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

Clinical Study Award

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

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 Clinical Study Award Focus Areas

To meet the intent of the FY17 JPC-2/MIDRP Clinical Study Award (CSA) mechanism, applications ***MUST contain only one*** clinical trial/testing with a distinct study design and address at least one of the Focus Areas listed below. Applications focused on areas other than those listed below will not be considered for funding.

FOCUS AREAS:

- **Therapeutics.** Evaluation of optimum preventive or directive therapies for combat-related or trauma-induced wound infections using Food and Drug Administration (FDA)-approved drugs, biologics, or devices either alone or in combination. Studies focusing on new indications of FDA-approved drugs/biologics/devices or investigational new drugs/biologics/devices will be accepted.
- **Rapid detection of pathogens and/or anti-microbial drug resistance markers.** Evaluation of a functional prototype device or assay for the rapid detection of pathogens and/or anti-microbial drug resistance markers in combat-related or trauma-induced wounds. Research outcomes should support the development of an FDA-regulated device or assay.

- **Rapid detection of biomarkers.** Evaluation of a functional prototype device or assay for the rapid detection of novel and specific *in vivo* or *in vitro* biomarkers (from wound, serum, saliva, or urine) that predict development of infection or discriminate between infection and colonization. Research outcomes should support the development of an FDA-regulated device or assay.

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 multidrug-resistant organisms (MDROs), particularly, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, extended-spectrum beta-lactamase producing *Enterobacteriaceae* (including *Escherichia coli* and *Klebsiella pneumoniae*), methicillin-resistant *Staphylococcus aureus* (MRSA), and/or invasive fungal (mold) pathogens.

C. Award Information

The FY17 JPC-2/MIDRP CSA is intended to support military relevant early phase clinical trials and *in vitro* diagnostic medical device clinical investigations with the potential to have a major impact on the prevention, screening, diagnosis, and/or treatment of combat-related or trauma-induced wound infections. Early phase clinical trials and medical device testing ***supported by this award range from proof of concept (i.e., first in human or Phase 0) trials through Phase II clinical trials, as well as Class I, II, or III medical device testing. Phase III trials for FDA licensure of drugs or definitive testing for device or assay clearance by the FDA will NOT be permitted under this Program Announcement/Funding Opportunity.*** Proposed projects should be designed to demonstrate the safety and efficacy of novel therapies and diagnostics in human subjects or human clinical samples to accelerate their translation to clinical utility. Therefore, proposed projects should be focused on testing and translating investigational interventions or devices already proven in relevant definitive animal models and moving those interventions or devices into advanced clinical development.

Funding from this Program Announcement/Funding Opportunity must support a clinical trial or medical device testing and may not be used for preclinical research studies. For this Program Announcement/Funding Opportunity, the term "human subjects" refers to individuals who will be recruited for or who will participate in the proposed clinical trial. 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. A medical device testing is defined as clinical investigations of *in vitro* diagnostic (IVD) devices involving human specimens. IVD devices include assays, reagents, instruments, and systems for diagnostic or prognostic determination of the state of health, in order to prevent, screen, mitigate, and/or treat combat-related or trauma-induced wound infections and their sequelae. Principal Investigators (PIs) seeking support for preclinical research studies should apply to the FY17 JPC-2/MIDRP Applied Research Award (Funding Opportunity Number: W81XWH-17-DMRDP-MID-ARA).

All of the following are important aspects of FY17 JPC-2/MIDRP CSA application submission:

- Include only one early-phase clinical trial (Phases 0, I, and II) or IVD diagnostic medical device testing (Classes I, II, and III) that begins no later than 12 months after the award date.
- Inclusion of preliminary data relevant to the proposed research project is required. Any unpublished preliminary data should originate from the laboratory of the PI(s), collaborator(s), or subawardee(s) named in the application.
- Demonstrate sound scientific rationale established through logical reasoning and critical review and analysis of the literature.
- Demonstrate and document availability of and access to the drug/compound, device, and/or other materials needed. Quality should be commensurate with U.S. Food and Drug Administration (FDA) manufacturing standards applicable to the type and phase of product being developed (i.e., Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), and Quality System Regulation).
- Demonstrate and document availability of and access to a suitable human subject population and/or resources that will support a meaningful outcome for the clinical trial/testing.
- If applicable, include a discussion of how accrual goals will be achieved and how standards of care may impact the study population.
- Describe appropriate and clearly defined endpoints for the proposed clinical trial/ testing.
- Include a clearly articulated statistical analysis plan, as well as appropriate statistical expertise and a power analysis reflecting sample size projections that will clearly answer the objectives of the study.
- Discuss the potential impact of the study results on prevention, screening, diagnosis, and/or treatment of combat-related or trauma-induced wound infections.
- If applicable, include a study coordinator(s) who will guide the clinical protocol through the local Institutional Review Board (IRB) of record and other regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate human subject accrual.
- For studies determined to be greater than minimal risk to human subjects by the local IRB of record, an independent research monitor with expertise consistent with the nature of risk(s) must be identified within the research protocol.
- Demonstrate institutional support and access to institutional resources for all participating organizations.
- Include a Transition Plan that describes a clear path to further develop the research results, including a plan and potential funding source for the next phase of development after the successful completion of the proposed study.

Partnering PI Option: The FY17 JPC-2/MIDRP CSA includes a Partnering PI Option 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 partners should collaborate in the development and submission of the proposed research project.*** It should be clear that each partner 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.

Multi-Institutional Clinical Trials/Testing: If the proposed research is multi-institutional, plans for communication and data transfer among the collaborating institutions, as well as how data, specimens, imaging products, and/or other materials obtained during the study will be handled, should be included in the appropriate sections of the application(s). A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional clinical trials/testing.

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 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.

Investigational New Drug/Investigational Device Exemption (IND/IDE): If the clinical trial involves the use of a drug that has not been approved by the FDA for the proposed investigational use, evidence that an IND application that meets all requirements under the Code of Federal Regulations, Title 21, Part 312 (21 CFR 312) has been submitted or will be submitted to the FDA is required. If the investigational product is a device, evidence that an IDE application that meets all requirements under 21 CFR 812 has been submitted or will be submitted to the FDA, or that the device is exempt from an IDE, is required. The Government reserves the right to withdraw funding if the documented status of the IND or IDE has not been obtained within 6 months of the award date.

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.

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

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

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 and 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 $**2.5 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 $**2.5M** 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 **$2.5M**. 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 $**2.5M** 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
- Research supplies
- Research-related subject costs
- Clinical research/trials costs
- Equipment costs up to $10,000
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs 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 $13.9M of the anticipated FY17-FY19 DHP RDT&E appropriations to fund approximately five Clinical Study Award applications, depending on the quality and number of applications received. Of the total amount, approximately $4.3M 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 CSA 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-CSA 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 this is 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 CSA programmatic panel and should not be involved in any pre-application or application. For questions related to the FY17 JPC-2/MIDRP CSA 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 clinical trial/testing is based. Clearly specify which type (e.g., drug, device, behavioral) of clinical trial/testing is being proposed and indicate the phase of trial and/or class of device and regulatory status as appropriate. Concisely state the project's objectives and specific aims.
- **Personnel:** Briefly state the qualifications of the PI(s) and key personnel to perform the described research project.
- **Impact:** State explicitly how the proposed work will have an impact on research and patient care for combat-related or trauma-induced wound infection. Describe how the study will accelerate the movement of promising treatments/devices/assays into clinical practice.
- **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 CSA 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:** How well the qualifications and expertise of the PI(s) and key personnel are appropriate to perform the proposed research project.
  - **Impact:** How well the clinical trial/testing addresses an important problem relevant to combat-related or trauma-induced wound infection prevention and/or management, and antimicrobial countermeasures. If successful, how the outcomes will improve our capabilities to prevent, screen, diagnose, and/or treat combat-related or trauma-induced wound infections. To what degree the clinical trial/testing will accelerate the movement of promising treatments/devices/assays into clinical practice.
  - **Military Benefit:** To what degree the proposed clinical trial/testing 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 CSA 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 Clinical Study 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.

   The Project Narrative is NOT the formal clinical trial/testing protocol. Instead, all essential elements of the proposed clinical trial/testing necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 6-9 described below. Failure to submit these attachments as part of the application package will result in rejection of the entire application.

   - **Attachment 1: Project Narrative (20-page limit): Upload as "ProjectNarrative.pdf."** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and 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. Provide a literature review and describe the preliminary studies and/or preclinical data, published or unpublished, that led to the development of the proposed clinical trial/testing. Provide a summary of other relevant ongoing, planned, or completed clinical trials/testing and describe how the proposed study differs. Include a discussion of any current clinical use of the intervention or device under investigation, and/or details of its study in clinical trials/testing for other indications (as applicable). The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should establish the relevance of the clinical trial/ testing to at least one of the FY17 JPC-2/MIDRP CSA Focus Areas and explain the applicability of the proposed findings.

  If the proposed clinical trial/testing was initiated using other funding prior to this application, explain the history and background of the clinical trial/testing and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.

- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/ hypotheses.

- **Study Design:** As applicable to the proposed project, describe the type of study to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.

  - Describe the intervention or device to be tested and the projected outcomes or measures.
  - Define the study variables, outline why they were chosen, and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
  - Describe the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects and/or samples (e.g., convenience, simple random, stratified random).
  - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
  - Document the availability and accessibility of the drug/compound, device, or other materials needed for the proposed research.

- **Statistical Plan and Data Analysis:** Describe the data collection plan, statistical model, and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled or number of

human samples to be studied. If multiple study sites are involved, state the approximate number to be enrolled or samples collected at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. If a subpopulation of a sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study.

- **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.
- **Ethical Issues:** Include a clear and detailed description of the potential ethical issues raised by the proposed study and provide a detailed plan for how the ethical issues will be addressed.
- **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 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.
- Letters of Commitment (if applicable): If the proposed study involves use of proprietary material(s) such as commercially produced investigational drug, device, or biologic, provide a letter of commitment from each source entity indicating availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.
- 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 all 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. The application should acknowledge the commitment to filing the study in the National Institutes of Health clinical trials registry, www.clinicaltrials.gov.

- **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 rationale behind the proposed work.
  - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence 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 CSA Focus Area(s) to be addressed and briefly describe how the proposed project may 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 and impact of the research.
    - Which FY17 JPC-2/MIDRP CSA Focus Area(s) will be 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 CSA mechanism, use the SOW format example titled "SOW for Clinical Research (Including Trials, Special Populations)." 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: Human Sample Acquisition and Safety Procedures, if applicable (no page limit). Upload as "HumSamProc.pdf."** The Human Sample Acquisition and Safety Procedures attachments should include the components listed below:

  a. Study Population: Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the samples, data, or other resources will be recruited/drawn). Describe how anticipated findings in the proposed population(s) are relevant to military population(s). Discuss past efforts in recruiting human subjects from the target population for previous studies, (if applicable). Address potential barriers to accrual and plans for addressing any delays. Include justification of any age, race, ethnicity, or sex limitations provided. ***For studies proposing to include military personnel as volunteers, refer to the General Application Instructions, Appendix 5, for more information.***

  b. Inclusion/Exclusion Criteria: List the inclusion and exclusion criteria evaluation of samples for the proposed research. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

  Inclusion of Women and Minorities in Study. Consistent with the Belmont Report, "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.

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. Some screening procedures may require a separate consent or waivers of consent. Informed consent or appropriate waivers of consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

d. Description of the Informed Consent Process: In certain cases, Federal regulations allow the IRB to approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or to waive the requirement to obtain any informed consent. Most complete waivers of consent involve studies in which there are minimal risks to subjects. Specifically describe the plan for obtaining informed consent or appropriate waivers of informed consent for clinical samples from human subjects.

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

outside of the research context. This paragraph only also applies to FDA-regulated studies per 21 CFR 56.109(c)(1).

- State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial to be in compliance with Title 10 United States Code Section 980 (10 USC 980). If applicable, refer to the General Application Instructions, Appendix 5, for more information.

e. Risks/Benefits Assessment:

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

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

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

- Procedures that will be employed to monitor QC (i.e., how often other QC types should be run or whether the QC replaces other, more traditional external types of QC).
- Review of sample labeling for accuracy,
- Determination/inclusion of manufacture protocols and protocols to ensure stability.

- **Attachment 7: Human Subjects Recruitment and Safety Procedures, if applicable (no page limit). Upload as "HumSubProc.pdf."** The Human Subject Recruitment and Safety Procedures document should include the following components:

a. Study Population: Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the samples, data, or other resources will be recruited/drawn). Describe how anticipated findings in the proposed population(s) are relevant to military population(s). Discuss past efforts in recruiting human subjects from the target population for previous studies, (if applicable). Address potential barriers to accrual and plans for addressing any delays. Include justification of any age, race, ethnicity, or sex limitations provided. ***For studies proposing to include military personnel as volunteers, refer to the General Application Instructions, Appendix 5, for more information.***

b. Inclusion/Exclusion Criteria: List the inclusion and exclusion criteria for the proposed research. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

Inclusion of Women and Minorities in Study. Consistent with the Belmont Report, "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 women and/or minorities will be excluded from the proposed research.

c. Description of the Recruitment Process: Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, healthcare provider identification).

- Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
- Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
- Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

d. Description of the Informed Consent Process: Specifically describe the plan for obtaining informed consent from human subjects.

- ***For the proposed study, provide a draft, in English, of the Informed Consent Form.*** A plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial should be included.
- Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human

subjects' questions will be addressed during the consent process and throughout the trial.

- Include information regarding the timing and location of the consent process.
- Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
- Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
- Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
- Describe the plan for the consent of the individual's LAR to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (http://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.
- ***Assent.*** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.

e. Screening Procedures: List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

f. Risks/Benefits Assessment:

- **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. 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 how safety surveillance and reporting to the IRB, ORP, and FDA (if applicable) will be managed and conducted.
    - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
    - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
    - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
    - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
    - For a study in which the IRB determines there is greater than minimal risk to human subjects, the DoD requires an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol. If applicable, refer to the General Application Instructions, Appendix 5, for more information on study reporting authorities and responsibilities of the research monitor.
- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.

- **Attachment 8: Intervention or Diagnostic (no page limit): Upload as "Intervention.pdf."** The Intervention attachment should include the components listed below.

    a. Description of the Intervention or Diagnostic: As applicable, the description of an intervention should include the following components: complete name and composition, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed.

    Description of devices should include general concept of design, detailed operational instructions, any potential risks to users, and intended benefits.

    Description of diagnostic assays should include: target(s) to be measured/assessed, type of assay (end point, kinetic, quantitative, semi-quantitative, qualitative, PCR, multiplex, immuno, direct, indirect, etc.), time required, reagents [sample, equipment] needed, protocol overview, and detailed

protocol. Other types of interventions, devices, or diagnostics should be fully described.

Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety of the intervention, device, or diagnostic assay.

b. Study Procedures: Describe the interaction with the human subject to include the study intervention, device, or diagnostics that he/she will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Discuss how compliance with Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), and other regulatory considerations will be established, monitored, and maintained, as applicable.

c. Clinical Monitoring Plan (if applicable): Describe how the study will be conducted by and monitored for ICH E6 (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) Good Clinical Practices (GCP) compliance, by an independent clinical trial monitor (or clinical research associate). The monitoring plan should describe the types of monitoring visits to be conducted, the intervals (based on level of risk), how corrective actions will be reported to the Sponsor and PI(s), and how they will be corrected and prevented by the research site/PI(s).

- **Attachment 9: Data Management (no page limit): Upload as "Data_Manage.pdf."** The Data Management attachment should include the components listed below.

  a. Data Management: Describe all methods used for data collection to include the following:

  - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
  - **Confidentiality**
    - Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
    - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DoD are eligible to review study records.
    - Address requirements for reporting sensitive information to state or local authorities.
  - **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy)

will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. For FDA-regulated studies, compliance with 21 CFR 11 is required.

- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.

b. Laboratory Evaluations:

- **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
- **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
- **Storage:** Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
- **Laboratories performing evaluations and special precautions:** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

- **Attachment 10: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as "Personnel.pdf."** The Study Personnel and Organization attachment should include the components listed below.

a. Organizational Chart: Provide an organizational chart identifying key members of the study team including institution/center/department and name each person's position on the project. If applicable, include any external consultants or other experts who will assist with FDA applications. While there is no specified format for this information, a table(s) or diagram is recommended.

b. Study Personnel Description: Briefly describe the roles of the individuals listed in the organizational chart on the project. Describe relevant experience and qualifications that demonstrate appropriate expertise for the given role. A research monitor (external to the study), study coordinator(s), and a statistician should be included if applicable.

c. Study Management Plan: Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial/testing is multi-institutional, plans for communication and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, should be included. Provide a plan for real-time communication among collaborating institutions (if applicable).

- **Attachment 11: Surveys, Questionnaires, and Other Data Collection Instruments, if applicable (no page limit): Upload as "Surveys.pdf."** The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instruments will be administered. Describe how the survey is adapted to the subject population.

- **Attachment 12: Transition Plan (two-page limit). Upload as "Transition.pdf."** Provide information on the methods and strategies proposed to move the product or knowledge outcomes to the next phase of clinical trials, commercialization, and/or delivery to the civilian or military market after successful completion of the award. The transition plan should include the components listed below.
    - The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication.
    - Details of the funding strategy that will be used to bring the outcomes to the next level of development and/or commercialization (e.g., specific potential industry partners, specific funding opportunities to be applied for).
    - For knowledge products, a description of how the knowledge will be further developed, disseminated, and incorporated into clinical care.
    - A description of collaborations and other resources that will be used to provide continuity of development. For industry partner(s), include a description of their product development and/or marketing experience.
    - A brief schedule and milestones for bringing the outcome(s) to the next phase of clinical trials, commercialization, and/or delivery to the military or civilian market, including when it can be anticipated to be transitioned to an industry partner or approved by the FDA, if applicable.
    - 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 13: IND/IDE Documentation, if applicable (no page limit): Upload as "IND-IDE.pdf."** If submitting multiple documents, start each document on a new page. Combine all documents and upload as a single file.

  a. Complete the IND/IDE Documentation Form, which is available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm).

  b. Provide one of the following:

  - Evidence that an IND or IDE application has been submitted and includes an explanation of the current status (e.g., past the critical 30-day review period, pending response to questions raised by the Agency, on clinical hold). Inclusion of copies of any Agency meeting minutes or other relevant correspondence (e.g., submission documents, email) is encouraged but not required to support this explanation.
  - Evidence that an IND or IDE application will be submitted and include a description of the submission plan. If applicable, indicate time required for submission and/or approval of IND or IDE applications to the FDA, or appropriate regional regulatory authority if the study will be conducted outside of the United States.
  - If the proposed study has been previously exempted by the FDA from IND or IDE regulation (or international equivalent thereof), provide evidence in the form of formal communication (e.g., letterhead correspondence) from the FDA or regional regulatory authority to that effect.
  - Studies that require an FDA IND/IDE application (or international equivalent thereof) must submit documentation of regulatory approval to the DoD no later than 6 months after submission of the application to demonstrate continued progress and ensure continuation of payment.

- **Attachment 14: Impact and Military Benefit Statement (two-page limit): Upload as "ImpactMilBen.pdf."** Address the impact of the proposed research on at least one of the FY17 JPC-2/MIDRP CSA Focus Areas.

  Describe the short-term impact: Describe the anticipated short-term outcome(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 proposed project. 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 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 beneficiaries).

- **Attachment 15: 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 [https://ebrap.org/eBRAP/public/Program.htm]), 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.

      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 anticipated combined total costs (direct and indirect) budgeted for the entire period of performance for the Initiating and Partnering PIs' applications will not exceed $2.5M. 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 $2.5M 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 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 located within the same organization. The anticipated combined total costs (direct and indirect) budgeted for the entire period of performance for the Initiating and Partnering PIs' applications will not exceed $2.5M. 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 $2.5M 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., 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. 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:

    - **Clinical Impact and Military Benefit**
        - How well the proposed research addresses at least one of the FY17 JPC-2/MIDRP CSA Focus Areas.
        - How applicable the anticipated outcomes of the proposed clinical trial/testing are to at least one of the FY17 JPC-2/MIDRP CSA Focus Areas.
        - How well the proposed population represents the targeted patient population that might benefit from the proposed intervention, device, or diagnostic.
        - To what degree the potential outcomes of the proposed research will impact trauma-induced or combat-related wound infections research and/or clinical care in the short-term and long-term?

- How well the anticipated outcomes address the health care needs of military Service members, Veterans, and other Military Health System beneficiaries affected by combat-related or trauma-induced wound infections.

- **Research Strategy**
  - How well the scientific rationale for the proposed research is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory/preclinical evidence.
  - How well the study aims, hypotheses, objectives, experimental design, methods, data collection procedures, and analyses are designed to answer clearly the research questions.
    - 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.
    - If applicable, how well plans to collect specimens and conduct laboratory evaluations are addressed.
  - If applicable, to what degree the data collection instruments (e.g., surveys, questionnaires), are appropriate to the proposed study.
  - 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.
  - 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).

- **Statistical Plan**
  - To what degree the statistical model and data analysis plan are suitable for the planned study.
  - Whether the statistical plan, including sample size projections and power analysis, is adequate for the proposed research.
  - If applicable, whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.

- **Intervention or Device**
  - Whether there is adequate evidence of support to indicate availability of the intervention, device, diagnostic or their components from their source, for the duration of the proposed research.
  - To what degree the intervention or device addresses the clinical need(s) described.

- To what extent the proposed intervention, device, or diagnostic, if successful, advances patient care beyond what is currently available (i.e., standard of care).
- To what degree the PI has provided preclinical and/or clinical evidence to support the safety of the intervention, device, or diagnostic.
- If applicable, whether a member of the study team or a sponsor holds the IND/IDE for the indication proposed or whether the timeline proposed for obtaining the IND/IDE is appropriate.
- For investigator-sponsored IND/IDEs, whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA.
- As applicable to the proposed research, whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.
- If applicable, whether measures are described to ensure the consistency of dosing of active ingredients for nutritional supplements (if applicable).
- How the intervention, device, or diagnostic compares with currently available interventions, devices, diagnostics, and/or standards of care.

- **Recruitment, Accrual, and Feasibility**
  - Whether the availability and accessibility of human subjects, data, samples, or other resources for the proposed study is demonstrated.
  - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects or sample acquisition are appropriate for the proposed research.
  - How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate contingency plans to resolve them.
  - To what extent the proposed clinical trial/testing might affect the daily lives of the individual human subjects participating in the study (e.g., Will human subjects still be able to take their regular medications while participating? Are human subjects required to stay overnight in a hospital?) 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**
    - Whether the funding strategy described to bring the outcome(s) to the next level of development (e.g., higher phase clinical trial, transition to industry, delivery to the market, incorporation into standard practice) is appropriate.
    - To what degree the development plan to support a product label change, if applicable, is appropriate and well described.
    - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
    - How the schedule and milestones for bringing the outcome(s) to the next level of development (e.g., higher phase clinical trial, transition to industry, delivery to the market, incorporation into standard practice) are appropriate.
    - How well the risk analysis for cost, schedule, manufacturability, and sustainability is developed.
    - How well the application identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this Program Announcement/Funding Opportunity.
    - For knowledge products, to what degree the transition includes appropriate strategies for further knowledge development, dissemination, and incorporation into clinical care.
- **Personnel and Communication**
    - Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
    - To what degree the study team's background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the subject matter, and clinical studies).
    - How the levels of effort of the study team members are appropriate for successful conduct of the proposed research.
    - How well the logistical aspects of the proposed research (e.g., study management plan) meet the needs of the proposed research.
    - If applicable, whether the plans for communication and data transfer, handling, and storage among all collaborating institutions, is appropriate.
    - Partnering PI Option: To what extent each 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.

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

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Environment**
  - To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical trial/testing at each participating center or institution (including collaborative arrangements).
  - If applicable, whether there is evidence for appropriate institutional commitment from each participating institution, such as a separate intellectual and material property plan agreed upon by all participating institutions for multi-institutional clinical trials/testing.
- **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

   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.
- Human Sample Acquisition and Safety Procedures (Attachment 6) or Human Subject Recruitment and Safety Procedures (Attachment 7), as appropriate, is missing.
- Intervention, Device, or Diagnostic (Attachment 8) is missing.
- Data Management (Attachment 9) 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 CSA 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 CSA 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 preclinical research 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 the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

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

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

Refer to the General Application Instructions, Appendix 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	Human Sample Acquisition and Safety Procedures: Upload as Attachment 6 with file name "HumSamProc.pdf."		
	7	Human Subject Recruitment and Safety Procedures: Upload as Attachment 7 with file name "HumSubProc.pdf."		
	8	Intervention or Diagnostic: Upload as Attachment 8 with file name "Intervention.pdf."		
	9	Data Management: Upload as Attachment 9 with file name "Data_Manage.pdf."		
	10	Study Personnel and Organization: Upload as Attachment 10 with file name "Personnel.pdf."		
	11	Surveys, Questionnaires, and Other Data Collection Instructions: Upload as Attachment 11 with file name "Surveys.pdf."		
	12	Transition Plan: Upload as Attachment 12 with file name "Transition.pdf."		
	13	IND/IDE Documentation: Upload as Attachment 13 with file name "IND-IDE.pdf."		
	14	Impact and Military Benefit Statement: Upload as Attachment 14 with file name "ImpactMilBen.pdf."		

Grants.gov Application Components	Upload Order	Action	Single or Initiating PI Completed	Partnering PI(s) Completed
	15	Collaborating DoD Military Facility Budget Form(s): Upload Attachment 15 with 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.		
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.		
Research & Related Budget		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Project/Performance Site Location(s) Form		Complete form as instructed.		
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.		