat-related wound infections.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf."** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Lay abstracts should be written using the outline below. Do not duplicate the technical abstract. Abstracts of all funded research projects will be posted on the CDMRP website (http://cdmrp.army.mil); therefore, proprietary or confidential information should not be included.

  - Describe the objectives and rationale for the proposed study in a manner that will be readily understood by readers without a background in science or medicine.
  - Describe the ultimate applicability of the research.
    - Which FY17 JPC-2/MIDRP 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 Service members, Veterans, and/or other Military Health System beneficiaries will it help, and how will it help them?
    - What are the likely contributions of this study to advancing the field of trauma-induced or combat-related wound infection research or patient care?

- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf."** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the JPC-2/MIDRP ARA mechanism, use the SOW format example titled "SOW for Advanced Tech Development Research." The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.

  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: Impact and Military Benefit Statement (two-page limit): Upload as "ImpactMilBen.pdf."** Describe the anticipated impact and military benefit of the proposed research.

  Describe the short-term impact: Describe the anticipated short-term outcome(s)/product(s) (intellectual and/or material) that will be directly attributed to the results of the proposed research.

  Describe the long-term impact: Describe the anticipated long-term gains of the research. Compare to the information known/products currently available, if applicable. Describe the indication and discuss whether the project will lead toward transforming the standard of care. Describe any non-trauma-related indications that would expand the market for the proposed product.

  Military Benefit: Describe how the proposed study is responsive to the health care needs of military Service members, Veterans, and/or other Military Health System beneficiaries affected by combat-related or trauma-induced wound infections. Provide information about the incidence and/or prevalence of combat-related or trauma-induced wound infections in military Service members, Veterans, and/or other Military Health System beneficiaries. If active duty military, military families, and/or Veteran population(s) or datasets will be used in the proposed research project, describe the population(s)/dataset(s), the appropriateness of the population(s)/dataset(s) for the proposed study, and the feasibility of accessing the population(s)/dataset(s). 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, Veterans, and/or other Military Health System beneficiaries).

- **Attachment 7: Transition Plan (two-page limit). Upload as "Transition.pdf."** Provide information on the methods and strategies proposed to move the anticipated research outcomes to the next phase of research and development. As applicable to the proposed research, 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 Subject/Sample Acquisition and Safety Procedures (if applicable; no page limit): Upload as "HumSubProc.pdf."** The Human Subject/Sample Acquisition and Safety Procedures document should include the following components:
    - **Study Population**
        - Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from which the samples, data, or other resources will be obtained). Describe how the anticipated findings in the proposed population(s) are relevant to military population(s). Demonstrate that the research team has access to the proposed study population/database/resource.
            - If applicable, discuss past effort in recruiting human subjects from the target population for previous studies. Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.
    - **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, "Ethical Principles and Guidelines for the Protection of Human Subjects," and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the DoD. 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 proposed research.
    - **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. 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.
    - **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.

- **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)[1], 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, refer to the General Application Instructions, Appendix 5, for more information.

- **Risk/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.

[1] Code of Federal Regulations, Title 45, Part 46.116(d).

- **Attachment 9: Animal Research Plan, if applicable: "Upload as AnimalPlan.pdf."**

  When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

  - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
  - Summarize the procedures to be conducted. Describe how the study will be controlled.
  - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
  - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- **Attachment 10: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as "MFBudget.pdf."** If a Military Facility (Military Health System facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP "Funding Opportunities & Forms" web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information.

   - PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf." The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used.
   - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

- Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf."
    - Partnering PI Option: Include biographical sketches for each Partnering PI.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
    - Partnering PI Option: Include previous/current/pending support for each Partnering PI.

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
    - Budget Justification (no page limit): Upload as "BudgetJustification.pdf." The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

      Partnering PI Option: Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for Partnering PI(s), even if they are located within the same organization. The anticipated combined total costs (direct and indirect) budgeted for the entire period of performance for the Initiating PI and the Partnering PIs' applications will not exceed $2M. If the Initiating PI's or Partnering PIs' budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget indirect costs in accordance with each organization's negotiated rate. The combined budgeted total costs approved by the Government will not exceed $2M and will not use an indirect rate exceeding each organization's negotiated rate.

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

Partnering PI Option: Application Components for the Partnering PI(s)

Each Partnering PI MUST follow the link in the email from eBRAP and complete the registration process prior to the application submission deadline in order to associate his/her Grants.gov application package with that of the Initiating PI.

The application submission process for Partnering PI(s) uses an abbreviated Grants.gov application package 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.3., 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.5., 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 efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for Partnering PI(s), even if they are located within the same organization. The anticipated combined total costs (direct and indirect) budgeted for the entire period of performance for the Initiating PI and the Partnering PIs' applications will not exceed $2M. If the Initiating PI's or Partnering PIs' budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget indirect costs in accordance with each organization's negotiated rate. The combined budgeted total costs approved by the Government will not exceed $2M and will not use an indirect rate exceeding each organization's negotiated rate.

4. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

5. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

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 either of these deadlines will result in submission 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. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers using a two-tier review process. The first tier is 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 DHA RDA Directorate and the OASD(HA), based on (a) technical merit and (b) the relevance to the mission of the DHP and JPC-2/MIDRP, and to 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 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 nondisclosure 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 Process

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

- **Impact and Military Benefit**
    - How well the proposed study addresses at least one of the FY17 JPC-2/MIDRP ARA Focus Area(s).
    - How relevant the anticipated research outcomes are to the FY17 JPC-2/MIDRP ARA Focus Area(s).
    - How significantly the anticipated short-term and long-term research outcomes impact combat-related or trauma-induced wound infection research and/or patient care.
    - How well the anticipated research outcomes address the health care needs of military Service members, Veterans, and/or other Military Health System beneficiaries affected by combat-related or trauma-induced wound infections.
- **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 research questions.
        - If applicable, how well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.
        - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling as applicable.
        - The extent to which the inclusion and exclusion criteria are well justified and meet the needs of the proposed research, if applicable.
    - How well the potential problems and risk areas were identified and the extent the proposed alternative methods and approaches address those areas.
    - If applicable, 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).
- **Accrual of Human Subjects or Samples (if applicable)**
    - Whether the availability and accessibility of human subjects, data, samples, or other resources for the proposed study is demonstrated.
    - 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.

- **Ethical Considerations**
  - How the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.
  - How well the evidence shows that the procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.
  - To what degree privacy issues are appropriately considered.
  - To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
- **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.
  - Partnering PI Option: To what extent the partnering PI's experience, expertise, and involvement represent a significant contribution to the proposed research project such that it could not be accomplished without his/her involvement.
- **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.

- **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 influence the review.

2. **Programmatic Review:** To make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

   a. 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.

   b. Relevance to the mission of the DHP and JPC-2/MIDRP, as evidenced by the following:

   - Adherence to the intent of the award mechanism
   - Relative impact and military benefit
   - Program portfolio balance

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 email notification of posting of the funding recommendation in eBRAP. 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 eBRAP 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.
- Partnering PI Option: All associated Initiating and Partnering PI applications are not submitted by the submission deadline.

B. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

C. Withdrawal

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

- A FY17 JPC-2/MIDRP ARA programmatic panel 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 documentation. FY16 JPC-2 members will serve as the FY17 JPC-2/MIDRP ARA programmatic panel. **A list of the FY16 JPC-2 members can be found at http://cdmrp.army.mil/dmrdp/jpc/16jpc_2.**
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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.

- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.
- If a clinical trial is proposed, the application will be withdrawn.

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, 2018. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in 2 CFR 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 3 for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 3, Section I, for general information on reporting requirements.

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

In addition to written progress reports, in-person presentations may be requested.

E. Award Transfers

Refer to the General Application Instructions, Appendix 3, Section M, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through eBRAP 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@eBRAP.org

B. Grants.gov Contact Center

Questions related to application submission through 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 Grants.gov application package. If the Grants.gov 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	Upload Order	Action	Single or Initiating PI Completed	Partnering PI(s) Completed
SF-424 (R&R) Application for Federal Assistance		Complete form as instructed.		
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."		
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."		
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."		
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."		
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."		
	6	Impact and Military Benefit Statement: Upload as Attachment 6 with file name "ImpactMilBen.pdf."		
	7	Transition Plan. Upload as Attachment 7 with the file name "Transition.pdf."		
	8	Human Subjects/Sample Acquisition and Safety Procedures: Upload as Attachment 8 with the file name "HumSubProc.pdf," if applicable.		
	9	Animal Research Plan: Upload as Attachment 9 with file name "AnimalPlan.pdf," if applicable.		
	10	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 10 with the file name "MFBudget.pdf," if applicable.		
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
		Attach PI Previous/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.		

Grants.gov Application Components	Upload Order	Action	Single or Initiating PI Completed	Partnering PI(s) Completed
		Attach Previous/Current/Pending (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.		