

# Program Announcement

for the

Department of Defense

Congressionally Directed Medical Research Programs

## Military Burn Research Program

### Burn Injuries Research Award

**Funding Opportunity Number: W81XWH-15-MBRP-BIRA**

**Catalog of Federal Domestic Assistance Number: 12.420**

#### SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), August 20, 2015
- **Invitation to Submit an Application:** October 2015
- **Application Submission Deadline:** 11:59 p.m. ET, December 3, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, December 8, 2015
- **Peer Review:** February 2016
- **Programmatic Review:** April 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.*

## TABLE OF CONTENTS

<b>I. Funding Opportunity Description.....</b>	<b>3</b>
A. Program Description .....	3
B. FY15 MBRP Topic Areas.....	3
C. Award Information.....	4
D. Eligibility Information .....	8
E. Funding .....	8
<b>II. Submission Information .....</b>	<b>10</b>
A. Where to Obtain the Grants.gov Application Package .....	11
B. Pre-Application Submission Content.....	11
C. Full Application Submission Content.....	14
D. Applicant Verification of Grants.gov Submission in eBRAP .....	25
E. Submission Dates and Times .....	26
F. Other Submission Requirements.....	26
<b>III. Application Review Information .....</b>	<b>26</b>
A. Application Review and Selection Process.....	26
B. Application Review Process .....	27
C. Recipient Qualification .....	29
D. Application Review Dates .....	29
E. Notification of Application Review Results .....	30
<b>IV. Administrative Actions.....</b>	<b>30</b>
A. Rejection .....	30
B. Modification.....	30
C. Withdrawal.....	30
D. Withhold .....	31
<b>V. Award Administration Information.....</b>	<b>31</b>
A. Award Notice .....	31
B. Administrative Requirements .....	31
C. National Policy Requirements .....	31
D. Reporting.....	31
E. Award Transfers.....	32
<b>VI. Agency Contacts.....</b>	<b>32</b>
A. CDMRP Help Desk.....	32
B. Grants.gov Contact Center.....	32
<b>VII. Application Submission Checklist.....</b>	<b>33</b>

## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications to the Fiscal Year 2015 (FY15) Military Burn Research Program (MBRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA). The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The MBRP was initiated in 2011 to address combat-related and trauma-induced burn injuries, as well as to improve health and performance outcomes for Service members and the general public at large. Appropriations for the MBRP from FY11 through FY14 totaled \$30 million (M). The FY15 appropriation is \$8M.

The objective of this Program Announcement/Funding Opportunity is to explore innovative approaches to accelerate the translation of advances in knowledge into new treatments of the injured Service member who sustains burn injuries. The results of the research funded through the **FY15 MBRP Burn Injuries Research Award** are expected to increase the body of knowledge and knowledge products available to professionals and practitioners in health, medical science, and related fields. The research impact is expected to benefit both civilian and military communities, particularly as it relates to the Topic Areas listed below.

### B. FY15 MBRP Topic Areas

The MBRP supports a broad research portfolio in the treatment of burns and the trauma associated with burn injuries sustained during combat or combat-related activities. It is expected that any research findings would also provide benefit to individuals in the general population affected by burn injuries.

To be considered for funding, each application for the FY15 MBRP Burn Injuries Research Award ***must address one, and only one, of the Topic Areas listed below***. Applications involving multidisciplinary collaborations among academia, industry, military services, Department of Veteran Affairs (VA), and other Federal agencies are highly encouraged. If applicants wish to address more than one Topic Area, separate applications must be submitted. The Government also reserves the right to reassign the application's Topic Area if submitted under an inappropriate Topic Area. ***Applications proposing research outside of the Topic Areas listed below OR applications addressing more than one topic area will be administratively withdrawn and not considered.***

#### 1. Fluid Resuscitation Studies (Human)

**Fluid Resuscitation:** Through multicenter prospective observational studies (retrospective or prospective), demonstrate the impact of various fluid resuscitation rates and techniques, as well as various adjunctive therapies (e.g., high-dose/low-dose vitamin C, albumin timing, etc.) on clinically relevant outcomes during acute burn resuscitation.

## 2. Organ Failure Studies (Human)

- a. **Organ Failure:** Through clinical study, provide insight into the epidemiology, prevention, early detection, and/or treatment of single or multiple organ failure in the burn/trauma patient.
- b. **Sepsis:** Provide a systematic approach to define sepsis in burns and the impact of sepsis-related outcomes through the identification and establishment of best practice while evaluating longitudinal adherence to established standards.

## 3. Wound Healing (Animal/Human)

- a. **Physiological Factors of Delayed Wound Healing:** Determine specific physiological factors that result in delayed wound healing, such as shock, edema, immune system dysregulation, etc.
- b. **Healing Acute Burns:** Evaluate or develop strategies (e.g., dressing, topicals, biologics, etc.) that optimize healing of acute burn wounds.
- c. **Failure of Wound Healing:** Identify diagnostic predictors (e.g., biomarkers, imaging techniques, physical wound changes, etc.) that can be used to indicate failure of wound healing.

## 4. Prolonged Field Care and Delayed Evacuation (Animal/Human)

- a. **Clinical Impact of Delayed Therapy:** Determine the clinical impact of delayed definitive therapy and/or resuscitation in a burn injury animal model.
- b. **Delayed Care Patient Outcomes:** Through observational or retrospective studies, describe the impact of delayed care at intermediary facilities, prolonged time to initial treatment, and/or extended transport times on short- and long-term patient outcomes (e.g., days on ventilator, development of organ complications, compartment syndrome, limb loss, infection, etc.)

## 5. Short- and Long-Term Functional Outcomes

**Functional Outcomes:** Through retrospective or prospective studies, identify issues that effect, as well as strategies to improve, physical and/or mental functional outcomes (both short- and long-term). Examples of items to include are social reintegration, duration in intensive care units, range of motion in the affected limb(s), number and types of procedures performed, the use of coping strategies/interventions to mitigate post-traumatic stress disorder, and other strategies that help improve patient outcomes after discharge.

## C. Award Information

The MBRP Burn Injuries Research Award is being offered for the first time in FY15. The FY15 MBRP Burn Injuries Research Award is focused on specific research topics related to the treatment of traumatic burn injuries that are relevant to military personnel. ***Awards funded by the Burn Injuries Research Award may not be used to support fundamental basic research.*** Basic research is defined as research directed toward greater knowledge or understanding of the

fundamental aspects of phenomena and of observable facts without specific applications towards process or products in mind.

The FY15 Burn Injuries Research Award is focused on **applied research**, defined as research that refines concepts and ideas into potential solutions to health and performance problems with a view toward evaluating technical feasibility; it includes studies and investigations leading to candidate solutions in preparation for initial human testing.

***Presentation of preliminary data is required.*** Inclusion of preliminary and/or published data relevant to the research question is required. In addition, investigators must demonstrate logical reasoning. To be competitive, the application must include a sound scientific rationale and a well-formulated, testable hypothesis established through a critical review and analysis of the literature. Clinical trials are allowed. Applications for promising pharmaceutical or biologic candidates and medical devices and technologies may be selected for initial safety and efficacy testing in small scale human clinical trials. A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction.

The term “human subjects” is used in this Program Announcement/Funding Opportunity to refer to individuals who will be recruited for or who will participate in the proposed clinical trial. For more information, a Human Subject Resource Document is provided at <https://ebrap.org/eBRAP/public/Program>

**Research Scope:** Research proposed under the FY15 MBRP Burn Injuries Research Award may include small- to large-scale projects such as efficacy studies, effective comparison studies, human use, observational studies, clinical trial development, and clinical trials. These awards are expected to yield potential health products, approaches, or technologies positioned for human testing. Applications may include Phase I or early Phase II clinical trials, but not late Phase II or Phase III, large-scale effectiveness clinical trials or advanced development of products and capabilities. Activities allowed under the FY15 Burn Injuries Research Award may include, but are not limited to:

- Refinement of concepts and ideas into potential solutions with a view toward evaluating technical feasibility of emerging approaches, technologies, and promising new products
- Evaluation, maturation, and/or down-selection of potential product candidates (drugs, biologic/vaccine constructs, or devices/systems) in vitro and/or in vivo
- Conducting preclinical safety and/or toxicity studies
- Preparation activities needed to support a future clinical trial or regulatory submission
- Clinical trials (Phase I or Phase IIa)

Two different funding levels, based on the scope of the research, are available under this Program Announcement/Funding Opportunity. ***It is the responsibility of the Principal***

***Investigator (PI) to select the funding level that is most appropriate for the proposed research project.***

The following are general descriptions, although not all-inclusive, of the scope of research projects that would be appropriate to propose under each funding level:

- **Funding Level 1:** Research that is already supported by preliminary data and has the potential to make significant advancements toward clinical translation. Demonstration of efficacy in in vivo models, as applicable.
- **Funding Level 2:** Advanced translational studies that have the potential to transform the clinical management of burn injuries. Clinical trials may apply.

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and 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.*** 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.

**IND/IDE Requirements:** If the study proposes to include the use of human subjects and to involve the use of a drug or biologic that has not been approved by the U.S. Food and Drug Administration (FDA) for the proposed investigational use, then an Investigational New Drug (IND) application to the FDA that meets all requirements under the Code of Federal Regulations, Title 21, Part 312 (21 CFR 312) may be required and must be submitted to the FDA ***within 6 months of the award date.*** If the study involves the use of a device that has not been approved or cleared by the FDA, then evidence that an Investigational Device Exemption (IDE) application that meets all requirements under 21 CFR 812 has been submitted to the FDA ***within 6 months of the award date,*** or that the device is exempt from an IDE, is required. The Government reserves the right to withdraw funding if an IND or IDE is indicated but has not been submitted to the FDA ***within 6 months of the award date,*** or if the documented status of the IND or IDE has not been obtained within 6 months of the award date.

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO must review and approve all animal use prior to the start of working with animals. PIs must submit the institutional animal use protocol,

IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” *Allow at least 3 to 4 months for regulatory review and approval processes for animal studies.* Refer to General Application Instructions, Appendix 5, for additional information.

**Use of Military and VA Populations or Resources:** If the proposed research involves access to military and/or VA population(s) and/or resource(s), the PI is responsible for establishing such access. If possible, access to target military and/or VA patient population(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 as part of Attachment 2 for studies involving Service members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. See [Section II.C.](#), Full Application Submission Content, Supporting Documentation.

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

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

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

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

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

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

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

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

Military Infectious Disease  
Research Program  
<https://midrp.amedd.army.mil>

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

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

Naval Medical Research Center  
<http://www.med.navy.mil/sites/nmrc>

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

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

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

U.S. Army Medical Research  
Acquisition Activity  
<http://www.usamraa.army.mil>

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

U.S. Army Research Laboratory  
<https://www.nrl.navy.mil>

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

U.S. Department of Defense Blast Injury  
Research Program  
<https://blastinjuryresearch.amedd.army.mil/>  
Walter Reed Army Institute of Research  
<http://wrair-www.army.mil>

***The CDMRP intends 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 all academic levels (or equivalent) are eligible to submit applications. Intramural (i.e., 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) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

#### **E. Funding**

***The requested budget level should be appropriate for the scope of research proposed.***

##### ***Funding Level 1:***

- The maximum period of performance is **3** years.
- The anticipated total costs (direct plus indirect) budgeted for the entire period of performance will not exceed **\$750,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$750,000** total costs or using an indirect rate exceeding the organization's negotiated rate.

##### ***Funding Level 2:***

- The maximum period of performance is **4** years.
- The anticipated total costs (direct plus indirect) budgeted for the entire period of performance will not exceed **\$2M**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$2M** total costs or using an indirect rate exceeding the organization's negotiated rate.



***For both funding levels:***

- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant must submit a comprehensive budget, broken down by year, that details the projected funding needed for the entire period of performance.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum period of performance.
- Regardless of the period of performance proposed, the award may not exceed the maximum allowable total costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

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 attend one program review meeting (e.g., MBRP In-Process Review meetings) per year during the award period of performance. For planning purposes, it should be assumed that such meetings will be held in the National Capital Area for approximately 2 days. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Research supplies
- Clinical research costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings in addition to the required 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 CDMRP expects to allot approximately \$6.7M of the \$8.0M FY15 MBRP appropriation to fund approximately one Level 1 and three Level 2 Burn Injuries Research Award applications, depending on the quality and number of applications received.***

***In addition to the FY15 appropriation, it is anticipated that up to \$7M in FY16 MBRP funds may be available to fund approximately four Level 1 and two Level 2 Burn Injuries Research Awards. As of the release date of this Program Announcement/Funding Opportunity, the FY16 appropriations are not known 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, subject to realignment, and contingent upon the availability of Federal funds for this program.***

## **II. SUBMISSION INFORMATION**

Submission is a two-step process requiring both (1) pre-application submission through the 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.

*Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.*

#### **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-15-MBRP-BIRA in Grants.gov (<http://www.grants.gov/>).

#### **B. Pre-Application Submission Content**

All pre-application components must be submitted by the PI 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.

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](mailto:help@eBRAP.org) or 301-682-5507.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

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.
- FY15 MBRP Working Group members should not be involved in any preapplication or application. A list of the FY15 MBRP Working Group members can be found at <http://cdmrp.army.mil/mbrp/panels/panels15>. For questions related to Working Group members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **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 application (including those with whom the PI has a personal or professional relationship).

- **Pre-Application Files – Tab 5**

*Notes: 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 any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

The Preproposal Narrative should include the following:

- **Alignment with Topic Area:** Explain how the proposed work addresses one of the FY15 MBRP Topic Areas.
- **Rationale:** State the ideas and reasoning on which the proposed research or clinical trial is based. Describe how the preliminary data and rationale support the research idea. State how this project meets the intent of the award mechanism.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Strategy:** Clearly describe the research being proposed and indicate the phase of trial and/or class of device and regulatory status as appropriate. Concisely state the project's objectives, specific aims, and ultimate endpoints. Describe the proposed methods and how they will accomplish the project's aims.

*For clinical trial applications,* identify the intervention to be tested and describe the projected outcomes. Describe the ideas and reasoning on which the proposed clinical trial is based; include relevant literature citations. Briefly describe the level of scientific evidence that supports the progression of this research to a clinical trial. Clearly specify which type (e.g., drug, device, surgical) of clinical trial is being

proposed and indicate the phase of trial and/or class of device and regulatory status, as appropriate.

- **Impact:** State explicitly how the proposed work may ultimately have an immediate- and long-term effect on patient care for those who have sustained combat-related or traumatic burn injuries.
- **Military Benefit:** Describe how the proposed work would impact the healthcare needs of Service members and/or U.S. Veterans who have sustained combat-related or traumatic burn injuries, as well as their families, caregivers, and the general public.
- **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research or clinical trial.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual 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). The five-page National Institutes of Health Biographical Sketch may also be used.
- **Quad Chart:** The Quad Chart template is a one-page PowerPoint file that must be downloaded from eBRAP at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/), completed, and saved as a PDF file using Adobe Acrobat Reader.

- **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 MBRP, 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 the MBRP. How the endpoints are appropriate for the proposed study. Whether the proposed methodology is appropriate.
- **Alignment with Topic Areas:** How well the project addresses one of the FY15 MBRP Topic Areas.

- **Impact:** If successful, to what extent the study could impact immediate- and long-term patient care for those who have sustained combat-related or traumatic burn injuries.
- **Military Benefit:** How the proposed work, if successful, would provide a significant benefit to military Service members and Veterans who have sustained combat-related burn injuries or traumatic burn injuries.
- **Personnel:** How the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research.
- **Notification of Pre-Application Screening Results**

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

### C. Full Application Submission Content

*Applications will not be accepted unless the 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*.

**Grants.gov application package components:** For the MBRP Burn Injuries Research Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

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

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer

than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

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

Describe the proposed project in detail using the outline below, noting potential challenges and alternative solutions where appropriate:

- **Background:** State the FY15 MBRP Topic Area that is being addressed. Establish the relevance of the study to the FY15 MBRP Topic Area and explain the applicability of the proposed findings. Describe in detail the rationale for the study and include a literature review, preliminary studies, and/or preclinical data that led to the development of the proposed project. The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses.

***For clinical trials/clinical research:***

- Provide a summary of relevant clinical trials/clinical research and distinguish how the proposed study differs from other relevant or recently completed studies.
- Clearly support the choice of study variables and explain the basis for the study questions and/or study hypotheses.
- **Objectives/Specific Aims/Hypotheses:** State the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
- **Research Strategy:** Describe the experimental design, methods, and analysis including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches.

***For clinical trials:***

- State the intervention to be tested and describe the projected outcomes.

***For clinical trials and clinical research involving human subjects:***

- Provide detailed plans for initiating and conducting the clinical trial/clinical research project. Outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate. Define the study variables and describe how

they will be measured. Include a description of appropriate controls and the endpoints to be tested.

- Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).
- Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
- **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.
- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives as appropriate to type of study. For clinical trials and research involving human subjects, specify the approximate number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
- **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:** 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.

- Current Quad Chart: Provide a current Quad Chart in the same format as the pre-application. If no changes have been made to the project, the same Quad chart submitted with the pre-application may be used.
- 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.
- 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, to include:
  - Availability of and access to research resources, and/or
  - Availability of and access to appropriate populations (and/or access to available samples/data or databases), if applicable.
- Letter(s) of Support for Use of Military and VA Populations or Resources (if applicable): If the proposed research plan involves access to active duty military and/or VA patient populations or resources, include a letter(s) of support, signed by the lowest ranking person with approval authority, confirming such access. 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 and access to the relevant population(s) and/or resources.
- Intellectual Property
  - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

- **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.

The technical abstract is used by all reviewers. Therefore, clarity and completeness within the space limits of the technical abstract are highly important. Use the outline below. Proprietary or confidential information *should not* be included.

- Background: State the FY15 Topic Area that will be addressed by the proposed research. Present the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design, including appropriate controls.
- Military Benefit: Briefly explain how the proposed project will have an immediate and/or potential long-term impact on the health and well-being of Service members and/or U.S. Veterans who sustained burn injuries, as well as their family members, caregivers, and the general public.

- **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.

The lay abstract is used by all reviewers. Therefore, clarity and completeness within the space limits of the lay abstract are highly important. **Do not duplicate the technical abstract.** Use the outline below. Proprietary or confidential information *should not* be included.

Clearly describe the objectives and rationale for the application in a manner that will be readily understood by readers without a background in science or medicine.

- Describe the ultimate applicability of the research.
- Which FY15 Topic Area will be addressed?
- How will the proposed research impact the Topic Area addressed?
- What are the potential clinical applications, benefits, and risks?
- What is the projected timeline it may take to achieve the expected patient-related outcome?
- Describe how the proposed project will benefit Service members and/or U.S. Veterans who sustained burn injuries, as well as their families, caregivers, and the general public.

- **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 MBRP Burn

Injuries Research Award mechanism, use the SOW format example titled “SOW Generic Format.” 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.

- **Attachment 6: Impact and Military Benefit (two-page limit): Upload as “MilBen.pdf.”**
  - Describe the potential immediate and long-term effect on patient care and how the proposed work would impact the health care needs of Service members and/or U.S. Veterans as well as their families, caregivers, and the general public.
  - Describe how the proposed study is responsive to the healthcare needs of military Service members and Veterans recovering from traumatic burn injury. Provide information about the incidence and/or prevalence of the burn injuries in military Service members and/or Veterans, if appropriate and available. Show how the proposed study complements ongoing DoD and VA areas of research interest.
  - If active duty military and/or Veteran population(s) or dataset(s) will be used in the proposed research, 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, explain how the population simulates the targeted population (i.e., military Service members or Veterans). If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military services and/or the U.S. Veteran population). Show how the proposed study complements ongoing DoD areas of burn research interest. Describe how the study design will replicate field conditions, if applicable.
  - Describe the short-term impact, as well as the anticipated long-term benefits of the proposed research. Include details about the anticipated outcomes that will be directly attributed to the results of the proposed research.
- **Attachment 7: Transition Plan (one-page limit). Upload as “Transition.pdf.”** Provide information on the methods and strategies proposed to move the product to the next phase of research or delivery to the military or civilian market after successful completion of the award. The transition plan should include the components listed below.
  - Details of the funding strategy that will be used to bring the outcomes to the next level (e.g., specific potential industry partners, specific funding opportunities to be pursued).
  - A description of collaborations and other resources that will be used to provide continuity of development. For any industry partner(s), include a description of their product development and/or marketing experience.
  - A brief schedule and milestones for bringing the outcome(s) to the next level.

- The involvement of appropriate intellectual property, licensing, and/or business professionals.
- A risk analysis for cost, schedule, manufacturability, and sustainability.
- A description of relevant product patents and intellectual property ownership, and their potential impact on product development and the Government’s ability to access any technology or products supported with this award.
- **Attachment 8: IND/IDE Documentation (if applicable):** If submitting multiple documents, start each document on a new page. **Combine and upload as a single file named “IND-IDE.pdf.”**
  - Complete the IND/IDE Documentation Form, which is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity on Grants.gov. State whether the trial requires regulation by the FDA. If FDA regulation is required, describe the planned indication for the proposed product and whether an IND/IDE is necessary.
  - If an IND or IDE has been submitted, indicate when it was submitted to the FDA and provide an explanation of the status of the IND or IDE application (e.g., past the critical 30-day period, pending response to questions raised by the Agency, on clinical hold). Provide a summary of previous meetings with the FDA on development of this product, if appropriate. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application.
  - If an IND or IDE is not required for the proposed study, provide evidence in the form of communication from the FDA or the IRB of record to that effect.
- **Attachment 9: Human Subject Recruitment and Safety Procedures (if applicable; required for all studies recruiting human subjects; no page limit): Upload as “HumSubProc.pdf.”** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
  - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from whom the sample will be recruited/drawn). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.
  - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

***Inclusion of Women and Minorities in Study.*** Consistent with the Belmont Report, “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 USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical trial.

- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, and health care provider identification).
  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
  - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
- **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.***
  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects’ questions will be addressed during the consent process and throughout the trial.
  - Include information regarding the timing and location of the consent process.
  - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
  - Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
  - Describe the plan for the consent of the individual’s Legally Authorized Representative (LAR) to be obtained prior to the human subject’s participation in the study. State law defines who may act as the LAR. The

local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial to be in compliance with Title 10 United States Code Section 980 (10 USC 980)

(<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>). If applicable, please refer to the General Application Instructions, Appendix 5, for more information.

- **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.
- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Please note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.
- **Risks/Benefits Assessment**
  - **Foreseeable risks:** Clearly identify all study risks. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
  - **Risk management and emergency response**
    - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
    - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
    - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
    - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.

- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.
- **Attachment 10: Intervention (if applicable; no page limit): Upload as “Intervention.pdf.”** The Intervention attachment should include the components listed below.
  - a. **Description of the Intervention:** As applicable, the description of the 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 detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described.
 

Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety of the intervention.
  - b. **Study Procedures:** Describe the interaction with the human subject to include the study intervention 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:** 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, and how they will be corrected and prevented by the clinical trial site/PI.
- **Attachment 11: Data Management (if applicable; required for all studies recruiting human subjects; no page limit): Upload as “Data\_Manage.pdf.”** The Data Management attachment should include the components listed below.
  - a. **Data Management:** Describe all methods used for data collection to include the following:
    - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
    - **Confidentiality**
      - Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the

privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.

- Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
- Address requirements for reporting sensitive information to state or local authorities.
- **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 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.
- **Labs 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 12: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a



DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP “Funding Opportunities & Forms” web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.

- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.
  - 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.”
  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
- 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.
- 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.

#### **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 application rejection.

#### **F. Other Submission Requirements**

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

All applications must be submitted through Grants.gov. 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 consumer advocates 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 Commanding General, USAMRMC, based on (a) technical merit and (b) the relevance to the mission of the DoD and MBRP, 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 listed in decreasing order of importance:

- **Research Strategy and Feasibility**

- How well the preliminary data and scientific rationale support the research project.
- How well the proposed study addresses one of the FY15 MBRP Topic Areas.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project and how well they address the need(s) described.
- How consistent the methods and procedures are with sound research design.
- How well the potential problem and risk areas in the experimental approach were identified and the extent the proposed alternative methods and approaches address those areas.
- How well the PI has outlined a plan for management and sharing of research data as appropriate for the type of study.
- The degree to which the plan to study military populations, if applicable, is appropriate and feasible.

***For clinical trials and clinical research involving human subjects:***

- How well the PI describes the population(s) of interest, demonstrates access to these populations, has a viable plan for recruitment, consent, screening, and retention of appropriate subjects, and identifies sampling methods to gain a representative sample from the population(s) of interest.
- How well the PI describes the study design and the feasibility of project implementation.
- How well plans for addressing ethical and regulatory considerations have been developed, including mitigation of risk, consideration of privacy issues, and process for obtaining informed consent.
- How the plan for addressing unanticipated delays (e.g., slow accrual) is likely to lead to success in completing the proposed study within the period of performance.
- If applicable, whether there is evidence demonstrating availability of the device/intervention from its source for the duration of the proposed study.
- If applicable, how well the plan will evaluate clinical endpoints and translate into clinical practice.
- If applicable, how well the PI addresses any anticipated interactions with, and/or plans for obtaining regulatory approval for the use of investigational drugs, biologics, or devices, from the FDA.

- **Impact and Military Benefit**
  - How well the PI describes the potential immediate and long-term effect on patient care.
  - The potential immediate or long-term benefit and usability of the proposed research on the health and well-being of Service members, Veterans, and/or their families or communities.
- **Statistical Plan**
  - To what degree the statistical model and data analysis plan are suitable for the planned study.
  - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
- **Transition Plan**
  - Whether the funding strategy described to bring the outcome(s) to the next level of development and/or delivery to the military or civilian market is appropriate.
  - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
  - How well the potential 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 (if applicable).
  - Whether key regulatory milestones have been established (if applicable)
- **Personnel**
  - How the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed research or clinical trial.
  - Whether the composition of the research or study team (e.g., study coordinator, statistician) is appropriate.
  - How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
  - How the investigator(s) record(s) of accomplishment demonstrates his/her ability to accomplish the proposed work.
  - How the research team's background and expertise are appropriate to accomplish the proposed work.

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

- **Environment**

- How the scientific environment is appropriate for the proposed research or clinical trial.
- How the research or trial requirements are supported by the availability of and accessibility to facilities and resources.
- How the quality and extent of institutional support are appropriate for the proposed project.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).

- **Budget**

- Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**

- To what extent the writing, clarity, and presentation of the application components influence the review.

**2. Programmatic Review:** To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, 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 FY15 MBRP, as evidenced by the following:**

- Adherence to the intent of the award mechanism
- Relative Impact and Military Relevance
- Programmatic relevance
- 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.

### **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 FY15 MBRP Working Group 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. A list of the FY15 MBRP Working Group members can be found at <http://cdmrp.army.mil/mbrp/panels/panels15>.
- 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.
- The invited application does not propose the same research project described in the pre-application.
- The application does not address one, and only one, of the FY15 MBRP Topic Areas.

#### **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 made using FY15 funds will be made no later than September 30, 2016. 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 technical progress reports and quad charts will be required.

#### **E. Award Transfers**

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

### **VI. AGENCY CONTACTS**

#### **A. CDMRP Help Desk**

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

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto: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](mailto: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	Completed
SF-424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Impact and Military Benefit: Upload as Attachment 6 with file name "MilBen.pdf"	
	7	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf"	
	8	IND/IDE Documentation: Upload as Attachment 8 with file name "IND-IDE.pdf," if applicable.	
	9	Human Subject Recruitment and Safety Procedures: Upload as Attachment 9 with file name "HumSubProc.pdf," if applicable.	
	10	Intervention: Upload as Attachment 10 with file name "Intervention.pdf," if applicable.	
	11	Data Management: Upload as Attachment 11 with file name "Data_Manage.pdf," if applicable.	
	12	Collaborating DoD Military Facility Budget Form(s): Upload Attachment 12 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.	
Confidential Letters of Recommendation		Confirm upload to eBRAP.	