

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Congressionally Directed Medical Research Programs

Military Burn Research Program

Clinical Translational Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-19-MBRP-CTRA

**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), April 17, 2019
- **Invitation to Submit an Application:** May 17, 2019
- **Application Submission Deadline:** 11:59 p.m. ET, July 10, 2019
- **End of Application Verification Period:** 5:00 p.m. ET, July 15, 2019
- **Peer Review:** September 2019
- **Programmatic Review:** November 2019

This Program Announcement must be read in conjunction with the General Application Instructions, version 20190218. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”

TABLE OF CONTENTS

I. OVERVIEW OF THE FUNDING OPPORTUNITY.....	1
II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY.....	3
II.A. Program Description.....	3
II.A.1. FY19/20 MBRP Focus Areas.....	3
II.B. Award Information.....	4
II.C. Eligibility Information.....	8
II.C.1. Eligible Applicants.....	8
II.C.2. Cost Sharing.....	9
II.C.3. Other.....	9
II.D. Application and Submission Information.....	10
II.D.1. Address to Request Application Package.....	10
II.D.2. Content and Form of the Application Submission.....	10
II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM).....	29
II.D.4. Submission Dates and Times.....	29
II.D.5. Funding Restrictions.....	30
II.D.6. Other Submission Requirements.....	32
II.E. Application Review Information.....	32
II.E.1. Criteria.....	32
II.E.2. Application Review and Selection Process.....	36
II.E.3. Integrity and Performance Information.....	36
II.E.4. Anticipated Announcement and Federal Award Dates.....	37
II.F. Federal Award Administration Information.....	37
II.F.1. Federal Award Notices.....	37
II.F.2. Administrative and National Policy Requirements.....	38
II.F.3. Reporting.....	38
II.G. Federal Awarding Agency Contacts.....	39
II.G.1. CDMRP Help Desk.....	39
II.G.2. Grants.gov Contact Center.....	39
II.H. Other Information.....	39
II.H.1. Program Announcement and General Application Instructions Versions.....	39
II.H.2. Administrative Actions.....	40
II.H.3. Application Submission Checklist.....	42
APPENDIX 1: ACRONYM LIST.....	44
APPENDIX 2: DOD AND VA WEBSITES.....	46

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Years 2019 and 2020 (FY19/20) Military Burn Research Program (MBRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). The execution management agent for this Program Announcement 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. Appropriations for the MBRP from FY11 through FY18 totaled \$62 million (M). The FY19 appropriation is \$8M. The CDMRP expects to allocate a portion of both FY19 and FY20 funding, if appropriated, to fund awards selected through this Program Announcement.

II.A.1. FY19/20 MBRP Focus Areas

The overarching goal for the FY19/20 MBRP is to support the development or refinement of interventions or technologies that will enable non-medical or medical first responders to provide appropriate burn care closer to the point of injury to enhance the potential for better long-term outcomes. The MBRP anticipates that outcomes of successful applications will lead to the near-term delivery of interventions, products, or care guidelines that will assist fellow Service members, first responders, and/or civilians in the pre-hospital care of the severe burn casualty.

To meet the intent of the award mechanism, an application must address at least one of the following FY19/20 MBRP Focus Areas. Selection of the appropriate primary Focus Area is the responsibility of the applicant.

1 – Conversion: Novel therapeutic interventions to prevent burn wound conversion, including but not limited to, pre-hospital dressings, fluid resuscitation therapies, and vitamin delivery products. Investigation of interventions that have been established for other indications is also welcome. Addition of comparative analysis studies of different formulations of the proposed intervention is encouraged, if appropriate and feasible.

2 – Debridement: Development and/or validation of non-surgical burn wound debridement strategies for the pre-hospital environment or prolonged field care scenario.

3 – Coverage: Development of temporary coverage products for large second- and third-degree burn wounds that will prevent infection, promote healing, and prevent further morbidity or mortality. Comparative analysis of the proposed product with commercially available products is welcome.

II.B. Award Information

The MBRP Clinical Translational Research Award (CTRA) is intended to support clinical research projects that are likely to have a major impact on therapy by applying promising and well-founded laboratory, preclinical, or clinical research findings to the care of the burn-injured patient.

Burns have comprised some 5%-20% of the casualties sustained in post-World War II conflicts.¹ Potential future conflicts may cause a rise in the number of burn injuries sustained by Service members and the general public should those conflicts occur in rural areas, austere combat zones, and in mass casualty events, whereby medical resources are limited and/or access to medical care is delayed for hours, days, or weeks. In order to prepare the military and the Nation for such potential future conflicts, the FY19/20 MBRP is soliciting research to provide burn care solutions closer to the point of injury for the pre-hospital setting and for a prolonged field care scenario.

The North Atlantic Treaty Organization (NATO) defines prolonged field care (PFC) as field trauma care extended beyond doctrinal timelines until the patient can be transported from the point of injury to an appropriate level of care. PFC has been identified as a high priority capability gap across the Army and other Services. Additional information regarding PFC can be found in the following articles, [Prolonged Field Care: Beyond the 'Golden Hour'](#)² and [Prolonged Field Care the New Normal says Army, MRMC Brass](#).³

Although encouraged, applications submitted to the FY19/20 MBRP CTRA are **not required** to address PFC. However, the proposed research must be relevant to active duty Service members, Veterans, military beneficiaries, and/or the American public.

Funding from this award mechanism must support clinical research involving human subjects; **animal research is not allowed under this funding opportunity**. Principal Investigators (PIs) seeking funding for a preclinical research project should consider the [FY19/20 MBRP Idea Development Award Program Announcement](#), if appropriate.

The anticipated total costs budgeted for the entire period of performance for an FY19/20 MBRP CTRA will not exceed **\$1.55M**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

The CDMRP expects to allot approximately \$4.65M of the combined FY19 MBRP appropriation to fund approximately three (3) FY19/20 MBRP CTRA applications. In addition, up to \$4.65M of the FY20 MBRP appropriation may be available to fund an additional three (3) FY19/20 MBRP CTRA applications, if appropriated. Funding of

¹ Kauvar DS, Wade CE, and Baer DG. 2009. Burn hazards of the deployed environment in wartime: Epidemiology of noncombat burns from ongoing United States military operations. *Journal of the American College of Surgeons* 209(4):453e460.

² Keenan S and Riesberg JC. 2017. *Wilderness & Environmental Medicine* 28:S135-S139. Published online at [https://www.wemjournal.org/article/S1080-6032\(17\)30063-7/fulltext](https://www.wemjournal.org/article/S1080-6032(17)30063-7/fulltext).

³ Kahlili RA. 2017. Prolonged Field Care the New Normal says Army, MRMC Brass. USAMRMC website. https://mrmc.amedd.army.mil/index.cfm?pageid=media_resources.articles.prolonged_field_care_the_new_normal

applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this funding opportunity will be funded with FY19 and FY20 MBRP funds, which must be obligated by September 30, 2020, and September 30, 2021, respectively.

Awards will be made no later than September 30, 2021. For additional information, refer to [Section II.F.1, Federal Award Notices](#).

The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of the Department of Defense (DoD) during project performance is the key factor in determining whether to award a grant or cooperative agreement.

An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305) and the award will identify the specific substantial involvement. Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The proposed research must address one of the FY19/20 MBRP CTRA Focus Areas. The proposed study must include clinical research, and may include initial proof of concept trials, studies involving use of human anatomical substances, observational studies, and/or involve some retrospective data analysis. ***Large randomized clinical trials are discouraged.***

New FY19 definition: A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. These outcomes represent a direct effect on the subject of that intervention or interaction. Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available Federal website in accordance with Federal requirements described in Code of Federal Regulations, Title 32, Part 219 (32 CFR 219).

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

The following are important aspects of the MBRP CTRA:

- ***Inclusion of preliminary data relevant to the proposed clinical research is required.***
- The proposed clinical research study outcomes should provide burn care solutions closer to the point of injury, and/or benefit the burn casualty in a prolonged field care scenario.
- The proposed clinical research study must be based on sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature.
- The proposed clinical research study is expected to begin no later than 12 months after the award date, or 18 months for U.S. Food and Drug Administration (FDA)-regulated studies.
- The application should demonstrate availability of, and access to, a suitable patient population that will support a meaningful outcome for the study.
- The application should include a clearly articulated statistical analysis plan, appropriate statistical expertise on the research team, and a power analysis reflecting sample size projections that will answer the objectives of the study.
- The application should include a Transition Plan (including potential funding and resources) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of the FY19/20 MBRP CTRA.

If the application proposes a clinical trial that involves the use of a drug that has not been approved by the FDA for the proposed investigational use, then an Investigational New Drug (IND) application to the FDA that meets all requirements under 21 CFR 312 may be required and ***must be submitted to the FDA within 12 months of the award date.*** The IND should be specific for the product (i.e., the product should not represent a derivative or alternate version of the investigational agent described in the IND) and indication to be tested in the proposed clinical trial. For more information on IND applications, the FDA has provided guidance at <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/appraisalapplications/investigationalnewdrugindapplication/default.htm>.

If the investigational product is a device, then an Investigational Device Exemption (IDE) application to the FDA that meets all requirements under 21 CFR 812 may be required. It is the responsibility of the applicant to provide evidence from the IRB of record or the FDA if an IDE is not required, or if the device qualifies for an abbreviated IDE. If an IDE is required, the IDE application ***must be submitted to the FDA within 12 months of the award date.*** The IDE should be specific for the device (i.e., should not represent a derivative or modified version of the device described in the IDE application) and indication to be tested in the proposed clinical trial.

Refer to [Attachment 7, Regulatory Strategy](#), for additional details on documentation of FDA applications. The Government reserves the right to withdraw funding if an IND or IDE application is necessary but has not been submitted within 12 months of the award date.

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 U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC 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/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

If the IRB determines that a trial presents greater than minimal risk to human subjects, the DoD requires an independent research monitor with expertise consistent with the nature of risk(s) identified within the research protocol. If applicable, refer to the General Application Instructions, Appendix 1, for more information on study reporting authorities and responsibilities of the research monitor.

Multi-Institutional Clinical Trials: If the proposed clinical trial is multi-institutional, plans for the multi-institutional structure governing the research protocol(s) should be outlined in [Attachment 8: Study Personnel and Organization](#). The lead organization responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements. A single IRB or EC pathway is strongly recommended whenever possible. The master protocol and consent form must be reviewed by the HRPO prior to distribution to the additional sites for IRB/EC review. Communication and data transfer among the collaborating institutions, as well as how specimens and/or imaging products obtained during the study will be handled, should be included in the appropriate sections of the application. A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional clinical trials.

PIs are encouraged to integrate and/or align their research projects with DoD and/or Department of Veterans Affairs (VA) research laboratories and programs. Collaboration with the DoD or VA is also encouraged ([Appendix 2](#)). Potential for future product development partnerships with the U.S. Army Medical Materiel Development Activity (<https://www.usammda.army.mil/>) may be available depending on the maturity and impact of the product on the military.

Recruitment Milestones: For research involving human subject enrollment, the application must indicate the quarterly enrollment targets across all sites in [Attachment 5: Statement of](#)

Work. Successful applicants will work with USAMRAA to establish milestones for human subject recruitment. Continued support for the project will be based upon satisfactory progress in meeting the established milestones.

Use of DoD or VA Resources: If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement 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 2, Section K.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.

Government Agencies Within the United States: Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal

programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this Program Announcement may be submitted by extramural and intramural organizations, these terms are defined below.

Extramural Organization: An eligible non-DoD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, Federal Government organizations other than the DoD, and research institutes.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center.

Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov through a research foundation.

The USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Independent investigators at all academic levels (or equivalent) may be named as a PI in the application.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <https://orcid.org/>.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

There are no limitations on the number of applications for which an investigator may be named as a PI.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

II.D. Application and 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 application(s).

Extramural Submission: An application submitted by an organization to Grants.gov.

Intramural DoD Submission: An application submitted by a DoD organization to eBRAP.

II.D.1. Address to Request Application Package

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.

Extramural Submissions:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

Intramural DoD Submissions:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

II.D.2. Content and Form of the Application Submission

Submission is a two-step process requiring both *pre-application* and *full application* as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-Application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP.org.

Full Application Submission: Full applications must be submitted through the online portals as described below.

Extramural Organization Submissions: Full applications from extramural organizations must be submitted through a Grants.gov Workspace. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions. Applications from

extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in [Section II.C.1, Eligible Applicants](#).

Intramural DoD Organization Submissions: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP.

For Both Extramural and Intramural Applicants: eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement 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.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

II.D.2.a. Step 1: Pre-Application Submission Content

During the pre-application process, each submission is assigned a unique log number by. This unique eBRAP log number is required during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

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

The applicant organization and associated PIs 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 applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

PIs with an ORCID identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

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):

- **Tab 1 – Application Information**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://ebrap.org/eBRAP/public/Program.htm>. Note that the codes have recently been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

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 SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that applicants identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

Enter the name, organization, and role of all collaborators and key personnel associated with the application.

[FY19/20 MBRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest (COI) in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

Note: Upload documents 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 (four-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) 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:

- **Background/Research Idea:** Briefly describe the scientific evidence that supports the proposed research, and include relevant literature citations. State the ideas and reasoning on which the proposed clinical research is based. Clearly specify if the proposed research will be regulated by the FDA based on intervention type and level of risk. If applicable, state the intervention to be tested and indicate the phase of clinical trial and/or class of device.
- **Research Strategy:** Concisely state the project’s hypothesis and/or objectives, and specific aims. Briefly describe the scientific approach and study design. Identify the resources to be utilized, the data to be analyzed, and/or the patient population to be engaged during the study.
- **Impact and Alignment with Focus Area(s):** Explain how the proposed work addresses at least one of the FY19/20 MBRP CTRA Focus Areas. State explicitly how the proposed work may ultimately have an immediate and/or long-term impact on patient care for those who have sustained traumatic burn injuries. If applicable, discuss how the study will contribute toward the goal of treating burns closer to the point of injury and/or in the PFC environment.
- **Military Benefit:** Describe how the proposed research will enable non-medical or medical first responders to provide appropriate burn care closer to the point of injury to enhance the potential for better long-term outcomes. Identify where along the military (and civilian) pathway of care the proposed product or intervention will be applied. Note DoD or VA collaborations, if any.
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to the following:
 - **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, reference title, and reference source, including 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 (six-page limit per individual):** *All biographical sketches should be uploaded as a single combined file.* Biographical

sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

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:

- **Background/Research Idea:** How well the rationale supports the research idea. The degree to which the proposed research addresses the intent of the award mechanism and goals of the FY19/20 MBRP.
- **Research Strategy:** How well the specific aims, patient population, and study design support the research idea and will achieve the desired outcomes. Whether resources and/or the identified patient population(s) are appropriate for the proposed research.
- **Impact and Alignment with Focus Area(s):** The extent to which the study will make important contributions that will advance the field of burn injury research and enable non-medical or medical first responders to provide appropriate burn care closer to the point of injury and/or in a PFC scenario. How well the proposed research addresses a FY19/20 MBRP CTRA Focus Area.
- **Military Benefit:** The degree to which the proposed research, if successful, will provide a significant benefit to military Service members or Veterans that have sustained significant burn injuries. To what extent the study has the potential to improve outcomes of these individuals.

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

Following the pre-application screening, applicants 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 in [Section I, Overview of the Funding Opportunity](#). Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

II.D.2.b. Step 2: Full Application Submission Content

Applications will not be accepted unless notification of invitation has been received.

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 full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://www.grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the **same version** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-19-MBRP-CTRA from Grants.gov (https://www.grants.gov/) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-19-MBRP-CTRA from eBRAP (https://ebrap.org/).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	Tab 1 – Summary: Provide a summary of the application information. Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components:	Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file

Extramural Submissions	Intramural DoD Submissions
<ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form (if applicable) 	<p>can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package at least 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p>Note: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget 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 <i>prior to</i> the application submission deadline.</p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email.</p>
<u>Application Verification Period</u>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full</p>

Extramural Submissions	Intramural DoD Submissions
	application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form</i> . Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.
Further Information	
<p>Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

Both Extramural and Intramural organizations: Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Research & Related Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

II.D.2.b.ii. Full Application Submission Components

- **Extramural Applications Only**

SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full application package may not exceed 200 MB.

The Project Narrative is NOT the formal clinical study protocol. Instead, all essential elements of the proposed clinical study necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 6-7 described below.

- **Attachment 1: Project Narrative (16-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) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Describe in detail the rationale for the study and the clinical need(s) to be addressed. Identify the FY19/20 MBRP CTRA Focus Area(s) to be addressed. This section should establish the relevance of the study and explain the applicability of the proposed findings. Provide a literature review and describe the preliminary studies and/or preclinical data that led to the development of the proposed clinical research. Provide a summary of other relevant ongoing, planned, or completed clinical research or trials, and describe how the proposed study differs or builds on existing knowledge. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials 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. If the proposed clinical research is part of a larger ongoing effort, specifically identify the portions of the study that would 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. This information should agree with the primary aims and associated tasks described in the [Statement of Work \(Attachment 5\)](#).

- **Study Design:** Describe the type of study to be performed (e.g., treatment, prevention, diagnostic, retrospective, observational, comparative), the study phase or class (if applicable), and the study model (if applicable; e.g., single group, parallel, crossover). Outline the proposed methodology in sufficient detail to show a clear course of action.
 - Identify and briefly describe the product/intervention to be studied or tested, and the projected results.
 - Define the primary and any secondary or interim endpoints/outcome measures, outline why they were chosen, and describe how and when they will be measured. Include a description of appropriate controls. Outline the timing and procedures planned during the follow-up period, if applicable.
 - If applicable, describe the study population and recruitment plan, and discuss how accrual goals will be achieved and how standards of care may impact the study population. Define each arm/study group of the proposed research/trial and describe access and availability of human subjects for the clinical study, and the prospect of their participation and retention.
 - Specifically describe the plan for obtaining informed consent from human subjects.
 - Clearly identify all study risks, including potential safety concerns and adverse events. Describe the safety monitoring and reporting plan.
 - Outline whether subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.
 - If using psychometric measures, describe their reliability and validity.
 - Describe potential problem areas and discuss alternative methods/approaches that may be employed to overcome them. Estimate the potential for subject loss to follow-up, and how such loss will be handled/mitigated.
- **Statistical and Data Analysis Plan:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to 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. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application. Describe the data management plans, including how data will be collected, managed, reported, and analyzed.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative 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 Patents:** 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.
- **Quad Chart:** Upload as “QuadChart.pdf”. The Quad Chart template is a one-page PowerPoint file that must be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm> in the “Generic Forms for Application Submission” section, then completed and saved as a PDF file.
- **Letters of Organizational Support (one page limit per letter is recommended):** 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, such as those from members of Congress, do not impact application review or funding decisions.
- **Letters of Collaboration (if applicable; one page limit per letter is recommended):** 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.

If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- Letters of Commitment (if applicable; one page limit per letter is recommended): If the proposed study involves use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial 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.
- Intellectual Property: Information can be found in 2 CFR 200.315, “Intangible Property.”
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with and made available to the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Use of DoD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military patient populations and/or DoD resources or databases.
- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** 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 clarity and completeness within the space limits of the technical abstract are highly important for review of the application.

Technical abstracts should be written using the outline below.

- **Background:** Identify the primary FY19/20 MBRP CTRA Focus Area addressed by the proposed research. Present the ideas and rationale behind the proposed research.
- **Objective/Hypothesis:** State the objective to be reached and/or hypothesis to be tested.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design, including appropriate controls.
- **Impact and Military Benefit:** State briefly how the proposed project, if successful, will have an immediate and/or long-term impact on combat-related burn injury care closer to the point of injury and/or in a PFC scenario. Identify where along the military (and civilian) pathway of care the proposed product or intervention will be applied.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. **Do not include proprietary or confidential information.** 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.**

- Describe the objectives and rationale for the proposed study in a manner *readily understood by readers without a background in science or medicine.*
- Describe the ultimate applicability and impact of the research.
 - Which primary FY19/20 MBRP CTRA Focus Area will be addressed?
 - What types of patients (military and non-military) will it help, and how will it help them?
 - What are the potential clinical applications and benefits?
 - What is the projected timeline it may take to achieve the expected patient-related outcome?
 - Describe how the proposed project will benefit burn-injured Service members, Veterans, and/or the general public. Also, describe how the potential outcomes of the project would enable non-medical or medical first responders to provide appropriate burn care closer to the point of injury to enhance the potential for better long-term outcomes. Identify where along the military (and civilian) pathway of care the proposed product or intervention will be applied.

- **Attachment 5: Statement of Work (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 Clinical Translational Research Award 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.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
- Indicate the number (and type, if applicable) of research subjects projected or required for each task and at each site. Indicate quarterly enrollment targets. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
- Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.
- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., IND or IDE applications) by the FDA or other Government agency.
- **Attachment 6: Intervention (if applicable; required for projects proposing clinical trials) (no page limit): Upload as “Intervention.pdf”.** The Intervention attachment should include the components listed below.

- **Description of the Intervention:** Identify the intervention to be tested and describe the particular outcomes as it relates to the FY19/20 MBRP goal. 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 general concept of design, detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for conduct of the clinical trial.

Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.

- **Study Procedures:** Describe the interaction with the human subject, including 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. Clearly delineate research procedures from routine clinical procedures. Discuss how compliance with current Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) guidelines and other regulatory considerations will be established, monitored, and maintained, as applicable.
- **Clinical Monitoring Plan:** Describe how the study will be conducted by and monitored for current ICH E6 (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) Good Clinical Practice (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 7: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “Regulatory.pdf”.** Answer the following questions and provide supporting documentation as applicable.

- State the product/intervention name.

For products/interventions that do not require regulation by the FDA

- Explain why the product/intervention is exempt from FDA oversight. Provide confirmation that the trial does not require regulation by the FDA in writing from the IRB of record or the FDA. No further information for this Attachment is required.

For products/interventions that require regulation by the FDA

- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the U.S.
- If the product is marketed in the U.S., state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).
- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor

- commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.
- Identify the planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication.
 - If the clinical trial involves the use of a drug that has not been approved by the FDA for the proposed investigational use, then an IND application to the FDA that meets all requirements under the 21 CFR 312 may be required and must be submitted to the FDA *within 12 months of the award date*. If the investigational product is a device, evidence that an IDE application that meets all requirements under 21 CFR 812 has been submitted to the FDA *within 12 months of the award date*, or that the device is exempt or qualifies for an abbreviated IDE, is required. The Government reserves the right to withdraw funding if an IND or IDE is necessary but has not been submitted to the FDA within 12 months of the award date, or if documented status of the IND or IDE has not been obtained within 18 months of the award date.
 - If an IND or IDE has already been obtained for the investigational product, provide a copy of the acceptance from the FDA.
 - Provide the current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support Phase I testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).
 - Describe the overall regulatory strategy and product development plan that will support the planned product indication. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines.
- **Attachment 8: 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.
 - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments and name each person's position on the project. Include any separate laboratory or testing center. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, if appropriate. Identify and provide justification for the inclusion of international sites, as appropriate. If applicable, identify the FDA regulatory sponsor and 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.

- **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, including previous interactions with the FDA, if applicable. An external research monitor (if applicable) and study coordinator(s) should be included. Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable).
- **Attachment 9: Transition Plan (three-page limit): Upload as “Transition.pdf”.** Describe/discuss the methods and strategies proposed to move the product or intervention to the next phase of development (e.g., clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. **PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development.** The post-award transition plan should include the components listed below.
 - A description of collaborations and other resources that will be used to provide continuity of development.
 - Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., specific industry partners, specific internal and/or external funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.
 - For Knowledge Products, the description of collaborations and other resources that will provide continuity of development may include proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. A “Knowledge Product” is a non-materiel product that addresses an identified need, topic area, or capability gap, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support materiel solutions (systems to develop, acquire, provide, and sustain medical solutions and capabilities), and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.
 - A brief schedule and milestones for transitioning the product or intervention to the next phase of development (i.e., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by the FDA).
 - Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government’s ability to access such products or technologies in the future.
 - If applicable, a risk analysis for cost, schedule, manufacturability, and sustainability.

- **Attachment 10: Impact and Military Benefit Statement (three-page limit): Upload as “MilBen.pdf”.**
 - Describe the short- and long-term impact of this study on the lives of individuals recovering from combat-related burn injuries, including but not limited to how the expected results of the proposed work will contribute to the goals of decreasing the clinical impact of these injuries and provide better long-term outcomes.
 - If applicable, describe how the proposed study may impact point of injury care, PFC, or both. Describe how the study design will replicate field conditions, if applicable.
 - Demonstrate how the proposed study is responsive to the health care needs of the military Services and/or the Veteran population. Provide information about the incidence and/or prevalence of the project-relevant burn injury in military Service members and Veterans, as well as the incidence in the general population, if appropriate and available.
 - Describe how the product or intervention represents an improvement over currently available interventions and/or standards of care.
 - The following are examples of ways in which proposed studies, if successful, may demonstrate military benefit. *Although not all-inclusive*, these examples are intended to help applicants frame the military relevance of the proposed research:
 - Has the potential to change the standard of care for combat-related burn injuries
 - Proposes new paradigms or challenges existing paradigms in patient care of combat-related burn injuries
 - Contributes to development or validation of evidence-based policy or guidelines for patient evaluation and care of combat-related burn injuries
- **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 instrument(s) will be administered. Describe how the instrument(s) will be adapted to the subject population, if applicable.
- **Attachment 12: Representations, if applicable (extramural submissions only): Upload as “MandatoryReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- **Attachment 13: DoD Military Budget Form(s), if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical 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 DoD Military 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. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- PI Biographical Sketch (six-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 National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
- Key Personnel Biographical Sketches (six-page limit each): Upload as “Biosketch_LastName.pdf”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, 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.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 13. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all sub-recipient 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. Verify the status of the applicant’s organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement 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. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.

Intramural DoD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

The maximum period of performance is **4** years.

The anticipated total (direct and indirect) costs budgeted for the entire period of performance will not exceed **\$1.55M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the Government exceeding **\$1.55M** total costs or using an indirect cost rate exceeding the organization’s negotiated rate.

All funding amounts requested should be well-justified and appropriate for the scope of work proposed.

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 4 years.

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

- Travel funds for the PI to present project information or disseminate project results at two DoD-sponsored meetings (the Military Health System Research Symposium and/or an MBRP-specific meeting) in Years 3 or 4 of the period of performance. These travel costs are in addition to those allowed for annual scientific/technical meetings.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Research supplies
- Research-related subject costs
- Clinical research costs
- Clinical trial costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for one investigator to travel to two scientific/technical meetings per year, in addition to the required meetings described above. The intent of travel costs to scientific/technical meetings is to disseminate project results from the FY19/20 MBRP CTRA.

Must not be requested for:

- Animal research costs

Awards made to extramural organizations will consist solely of assistance agreements (grants and cooperative agreements). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

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

Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. The time is considered when

establishing the award's period of performance. It is anticipated that awards made from this FY19/20 funding opportunity will be funded with FY19 and FY20 funds, which will expire for use on September 30, 2025, and September 30, 2026, respectively.

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following **scored** criteria. Research Strategy and Feasibility is the most important criterion; all other scored criteria are of equal importance.

- **Research Strategy and Feasibility**
 - 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 and/or objective(s), experimental design, methods, data collection procedures, and analyses are designed to answer clearly the clinical objective.
 - How well the application addresses the access and availability of human subjects for the clinical study and the prospect of their participation and retention.
 - The degree to which the recruitment and retention plan will meet the needs of the proposed clinical study.
 - To what degree the potential challenges and alternative strategies for the proposed clinical study are described.
 - Whether plans for initiating the clinical project within the first year (or within 18 months for FDA-regulated studies) are described.
 - How well potential problems are acknowledged and alternative approaches are addressed.
 - To what degree the data collection instruments (e.g., surveys, questionnaires), if applicable, are appropriate to the proposed study.
- **Impact and Military Benefit**
 - How well the project addresses the selected primary FY19/20 MBRP CTRA Focus Area.

- To what degree the proposed research will make a major impact, in the short- and/or long-term, on the lives of burn-injured individuals.
- To what degree the outcomes from the proposed research will provide appropriate burn care solutions closer to the point of injury and/or in a PFC scenario, and enhance the potential for better long-term outcomes for the burn casualty.
- How well the project addresses a critical problem in combat-related burn injury research or medicine.
- The degree to which the proposed project, if successful, will advance the research methods, understanding, and/or treatment of combat-related burn injuries.
- **Intervention** (*if applicable; required for applications proposing a clinical trial*)
 - Whether there is evidence of support, indicating access to the intervention, for the duration of the proposed clinical trial (if applicable).
 - Whether the proposed intervention is feasible for use in its intended environment, and endpoints are rational.
 - To what degree the intervention addresses the clinical need(s) described in the application.
 - How the intervention compares with currently available interventions and/or standards of care.
 - To what degree preclinical and/or clinical evidence is provided to support the safety of the intervention.
 - How well research procedures are clearly delineated from routine clinical procedures.
- **Regulatory Strategy and Transition Plan**
 - Whether the regulatory strategy and transition plan are appropriate and well-described.
 - Whether the regulatory strategy and development plan to support the product indication or product label change, if applicable, are appropriate and well described.
 - Whether the application includes documentation that the study is exempt from FDA regulation, or, for products or interventions that require FDA regulation, that the plans for IND or IDE application submission to the FDA are appropriate.
 - Whether the identified next level of development and/or commercialization is realistic.
 - Whether the funding strategy described to bring the product/intervention to the next level of development (e.g., specific industry partners, internal and/or external funding opportunities to be applied for) is reasonable and achievable.

- Whether plans to comply with current GMP, GLP, and GCP guidelines are appropriate.
 - Whether the proposed collaborations and other resources for providing continuity of development are established and/or achievable.
 - Whether the schedule and milestones for bringing the product/intervention to the next level of development (next-phase clinical trials, transition to industry, delivery to the market, incorporation into standard practice, and/or approval by the FDA) are achievable.
 - How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on technology or product development and subsequent Government access to technologies or products supported by this Program Announcement.
 - For investigator-sponsored regulatory applications (e.g., IND, IDE), whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA.
- **Statistical and Data Analysis 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 study and all proposed correlative studies.
 - Whether the clinical study is designed with enough statistical power to lead to meaningful results.
 - 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.
- **Ethical Considerations**
 - How well the evidence shows that the procedures are consistent with sound research design.
 - Whether the population selected to participate in the trial (if applicable) stands to benefit from the knowledge gained.
 - Whether the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.

- To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
- Whether a research monitor with expertise consistent with the nature of the potential risk(s) is identified, if applicable.

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

- **Personnel**

- To what degree the study team’s background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in burn care, and clinical studies).
- Whether the levels of effort of the study team members are appropriate for successful conduct of the proposed research.

- **Environment**

- To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical research at each participating center or institution (including collaborative arrangements).
- Whether there is evidence for appropriate institutional commitment from each participating institution.

- **Budget**

- Whether the **total** maximum costs are equal to or less than the allowable total maximum costs as published in the Program Announcement.
- Whether the budget is appropriate for the proposed research.

- **Application Presentation**

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

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the FY19/20 MBRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism

- Program portfolio composition
- Programmatic relevance
- Relative impact and military benefit

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRMC. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.army.mil/about/2tierRevProcess>. A PI Information Paper describing the funding recommendations and review process for the award mechanisms for the MBRP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a 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 and approval 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 and approval 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 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the

applicant's integrity, business ethics, and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

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.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY19 and FY20 funds are anticipated to be made no later than September 30, 2020, and September 30, 2021, respectively. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from the USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. **The award document signed by the Grants Officer is the official authorizing document.**

Federal Government Organizations: Funding made to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

After email notification of application review results through eBRAP, and if selected for funding, a representative from the CDMRP will contact the Business Official authorized to negotiate on behalf of the PI's organization.

II.F.1.a. PI Changes and Award Transfers

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Unless otherwise restricted, changes in PI will be allowed at the discretion of the Grants Officer, provided that the intent of the award mechanism is met.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to the full text of the latest [DoD R&D General Terms and Conditions](#), the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#), and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Quarterly technical progress reports, quad charts, and annual progress reports, as well as a final progress report, will be required.

In-person presentations may be requested.

Funded studies that contain clinical trials are required to register the study in the National Institutes of Health (NIH) clinical trials registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 1, Section C, for further details.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template “Award Expiration Transition Plan,” available on the on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) under the “Progress Report Formats” section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission 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

II.G.2. Grants.gov Contact Center

Questions related to extramural 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; International 1-606-545-5035

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 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.

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20190218b. The Program

Announcement numeric version code will match the General Applications Instructions version code 20190218.

II.H.2. Administrative Actions

After receipt of pre-applications or applications, the following administrative actions may occur.

II.H.2.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.
- Intervention ([Attachment 6](#)) is missing, *for applications proposing a clinical trial*.
- Regulatory Strategy ([Attachment 7](#)) is missing.

II.H.2.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.

II.H.2.c. Withdrawal

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

- An FY19/20 MBRP 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. *A list of the FY19/20 MBRP Programmatic Panel members can be found at <https://cdmrp.army.mil/mbrp/panels/panels19>.*
- The application fails to conform to this Program Announcement description.

- 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).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY19, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- The proposed project includes animal research.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization 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.

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance (Extramural submissions only)	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)	Complete these tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Intervention: Upload as Attachment 6 with file name "Intervention.pdf"	
	Regulatory Strategy: Upload as Attachment 7 with file name "Regulatory.pdf"	
	Study Personnel and Organization: Upload as Attachment 8 with file name "Personnel.pdf"	
	Transition Plan: Upload as Attachment 9 with file name "Transition.pdf"	
	Impact and Military Benefit Statement: Upload as Attachment 10 with file name "MilBen.pdf"	
	Surveys, Questionnaires, and Other Data Collection Instruments: Upload as Attachment 11 with file name "Surveys.pdf"	
	Representations (extramural submissions only): Upload as Attachment 12 with file name "MandatoryReps.pdf" if applicable.	
DoD Military Budget Form(s): Upload as Attachment 13 with file name "MFBudget.pdf" if applicable.		
Research & Related Personal Data	Complete form as instructed.	

Application Components	Action	Completed
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 (Extramural submissions only)	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Budget (Intramural submissions only)	Complete the DoD Military Budget Form and justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
CTRA	Clinical Translational Research Award
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HRPO	Human Research Protection Office
ICH E6	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use)
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MBRP	Military Burn Research Program
MIPR	Military Interdepartmental Purchase Request
NATO	North Atlantic Treaty Organization
NIH	National Institutes of Health
NPC	Non-Profit Corporation
OMB	Office of Management and Budget
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PFC	Prolonged Field Care
PI	Principal Investigator

SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs

APPENDIX 2: DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with DoD and/or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DoD and VA areas of research interest, ongoing research or potential opportunities for collaboration.

Air Force Office of Scientific Research
<https://www.wpafb.af.mil/afrl/afosr/>

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

Armed Forces Radiobiology Research
Institute
<https://www.usuhs.edu/afri/>

Clinical and Rehabilitative Medicine
Research Program
https://mrmc.amedd.army.mil/index.cfm?pageid=medical_r_and_d.crmrp.overview

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

Congressionally Directed Medical Research
Programs
<https://cdmmp.army.mil>

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

Defense Health Agency
<https://health.mil/dha>

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

Defense Threat Reduction Agency
<http://www.dtra.mil/>

Military Health System Research
Symposium
<https://mhsrs.amedd.army.mil/SitePages/Home.aspx>

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

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

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

Navy Bureau of Medicine and Surgery
<https://www.med.navy.mil/>

Naval Medical Research Center
www.med.navy.mil/sites/nmrc

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

Office of Naval Research
<https://www.onr.navy.mil/>

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

Telemedicine and Advanced Technology
Research Center
<https://www.tatrc.org/>

Uniformed Services University of the Health
Sciences
<https://www.usuhs.edu/research>

U.S. Air Force 59th Medical Wing
<https://www.59mdw.af.mil/>

U.S. Army Aeromedical Research
Laboratory
<https://www.usaarl.army.mil>

U.S. Army Center for Environmental Health
Research
<https://usacehr.amedd.army.mil>

U.S. Army Institute of Surgical Research
<https://www.usaisr.amedd.army.mil/>

U.S. Army Research Institute of
Environmental Medicine
<https://www.usariem.army.mil/>

U.S. Army Medical Research Institute of
Infectious Diseases
<https://www.usamriid.army.mil/>

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

U.S. Army Research Laboratory
[https://www.arl.army.mil/www/default.cfm?
page=29](https://www.arl.army.mil/www/default.cfm?page=29)

U.S. Army Research, Development and
Engineering Command
[https://www.arl.army.mil/www/default.cfm?
page=20](https://www.arl.army.mil/www/default.cfm?page=20)

U.S. Army Resiliency Directorate
<https://www.army.mil/readyandresilient/>

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

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

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

Walter Reed Army Institute of Research
<https://www.wrair.army.mil/>