I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Military Burn Research Program

Patient-Centered Research Award

Announcement Type: Modified

Funding Opportunity Number: HT942524MBRPPCRA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), June 3, 2024
- **Invitation to Submit an Application:** July 21, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, September 9, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, September 16, 2024
- **Peer Review:** November 2024
- **Programmatic Review:** January 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. 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."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Military Burn Research Program (MBRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the MBRP 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 FY23 totaled $110 million (M). The FY24 appropriation is $10M.

Burn injuries sustained by military Service Members while in the line of duty, whether on the battlefield or in a military training environment, represent a continuous health burden on both the injured Service Member and the Department of Defense (DOD) health care systems in which they receive care. Historically, burn injuries afflicted some 5% to 20% of casualties during post-World War II conflicts.[1] In recent years, burns sustained during Operation Enduring Freedom/ Operation Iraqi Freedom affected nearly 9% of combat-related casualties.[2] While thermal burns represent the most common mechanism of burn injury, other injurious mechanisms such as frostbite, high-voltage electrical, chemical, directed energy, and radiation/nuclear exposure represent an additional formidable threat to the health and well-being of Service Members. The Armed Forces Health Surveillance Division reports an increased number of cold-related injuries in recent years; high-voltage accidents occur on and off the battlefield; and the threat of chemical, nuclear, or directed energy weapons is an ever-present danger. Regardless of mechanism, combat-associated burn injuries are devastating due, in part, to the high incidence of concurrent severe traumatic injuries. In addition, burns sustained in a deployed environment more often lead to severe burns than those sustained in the civilian setting. The majority of combat burns sustained in recent conflicts resulted from explosive device detonation, leading to a greater Injury Severity Score, an increase in inhalation injuries, and a larger, full-thickness burn size.[3] It is anticipated that in future conflicts the explosive weaponry used against U.S. forces will be more powerful than that seen in the past, likely resulting in a higher number of casualties with significant injuries and larger, more severe burns. Furthermore, the care provided to Service Members in a combat environment where evacuation may be significantly delayed may impact clinical outcomes. Irrespective of the injury mechanism, prolonged delay to definitive care renders assessment and treatment of burn wounds at or close to the point of injury

[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):453-460.
[2] Escolas SM, Archuleta DJ, Orman JA, et al. 2015. Postdischarge cause-of-death analysis of combat-related burn patients. *Journal of Burn Care and Research: Official Publication of the American Burn Care Association* 38(1):e158-e164.
[3] Kauver DS, Cancio LC, Wolf SE, et al. 2006. Comparison of combat and non-combat burns from ongoing U.S. military operations. *The Journal of Surgical Research* 132:195-200.

challenging to medical and non-medical first responders alike. There is an urgent need to develop, refine, or test novel burn therapies or technologies that would allow for better provision of care, particularly in resource-limited settings, and to improve both short- and long-term patient outcomes.

II.A.1. FY24 MBRP Focus Areas

To meet the intent of the funding opportunity, the program seeks to fund clinical research that enhances the ability to provide burn care, with emphasis toward care administered in resource-limited, austere settings consistent with a military operational environment. The program seeks to enhance the ability of medical and non-medical first responders and/or early-phase acute care medical providers to accurately assess burn severity, adequately treat burns, mitigate and/or treat burn-associated complications, and prevent progression of burn depth. Enhancing the ability to provide high-quality burn care at the point of injury and during the early, acute phase of care is expected to shorten the time to recovery and facilitate the physical and psychological health and well-being among burn-injured Service Members, with the potential for benefit among Veterans, military beneficiaries, and the American public. Within this context, the MBRP is interested in research proposals that address specific gaps in the area of military-relevant burns. Proposed research must address at least one of the following FY24 MBRP Focus Areas:

- **Atypical Burns:** Development and/or validation of methods to assess, treat, and/or prevent the progression of burns resulting from cold exposure, radiation, directed energy, chemical, or high voltage/combat-related electrical injuries.
- **Burn Knowledge Products:** Research to innovate best practices in the acute burn care continuum.
- **Burn Injury-Related Complications:** Development and/or validation of methods to prevent, assess, and/or treat burn injury-related complications including:
    - Over/under fluid resuscitation to include limited or low volume resuscitation
    - Acute respiratory distress syndrome (ARDS)
    - Sepsis
    - Inhalation injuries
    - Peripheral neuropathy
    - Chronification of pain (prevention only)

In order to meet the MBRP mission to "identify and close gaps in combat burn trauma care through military-focused research," the program is providing a list of MBRP research priorities, herein referred to as Areas of Encouragement, to assist researchers in developing highly relevant proposals. The Areas of Encouragement were developed to compliment the FY24 MBRP Focus Areas. The Areas of Encouragement were identified by the FY24 MBRP Programmatic Panel as high priority capability and knowledge gaps. ***Although applicants are not required to address***

any Area of Encouragement from the list below, the program encourages applicants to read and consider the Areas of Encouragement before preparing their applications.

Areas of Encouragement:

- Development or use of existing military-specific burn registries or informatics systems to characterize incidence, injury patterns, treatments, and outcomes. Military frostbite data are of particular interest.
- Methods to improve patient outcomes through effective training techniques in military-specific burn care, especially among non-specialist burn providers such as medics/corpsmen/paramedics (e.g., clinical validation of novel high-fidelity burn simulation aides on learning outcomes).
- Clinical evaluation of a combination burn wound care product that prevents infection, burn progression, and pain, and enhances healing through replacement or repair of the epidermis or dermis and that can be used at the point-of-injury or soon thereafter.
- Clinical evaluation of point-of-injury and/or early acute burn wound care products that can be used in delayed care scenarios for at least 5 days.
- Expanded, novel indications for U.S. Food and Drug Administration (FDA)-approved medical products to achieve burn relevance.
- Studies that test the safety and efficacy of frostbite treatment in a delayed evacuation field environment.
- Evaluation of therapeutics that mitigate burn-associated acute respiratory distress syndrome (ARDS) and/or refractory hypoxemia.
- Clinical research focused on burn wounds and/or burn lung injury from closed-space fires.
- Testing the safety and/or efficacy of medical countermeasures to prevent, or reduce the severity of, frostbite, steam, radiation, or directed energy burns (excludes clothing, or clothing-like products).
- Advanced, shelf-stable allografts for large surface area burns to be used and stored in austere conditions.
- Testing of advanced allografts or skin substitutes that reduce immunogenicity in order to eliminate or reduce autograft need.
- Testing of donor site sparing technologies for autografting.
- Testing of treatments or technologies to reduce neuropathy, neuralgia, and/or pruritis related to burn-associated peripheral nerve damage.
- Collaborative studies that align civilian and military burn research.

II.A.2. Award History

The MBRP Patient-Centered Research Award (PCRA) mechanism is offered for the first time in FY24.

II.B. Award Information

Maturing research ideas into clinical practice and patient benefit is at the heart of all CDMRP research programs. Despite significant investment, the gap between what is possible and what is achieved remains. Even after information, tools, and interventions have been successfully evaluated in their intended populations, the development of knowledge to support their broader dissemination and implementation has often remained outside the scope of previous clinically focused award mechanisms.

The FY24 MBRP PCRA intends to bridge the gap between research, practice, and policy by building a knowledge base that provides clinically useful findings about how interventions, clinical practices/guidelines, tools, and policies can be deployed to targeted populations at the appropriate time at the point of need. ***Funding from this award mechanism must support clinical research or clinical trials but cannot be used for preclinical or animal research.*** Applications may propose prospective or retrospective research involving human subjects, human subject data/records, and human anatomical substances.

The FY24 PCRA may support studies focusing on the following (not all inclusive):

- Research that accelerates the uptake and implementation of evidence-based research into clinical practice
- Comparative effectiveness research comparing the benefits and harms of emerging or established interventions and strategies to prevent, diagnose, treat, and monitor health conditions in "real-world" settings
- Development and evaluation of strategies to overcome barriers to the adoption, adaptation, integration, scale-up, and sustainability of evidence-based interventions, tools, policies, and guidelines
- Analysis of existing clinical data or clinical data resources to inform clinical practice
- Modification of established clinical tools for their intended population or environment
- Analysis of existing clinical tools to maximize patient-relevant outcomes
- Identification and analysis of the circumstances that create a need to stop or reduce ("de-implement") the use of interventions, tools, policies, and guidelines that are ineffective, unproven, low-value, or harmful
- Analysis of burn outcomes associated with the implementation of clinical practice guidelines, evidence-based practices, and process improvements

The following are important aspects of the FY24 MBRP PCRA:

- **Precision Medicine Approaches:** When appropriate, the MBRP encourages the use of precision medicine approaches. These tailored treatments deliver the right treatment at the right time while considering an individual's unique characteristics.

- **Preliminary data are required:** Inclusion of preliminary data relevant to the proposed clinical research/trial is required.

- **Study Population:** The application should demonstrate the availability of and access to a suitable patient population that will support a meaningful outcome for the study. The application should include a discussion of how accrual goals will be achieved, as well as the strategy for inclusion of women and minorities in the clinical trial appropriate to the objectives of the study. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

- **Clinical Trial Start Date:** If applicable, the proposed clinical trial is expected to begin no later than 6 months after the award date.

- **Intervention Availability:** If applicable, the application should demonstrate the documented availability of and access to the drug/compound, device, and/or other materials needed, as appropriate, for the proposed duration of the study.

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

Applications involving multidisciplinary collaborations among academia, industry, the military Services, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

Impact: The overall impact of the proposed research is a key component of this award mechanism. High-impact research will, if successful, lead to the clinical implementation of therapeutics, technologies, or clinical practice guidelines that advance the care of burn-injured casualties.

Relevance to Military Health: Relevance to the health care needs of burn-injured military Service Members is a key feature of this award.

Use of DOD or VA Resources: If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

Applicants are encouraged to integrate and/or align their research projects with DOD and/or VA research laboratories and programs. Collaboration with DOD or VA investigators is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 2.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human data,

human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of application submission is ***not*** required; however, local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of ***all required and complete*** documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the OHARO web page https://mrdc.health.mil/index.cfm/collaborate/research_protections for additional information.

If the proposed research involves more than one institution, a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution 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.

The types of awards made under the program announcement will be assistance agreements. An assistance agreement can take the form of a grant or cooperative agreement. The level of government involvement during the project's period of performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial government involvement" is anticipated, a grant will be made (31 USC 6304). Conversely, if "substantial government involvement" is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement means that members of the U.S. government will assist, guide, coordinate, or participate in project activities.

The award type, along with the start date, will be determined during the negotiation process.

The anticipated total costs budgeted for the entire period of performance for an FY24 MBRP Patient-Centered Research Award should not exceed **$2.2M**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately $4.4M to fund approximately two Patient-Centered Research Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer 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 FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

Extramural Organization: An eligible non-DOD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible organizations, not to individuals.

Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator

PIs at or above the level of Assistant Professor, or an independent investigator within the biomedical industry, may be named by the organization as the PI on the application.

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

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

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 to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or full application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

II.D.1. Location of Application Package

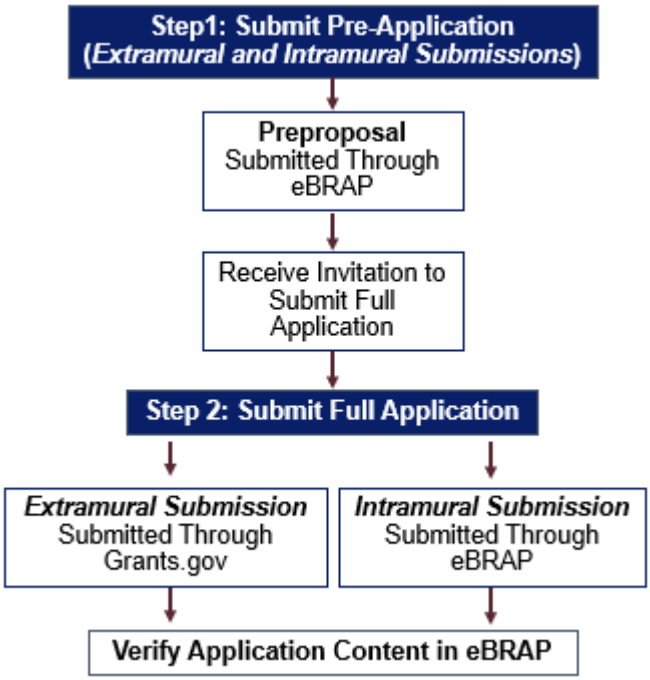
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a

DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524MBRPPCRA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524MBRPPCRA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

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

Submitting applications that 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).

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 MBRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/).

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, 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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for additional information on pre-application submission):

Note: Upload documents as individual PDF files unless otherwise noted.

- **Preproposal Narrative (two-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:

  - **Research Idea:** State the ideas and reasoning on which the proposed work is based. If applicable, state the intervention to be tested and indicate the phase of clinical trial and/or class of device (if applicable). State how the research addresses an important problem relevant to military burn injuries. Describe how the proposed study addresses an unmet need. Explain how the study results could help meet the needs of burn injured military Service Members.

  - **Research Strategy:** State the hypothesis to be tested and/or the objective(s) to be reached. Briefly describe the study design and methodology. Concisely state the scientific rationale, the preliminary findings that support the proposed study.

  - **Focus Area:** Describe how the proposed project addresses at least one of the FY24 MBRP Focus Areas.

  - **Transition Plan:** Briefly describe how the anticipated outcomes will support the translation of promising clinical findings into clinical application.

  - **Impact:** Describe the potential short-term and long-term impact of the results of the proposed study to one or more of the FY24 MBRP Focus Areas. Describe how the proposed project, if successful, will represent an improvement over current clinical care of burn-injured patients.

  - **Relevance to Military Health:** Describe (1) how the project addresses military-relevant burn injury; (2) how the therapy, technology, or knowledge gained from the proposed research addresses a military need; and (3) the role(s) of care within which the proposed study intervention or product is intended (e.g., prolonged field care, pre-hospital, emergency department, full-service hospital).

- **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.

II.D.2.a.ii. Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) and the MBRP, pre-applications will be screened based on the following criteria:

- **Clinical Research Product:** How well the proposed project addresses at least one of the FY24 MBRP Focus Areas. How well the pre-application addresses an important problem relevant to military burn injuries and addresses an unmet need. Whether the project is based on promising preclinical findings, sound scientific rationale, and demonstrated proof of concept.

- **Research Strategy:** How well the specific aims and proposed methodology support the research hypothesis and/or objectives and the development of the product.

- **Impact:** To what degree the research will result in improvements in the care of burn injuries. Whether the potential short-term and long-term outcomes (knowledge and/or materiel) of the proposed research, if successful, will impact a critical problem or question in the field of research and/or patient care within one or more of the FY24 MBRP Focus Areas.

- **Military Relevance:** How well the research will address military-relevant burn injuries; how well the therapy, technology, or knowledge gained from the proposed research could be implemented to address a military need; and the ability to use the proposed product within a military care environment (e.g., prolonged field care, pre-hospital, emergency department, full-service hospital).

II.D.2.a.iii. Notification of Pre-Application Screening Results

Following the pre-application screening, PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section I, Overview of the Funding

Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations ***must*** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

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

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

Each application submission must include the completed full application package for this program announcement. See Section II.H.3 of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B, for detailed information.

(b) 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 2.

- **Attachment 1: Project Narrative (15-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 (uniform resource locators)

that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

- **Background:** Describe how the proposed research project addresses at least one of the FY24 MBRP Focus Areas. Describe in detail the scientific rationale for the study. Provide a literature review and analysis. Describe the preliminary studies and/or preclinical data that led to the development of the proposed study. Provide a summary of other related ongoing, planned, or completed clinical research and describe how the proposed study differs. Describe how the proposed study improves upon current standards of care. 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. This section should establish the relevance of the study and explain the applicability of the proposed research outcomes to the relevant populations.

- **Hypothesis/Objective:** Clearly state the hypothesis to be tested, a purpose statement, and the objective(s) to be reached.

- **Specific Aims:** Concisely explain the project's specific aims. These aims should agree with the primary aims and associated tasks described in the Statement of Work (SOW). If the proposed work is part of a larger study, present only aims that this DOD award would fund.

- **Research Strategy and Feasibility:** Describe the proposed research strategy and feasibility of the approach, addressing the following:

    - Describe the study design (experimental, quasi-experimental, etc.), methods, and analyses, including appropriate controls, in sufficient detail for analysis and which support the specific aims.

    - Provide a well-developed, well-integrated research strategy that supports the translational feasibility, appropriateness, and promise of the approach.

    - Define the specific study outcomes and how they will be measured.

    - Describe the availability of and access to the necessary study resources.

    - Explain how the study is designed to achieve reproducible and rigorous results, including (if applicable) controls, sample size estimation, blinding, randomization, and data handling.

    - Describe human subject protection considerations including ethics approval and planned consent process.

- Describe data collection and handling, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, and identification of primary endpoints/outcomes.

- Clearly describe the statistical plan and the rationale for the statistical methodology.

- Provide a sample size estimate and the method by which it was derived, including power analysis calculation, if applicable.

- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, or international regulatory agency, if applicable.

- Address potential problems and present alternative methods and approaches.

- Describe how the research project will be completed within the proposed period of performance.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. 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.

  - **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 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 articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support (one-page limit per letter):** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. 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):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- **Intellectual Property:** Information can be found in the 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.

  - **Commercialization Strategy *(if applicable)*:** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions 3200.12. ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page

https://ebrap.org/eBRAP/public/Program.htm for more information about CDMRP's 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 populations and/or DOD resources or databases.

- **Use of VA Resources *(if applicable)*:** Provide a letter of support signed by 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, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization 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.*** 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:** Present the ideas and rationale behind the proposed research, including how it addresses one or more FY24 MBRP Focus Areas.

  - **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.

  - **Specific Aims:** State the specific aims of the study.

  - **Study Design:** Describe the study design, including appropriate controls.

  - **Impact and Military Relevance:** State briefly how the proposed project, if successful, will have an impact on the burn research field and/or the care of burn-injured patients and how the research will ultimately improve the lives of burn patients. State the role(s) of care within which the proposed study intervention or product is intended (e.g., prolonged field care, pre-hospital, emergency department, full-service hospital). Note any DOD or VA collaborations.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other

non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

Lay abstracts should be written using the outline below.

- Describe the objectives and rationale for the proposed study in a manner ***readily understood by readers without a background in science or medicine***.

- Clearly describe the critical problem or question to be addressed and the ultimate applicability and impact of the research. ***Do not duplicate the technical abstract.*** Consider the following:

  - How will one or more of the FY24 MBRP Focus Areas be addressed?

  - Describe how the results of the proposed project will ultimately benefit burn-injured Service Members, Veterans, and/or the general public.

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

  - For the MBRP PCRA mechanism, refer to either the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" or "Example: Assembling a Generic Statement of Work" for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6 *(Required for research that includes an intervention)*: Intervention (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 and clinical and/or operational needs, as it relates to the selected FY24 MBRP Focus Area. State where along the military and civilian pathway of care the proposed intervention will be applied. Describe how the intervention addresses clinical needs and how it compares with currently available interventions and/or standards of care. As applicable, the description of the intervention should include the following components: complete name of the investigational product, storage and handling information, source, dose, schedule, administration route, and duration of the intervention. Description of devices should include general concept of design, 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. Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).

- **Study Procedures:** Describe the interaction with the human subject, including the study intervention that they 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) guidelines, Good Manufacturing Practices (GMP), and other regulatory considerations will be established, monitored, and maintained, as applicable. Describe specimens to be collected, schedule, and amount. The collection schedule and estimated amount of material collected must also be clearly described. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects). Describe specimen storage, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to either discard specimens or store for future use, including considerations for informed consent and providing human subjects with an opportunity to decline participation in the study. Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

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

- **Attachment 7: Human Subject Recruitment and Safety Procedures (no page limit): Upload as "HumSubProc.pdf".** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.

  - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site, and describe the efforts that will be made to achieve accrual goals. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a

mitigation plan for slow or low enrollment or poor retention. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender.

  - If a military population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of using the population(s). For clinical trials proposing to include military personnel, refer to the General Application Instructions, Appendix 1, for more information.

  - If a non-military population will be used for the proposed research project, explain how the population represents a military population, or how statistical analysis incorporates subgroup analysis for populations representative of the military population.

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

- **Women and Minorities in the Study:** Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Describe the strategy for the inclusion of women and minorities in the clinical trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

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

  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.

- If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan.

- Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

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

  - For the proposed study, provide a draft, in English, of the Informed Consent Form.

  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.

  - Include information regarding the timing and location of the consent process.

  - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.

  - Address how privacy and time for decision-making will be provided and whether the potential human subject will be allowed to discuss the study with anyone before making a decision.

  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.

  - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. ***Note:*** In compliance with 10 USC 980 (https://www.govinfo.gov/content/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf), the application must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial. If applicable, refer to the General Application Instructions, Appendix 1, for more information.

  - Assent: If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.

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

- **Risks Assessment:**

  - Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is exposed to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. Consider how the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

  - Risk management and emergency response:

    - Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and Regulatory Agency (if applicable) will be managed and conducted.

    - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.

    - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.

    - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).

    - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.

- **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.

- **Attachment 8: Questionnaires and Other Data Collection Instruments, if applicable (no page limit): Upload as "DataCollection.pdf".** The Questionnaires and Other Data

Collection Instruments attachment should include a copy of the most recent version of 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 9: 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 investigational product/device name.

  For products/interventions, or non-interventional studies, that do not require regulation by the FDA

  - Explain why the product/intervention/proposed research 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 Attachment 9 is required if the proposed study does not require regulation by the FDA

  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 proposing a clinical trial that involves the use of a drug that has not been approved by the FDA for the proposed investigational use, 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 1 month (30 calendar days) 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/approvalapplications/investigationalnewdrugindapplication/default.htm. The government reserves the right to withdraw funding if an IND application has not been submitted to the FDA or international regulatory agency within 1 month (30 calendar days) of the award date.

- If the investigational product is a device, evidence that an Investigational Device Exemption (IDE) application that meets all requirements under 21 CFR 812 has been submitted to the FDA or international regulatory agency, if applicable, ***within 1 month (30 calendar days) of the award date***, or that the device is exempt or qualifies for an abbreviated IDE, is required. 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. The government reserves the right to withdraw funding if an IDE application has not been submitted to the FDA or international regulatory agency within 1 month (30 calendar days) 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 or international regulatory agency, if applicable.

- 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 1 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 or international regulatory agency, if applicable**,** meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines. For investigator-sponsored regulatory applications (e.g., IND, IDE), include evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA or international regulatory agency.

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

- **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 or international regulatory agency, if applicable, 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 (e.g., statistical expertise, expertise in burn care, and clinical studies), including previous interactions with the FDA or international regulatory agency, if applicable. A study coordinator(s) should be included. Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable).

- **Attachment 11: 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 or international regulatory agency, if applicable).

- 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 12: Impact and Military Relevance Statement (three-page limit): Upload as "MilBen.pdf".**

  - Describe the short- and long-term impact of this study and how it will make an impact on the lives of individuals who sustain military-relevant burn injuries.

  - Indicate whether the proposed burn care solution will require minimal, moderate, or substantial training for use.

  - Provide information about the incidence and/or prevalence of the research subject condition in military Service Members.

  - Describe how the product or intervention represents an improvement over currently available interventions and/or standards of care.

  - Identify where along the phase of care the proposed product or intervention will be applied and how the results of the proposed research address a military need within that phase of care.

  - Describe how the proposed study has the potential to improve the standard of care for military relevant burn injuries.

- **Attachment 13: Representations *(Extramural Submissions Only)*: Upload as "RequiredReps.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 8, Section B, Representations.

- **Attachment 14: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire

period of performance for each intramural DOD site and include a budget justification as instructed. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (6-page limit):** Upload as "Biosketch_LastName.pdf".
- **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".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 14.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, 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. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. 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 full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/content/home) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

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.

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity.

II.D.5. Funding Restrictions

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

The application's total costs budgeted for the entire period of performance should not exceed **$2.2M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the 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 costs for the PI to present project information or disseminate project results at one DOD-sponsored meeting (the Military Health System Research Symposium or an MBRP-specific meeting) in Year 3 or 4 of the period of performance. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Support for multi-institutional collaborations, including single IRB costs (if applicable).
- Travel costs for one investigator to travel to one scientific/technical meeting per year, in addition to the required meeting described above, to disseminate project results from the FY24 MBRP PCRA.

Must not be requested for:

- Animal research costs
- Costs for travel to scientific/technical meeting(s) beyond the limits stated above
- Tuition

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 funds 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*.**

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, 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 individually evaluated according to the following **scored criteria**, which are listed in decreasing order of 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 designed the study aims, hypotheses and/or objective(s), experimental design, methods, data collection procedures, and analyses are 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.
    - To what degree the recruitment plan will meet the needs of the proposed clinical study.
    - Whether plans for initiating the clinical research within 6 months are described.
    - How well potential problems (including slow accrual and attrition) are acknowledged and alternative approaches are addressed.
    - To what degree the data collection instruments (e.g., questionnaires), if applicable, are appropriate to the proposed study.
    - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
- **Impact and Military Relevance**
    - To what degree the proposed study population represents the target population that would benefit from the study as it relates to one or more of the FY24 MBRP Focus Areas.
    - How well the proposed study would impact the lives of individuals who sustain military-relevant burn injuries in both the short term and long term.
    - To what degree the proposed product or burn-care solution requires training for use (if applicable).
    - How well how the product or intervention represents an improvement over currently available interventions and/or standards of care.
    - To what degree the proposed research places emphasis on military-relevant burn injuries.
    - Whether incidence and/or prevalence of the problem supports the need for the proposed solution.
    - How well the results of the proposed research address a military need within Roles 1-3 of the military pathway of care.

- To what degree the proposed research improves the standard of care for management of military relevant 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 clearly delineated the research procedures are 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 or international regulatory agency, if applicable, regulation, or, for products or interventions that require FDA or international regulatory agency, if applicable, 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 or international regulatory agency, if applicable) 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 or international regulatory agency, if applicable.

- **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.

  - How well the data management plan describes how data will be collected, managed, reported, and analyzed.

  - 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.

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 accessibility of institutional resources support the clinical research at each participating center or institution (including collaborative arrangements).
    - Whether there is evidence for appropriate institutional collaboration from each participating institution (if applicable).
- **Budget**
    - Whether the **total** costs exceed 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 priorities of the DHP and FY24 MBRP, as evidenced by the following:
    - Adherence to the intent of the funding opportunity
    - Program portfolio composition
    - Relative impact and military relevance

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, USAMRDC. ***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.health.mil/about/2tierRevProcess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution 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 a 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 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. 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.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the MBRP award mechanisms.

The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. 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 (i.e., assistance agreement).***

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 7, Section F, for general information on organization or PI changes.

II.F.3. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, 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 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions for further information.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC OHARO, prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee, IRB, or EC review. Refer to the General Application Instructions, Appendix 6, for additional information.

II.F.4. Reporting

Annual technical progress reports and quad charts as well as a final technical progress report and quad chart will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

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 eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

PHS Inclusion Enrollment Reporting Requirement (only required for clinical research studies and clinical trials): Enrollment reporting on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (https://ebrap.org) in eBRAP.

Awards resulting from this program announcement may entail 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 $10M are required to provide information to SAM 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. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

Phone: 800-518-4726; International 1-606-545-5035

Email: support@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 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

After receipt of pre-applications or full 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 full application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Intervention (Attachment 6) is missing*, for applications proposing experimental research*.

- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the full application:

- An FY24 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, including letters of support/recommendation. ***A list of the FY24 MBRP Programmatic Panel members can be found at https://cdmrp.health.mil/mbrp/panels/panels24***.
- 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.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).
- 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.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.

- The proposed project includes animal research.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The invited application proposes a different research project other than that described in the pre-application.
- The PI does not meet the eligibility criteria**.**

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. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Intervention – Attachment 6, upload as "Intervention.pdf"	☐
Human Subject Recruitment and Safety Procedures – Attachment 7, upload as "HumSubProc.pdf"	☐
Questionnaires and Other Data Collection Instruments *(if applicable)* – Attachment 8, upload as "DataCollection.pdf"	☐
Regulatory Strategy – Attachment 9, upload as "Regulatory.pdf"	☐
Study Personnel and Organization – Attachment 10, upload as "Personnel.pdf"	☐
Transition Plan – Attachment 11, upload as "Transition.pdf"	☐
Impact and Military Relevance Statement – Attachment 12, upload as "MilBen.pdf"	☐
Representations (Extramural submissions only) – Attachment 13, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form (if applicable) – Attachment 14, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐
Budget *(Intramural submissions only)* Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ARDS	Acute Respiratory Distress Syndrome
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
ICH 36	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
LAR	Legally Authorized Representative
M	Million
MBRP	Military Burn Research Program
MIPR	Military Interdepartmental Purchase Request
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
PCRA	Patient-Centered Research Award
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management

SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. 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 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 within the FY24 MBRP Focus Areas.

Air Force Office of Scientific Research
https://www.afrl.af.mil/AFOSR/

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

Armed Forces Radiobiology Research Institute
https://afrri.usuhs.edu/home

Combat Casualty Care Research Program
https://cccrp.health.mil/Pages/default.aspx

Congressionally Directed Medical Research Programs
https://cdmrp.health.mil/

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

Defense Health Agency
https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/

Defense Suicide Prevention Office
https://www.dspo.mil/

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

Defense Threat Reduction Agency
https://www.dtra.mil/

Military Health System Research Symposium
https://mhsrs.health.mil/sitepages/home.aspx

Military Infectious Diseases Research Program
https://midrp.health.mil/

Military Operational Medicine Research Program
https://momrp.health.mil/

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

Naval Health Research Center
https://www.med.navy.mil/Naval-Medical-Research-Command/R-D-Commands/Naval-Health-Research-Center/

Navy and Marine Corps Public Health Center
https://www.med.navy.mil/Navy-and-Marine-Corps-Force-Health-Protection-Command/

Naval Medical Research Command
https://www.med.navy.mil/Naval-Medical-Research-Command/

Office of Naval Research
https://www.med.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

U.S. Army Aeromedical Research Laboratory
https://usaarl.health.mil/

U.S. Army Combat Capabilities Development Command
https://www.army.mil/devcom

U.S. Army Institute of Surgical Research
https://usaisr.health.mil/

U.S. Army Medical Materiel Development Activity
https://usammda.health.mil/

U.S. Army Medical Research and Development Command
https://mrdc.health.mil/

U.S. Army Medical Research Institute of Infectious Diseases
https://usamriid.health.mil/

U.S. Army Research Institute of Environmental Medicine
https://usariem.health.mil/

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

U.S. Army Sharp, Ready and Resilient Directorate
https://www.armyresilience.army.mil/sharp/index.html

U.S. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.health.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://wrair.health.mil/