Program Announcement for the Department of Defense
Defense Health Program

Military Burn Research Program
Patient-Centered Research Award

Funding Opportunity Number: HT942525MBRPPCRA

Pre-Application Due: June 23, 2025

Application Due: September 8, 2025

This program announcement must be read in conjunction with the General Application Instructions, version CD25_01.

Content

Before You Begin

- **Active SAM.gov, eBRAP.org, and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read the funding opportunity announcement in the order it is written before beginning to prepare application materials**. It is the responsibility of the applicant to determine whether the proposed research meets the intent of the funding opportunity and that all parties meet eligibility requirements.

Who to Contact for Support

eBRAP Help Desk

301-682-5507
help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Contact Center

800-518-4726
International: 1-606-545-5035
support@grants.gov

Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing Alt + left arrow key (Windows) or command + left arrow key (Macintosh) on your keyboard.

1. Basic Information About the Funding Opportunity

Summary: Despite significant research investment in combat-relevant burn care, a disparity exists between newly discovered knowledge in burn care and its implementation into clinical practice in the distributed operational battlespace. The fiscal year 2025 (FY25) Military Burn Research Program (MBRP) Patient-Centered Research Award (PCRA) seeks to bridge the gap between research, practice, and policy by developing a knowledge base that provides clinically useful findings about how interventions, clinical practices, guidelines, tools, and policies can be deployed to burn patients in an austere, resource-limited, distributed operational environment at the point of need.

Distinctive Features: Funding from this award mechanism ***must support clinical research or clinical trials but cannot support preclinical or animal research***. Applications may propose prospective or retrospective research involving human subjects or human subject data***.***

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $3.4 million (M) to fund approximately 2 Patient-Centered Research Award applications with total cost caps of $1.7M. The maximum period of performance is 4 years. It is anticipated that awards made from this FY25 funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 23, 2025
- **Invitation to Submit an Application:** July 18, 2025
- **Application Submission Deadline:** 11:59 p.m. ET, September 8, 2025
- **End of Application Verification Period:** 5:00 p.m. ET, September 15, 2025
- **Peer Review:** October 2025
- **Programmatic Review:** January 2026

Announcement Type: Initial

Funding Opportunity Number: HT942525MBRPPCRA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural organizations are eligible to apply***, including foreign and domestic organizations, for-profit and non-profit organizations, and public or private entities***.

Extramural Organization: An eligible non-Department of Defense (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.

2.1.2. Principal Investigator

Organizations may name Principal Investigators (PIs) at or above the level of Assistant Professor or an independent investigator within the biomedical industry 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.

Individuals affiliated with an eligible organization are eligible to be named as PI regardless of ethnicity, nationality, or citizenship status.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP at the U.S. Army Medical Research and Development Command (USAMRDC) is the program office managing this FY25 funding opportunity as part of the MBRP. Congress initiated the MBRP in 2011 to address the medical needs of traumatically burn-injured military Service Members. Appropriations for the MBRP from FY11 through FY24 totaled $120M. The FY25 appropriation is $10M.

Burn injuries sustained by military Service Members while in the line of duty, whether in the military operational battlespace or in a military training environment, represent a continuous health burden on both the injured Service Member and the DOD health care systems in which they receive care. Historically, burn injuries afflicted between 5% to 20% of casualties during post-World War II conflicts.[1] In more recent conflicts, burn injury affected 9% to 10% of combat casualties,[2,3,4] and 20% of those burn injuries are characterized as severe.[4] 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 additional formidable threats to the health and well-being of Service Members. Regardless of mechanism, combat-associated burn injuries are often devastating due, in part, to the high incidence of concomitant severe traumatic injuries. In addition, burns sustained in a combat environment are more likely to progress to a deeper wound, become infected, and lead to additional complications than burn injuries treated in the civilian setting. The majority of combat burn injuries in recent conflicts resulted from explosive device detonation, leading to a greater Injury Severity Score, an increase in inhalation injuries, and deeper, larger burns.[3] Military planners anticipate that future conflicts will include more powerful weaponry than that seen in the past,[5] likely resulting in a higher number of casualties with significant traumatic injuries and larger, more severe burns. Furthermore, compromised evacuation capabilities and interruptions to the medical supply chain could extend battlespace burn care from days to weeks thereby increasing the risk of negative clinical outcomes. Accurate burn wound assessment and proper treatment of burn wounds and associated complications in a prolonged distributed operational care environment remain difficult. Burn researchers are challenged to innovate, develop, refine, and test novel burn therapies, technologies, and/or clinical guidelines that facilitate delivery of high-quality burn care in an austere, resource-limited, distributed operational environment for the improvement of both short- and long-term outcomes.

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[1]David S. Kauvar et al, “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, no. 4 (2009): 453-60, https://doi.org/10.1016/j.jamcollsurg.2009.06.367.

[2]Sandra M. Escolas et al, “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, no. 1 (2015): e158-64, https://doi.org/10.1097/BCR.0000000000000319.

[3]David S. Kauver et al, “Comparison of Combat and Non-Combat Burns From Ongoing U.S. Military Operations,” *The Journal of Surgical Research* 132, no. 2 (2006): 195-200, https://doi.org/10.1016/j.jss.2006.02.043.

[4]Kevin K. Chung et al., “Evolution of Burn Resuscitation in Operation Iraqi Freedom,” *Journal of Burn Care & Research* 27, no. 5 (2006): 606-11, https://doi.org/10.1097/01.BCR.0000235466.57137.f2.

[5]“Global Trends 2040: The Future of the Battlefield,” Office of the Director of National Intelligence, National Intelligence Council, last modified March 2021, https://www.dni.gov/index.php/gt2040-home/gt2040-deeper-looks/future-of-the-battlefield.

In order to improve short- and long-term outcomes in combat burn casualties, an urgent need exists to bridge the gap between existing knowledge and its implementation into clinical practice in a combat health care environment.

3.1. Award History

The MBRP first offered the Patient-Centered Research Award mechanism in FY24. In response, the MBRP received 22 Patient-Centered Research Award applications, and recommended one for funding.

3.2. Intent of the Patient-Centered Research Award

Robust information, tools, and interventions have been successfully evaluated within the civilian burn care setting, but the development of knowledge to support their broader dissemination and implementation into combat burn care has often remained outside the scope of previous clinically focused award mechanisms. The FY25 MBRP PCRA seeks 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 burn patients in an austere, resource-limited, distributed operational environment at the point of need. A disparity exists between the development and discovery of new knowledge in burn care and its implementation into clinical practice in the combat battlespace.

Funding from this award mechanism must support clinical research or clinical trials but cannot support preclinical or animal research. Applications may propose prospective or retrospective research involving human subjects or human subject data/records.

3.2.1. Focus Areas for the Patient-Centered Research Award

The MBRP seeks to fund research that enhances the ability of non-burn specialists to accurately assess burn severity, adequately treat burns, mitigate and/or treat burn-associated complications, and prevent progression of burn depth in an austere, resource-limited, combat environment. Enhancing the ability to provide high-quality burn care at the point of injury and during the early, acute phase of care within the combat environment is expected to shorten the time to recovery and improve the long-term physical and psychological health and well-being of 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 ability to care for combat burn casualties at, or close to, the point of injury and in the early acute phase of care in a combat environment where evacuation delays are likely and medical resources are limited. Proposed research must address at least one of the following FY25 MBRP focus areas:

- Development and/or validation of methods to prevent, triage, and/or treat cold injury.
- Research to innovate best practices in the acute burn care continuum in a combat setting.
- Development and/or validation of methods that can be used in austere environments to prevent, assess, and/or treat burn injury-related complications including:
    - Over/under fluid resuscitation
    - Endotheliopathy
    - Sepsis
    - Inhalation injuries

- Fungal infections
- Hypermetabolism

- Interventions that can be applied at the time of burn injury or very soon thereafter that will mitigate long-term pain, neuropathy, and temperature dysregulation.

3.2.2. Key Elements for the Patient-Centered Research Award

The following are important aspects of the FY25 MBRP PCRA:

Impact: The overall impact of the proposed research is a key component of this award mechanism. The application must clearly demonstrate the project's potential to impact the care provided to burn casualties in austere, resource-limited, distributed operational environment. High-impact research will, if successful, lead to the development of knowledge to support the broad dissemination and implementation of burn-specific therapeutics, technologies, tools, policies, or clinical practice guidance into combat burn care.

Relevance to Military Health: Relevance to the care of burn-injured military Service Members in an austere, resource-limited, distributed operational environment is a key feature of this award.

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

Study Design Considerations:

- **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, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.
- **Human Participant Enrollment Start Date:** If applicable, enrollment of human study participants is expected to begin no later than six 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.

3.2.3. Other Important Considerations for the Patient-Centered Research Award

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. An ***intervention*** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

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.

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., "A call for transparent reporting to optimize the predictive value of preclinical research," *Nature* 490 (2012): 187-191, https://doi.org/10.1038/nature11556. 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. 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 3. 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.

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 4.3, Full Application Submission Components, for detailed information. Refer to the General Application Instructions, Appendix 4, for additional information.

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 three 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 Research Protections web page 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.

3.3. CDMRP-wide Encouragement

The following encouragement is broadly applicable across many CDMRP programs, including the MBRP. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research and meets the intent of this funding opportunity.

The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

3.4. Funding Instrument

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 involvement on the part of CDMRP during the project's period of performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial involvement" on the part of CDMRP is anticipated, a grant will be made (31 USC 6304). Conversely, if "substantial involvement" on the part of CDMRP is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement means that, after award, CDMRP staff will assist, guide, coordinate, or participate in project activities including but not limited to:

Include the specific activities CDMRP staff are anticipated to participate in. The following are only examples of potential involvement activities:

- Participating in the Steering Committee that oversees study conduct.
- Making recommendations for continued funding based on: (a) overall study progress, including sufficient patient and/or data accrual; (b) cooperation in carrying out the research (e.g., attendance at Steering Committee meetings, implementation of group decisions, compliance with the terms of award and reporting requirements); and/or (c) maintenance of a high quality of research.

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

3.5. Funding Details

Period of Performance: The maximum period of performance is **4** years.

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$1.7M**. 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.

The appropriateness of the budget for the proposed research will be assessed during peer review.

Direct Cost Restrictions: For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Support for multi-institutional collaborations, including single IRB costs (if applicable).
- Travel costs for one investigator travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY25 MBRP PCRA.
- 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.

Must not be requested for:

- Animal research cost.
- 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.***

4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP) and a ***full application*** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOD organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

4.2. Step 1: Pre-Application Components

Pre-application submissions must include the following components.

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 combat burn care in an austere, resource-limited, distributed operational environment. Describe how the proposed research will address an unmet need in combat burn care.
  - **Research Strategy:** State the hypothesis to be tested and/or the objective(s) to be reached. Briefly describe the preliminary findings that support the proposed study.
  - **Focus Area:** Describe how the proposed project addresses at least one of the FY25 MBRP focus areas.
  - **Impact:** Describe the potential impact of the research, both short term and long term. Describe how the proposed research will lead to the advancement combat burn care at, or close to, the point of injury, or in the early acute phase of care within a combat care environment. Describe how the proposed project, if successful, will represent an improvement over currently available standards of burn care.
  - **Relevance to Military Health:** Describe how the results of the proposed research are expected to be relevant to combat burn care, particularly in an austere, resource-limited, distributed operational environment.
- **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 Narratives 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 (no limit):** ***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.

4.3. Step 2: Full Application 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 Appendix 1 for a checklist of the full application components.

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

IMPORTANT: When completing the SF424 R&R, enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier.

(b) Attachments:

Each attachment of 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 FY25 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. If applicable, provide a summary of similar ongoing, planned, or completed clinical research and describe how the proposed study differs. Describe how the proposed study improves upon current standards of burn care and addresses an important problem relevant to combat burn care in an austere, resource-limited, distributed operational environment. 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/Objectives:** 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, methods, and analyses, including appropriate controls.
  - Describe 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. If human-derived biological specimens will be used, describe the sourcing and/or acquisition of samples. If human-derived specimens will be obtained from military Service Members, military Families, and/or Veteran population(s) or dataset(s), describe the feasibility of accessing the samples/dataset(s).
  - Explain how the study is designed to achieve reproducible and rigorous results, including (if applicable) controls, sample size estimation, power analysis, blinding, randomization, and data handling.
  - Describe the statistical plan and the rationale for the statistical methodology.
  - If applicable, explain how the statistical plan compensates for the use of a subpopulation within the recruited sample population to ensure appropriate power can be achieved within the subpopulation.
  - Describe data collection and handling, including rules for stopping data collection, how outliers will be defined and handled, and identification of primary endpoints/outcomes.
  - Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (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 Support (one-page limit per letter):** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOD collaborator(s) and/or access to military populations, databases, or DOD resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or individual designated by the VA Facility Director(s), confirming access to VA patients, resources, and/or VA research space.
- **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.
- **Sex as a Biological Variable Strategy (two-page limit is recommended):** Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data, or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.
- **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.

– **Data and Research Resources Sharing Plan:** Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe how data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical trial participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial 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. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study. Refer to CDMRP's Policy on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.

○ **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.

Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

– **Background:** Present the ideas and rationale behind the proposed research, including how it addresses one or more FY25 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 how the proposed project, if successful, will have an impact on the burn research field and/or the care of burn-injured combat casualties and how the research will ultimately improve the lives of combat burn casualties. Describe how the results of the proposed project will benefit burn-injured Service Members in an austere, resource-limited, distributed operational environment. Note any substantial 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 address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine***. Avoid overuse of scientific jargon, acronyms, and abbreviations.

- 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. Consider the following:
  - How will one or more of the FY25 MBRP focus areas be addressed?
  - Describe how the results of the proposed project will benefit burn-injured Service Members.

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the "Suggested SOW Format".

  For the FY25 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", whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW.

- **Attachment 6: Intervention (no page limit): Upload as "Intervention.pdf" *(Required for applications proposing clinical trials)*.** 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 FY25 MBRP focus area. State how the intervention represents care provided in an austere, resource-limited, distributed operational environment 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 described with sufficient details for reviewers to understand its nature, intended use, and attributes. 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 anticipated interaction with human study subjects, 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 monitored for compliance with current ICH E6 (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) Good Clinical Practices (GCP) guidelines 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 Subjects Recruitment and Safety Procedures (no page limit): Upload as "HumSubProc.pdf".** The Human Subjects 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).

    - 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.

    - Describe the relevance of the study population as related to combat burn casualties. If a predominantly non-military population will be studied, describe how the intended population represents a surrogate for the military burn population and 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 justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex. 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, 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, 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, race, and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP.

- **Recruitment:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification). 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.
  - Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention.
  - 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.
- **Informed Consent:** Describe human subject protection considerations including ethics approval and planned 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 the 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 subjects (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 reassessing 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, the application must describe a clear intent to benefit 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.

– **Risk 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 attached 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 one 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 this guidance. The government reserves the right to withdraw funding if an IND application has not been submitted to the FDA or international regulatory agency within one 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), nonclinical 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".** Impact should be written in a manner that will be ***readily understood by readers without a background in science or medicine.***
  - Describe the short- and long-term impact of this study and how the proposed research will lead to the advancement combat burn care at, or close to, the point of injury, or in the early acute phase of care within a prolonged combat care environment.
  - Describe how the anticipated burn care solution is compatible for use in an austere, resource-limited, distributed operational environment, whether it will require minimal, moderate, or substantial training for use, and whether it supports prolonged care with delayed evacuation.
  - Describe how the proposed project, if successful, will represent an improvement over currently available standards of burn care.
  - Describe how the proposed research will lead to the development of knowledge to support the broad dissemination and implementation of burn-specific therapeutics, technologies, tools, policies, or clinical practice guidance into combat burn care.
  - If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- **Attachment 13: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the "Required Representations" document that is available on eBRAP. 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 the performance of the project, complete a separate budget for that organization using the "Suggested Intragovernmental/Intramural Budget" form that is available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.

(c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).

(d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and senior/key person's current/pending support information must be attached to the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.

- **Biographical Sketch:** Upload as "Biosketch_LastName.pdf".

  The CDMRP staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.

  Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a

pdf form created in SciENcv for the National Institutes of Health (NIH) or the U.S. National Science Foundation (NSF).

- **Current/Pending Support:** Upload as "Support_LastName.pdf".

  Current and pending (other) support information are used to assess the capacity or any conflicts of commitment that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.

  Current and pending support documentation must conform to the federal wide format. To prepare their Current and Pending Support form, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for NIH or NSF.

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

- **Budget Justification (no page limit):** For instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c), Section L; for eBRAP submissions, refer to General Application Instructions, Section V.B.(c), Budget Justification Instructions.

(f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov Submissions only)*: Refer to the General Application Instructions, Section IV.C.(e), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload it through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward. Combine them into a single document, then upload the file to Grants.gov as an attachment named "IGBudget.pdf".

4.4. Other Application Elements

- If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.
- The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942525MBRPPCRA from Grants.gov or eBRAP, depending on which submission portal will be used.

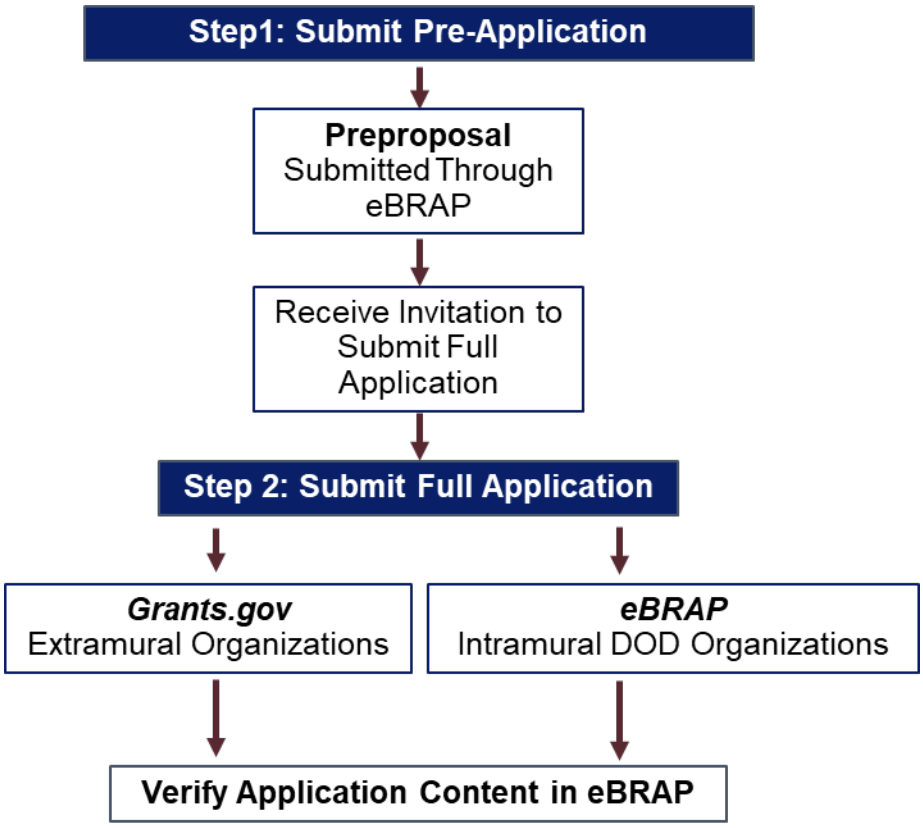
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration. More information regarding SAM registration can be found in the General Application Instructions, Section IV.A.

5.3. Submission Instructions

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

Application Submission Workflow



5.3.1. Pre-Application Submission

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

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.

When starting the pre-application, applicants will be asked to select a "Mechanism Option". Be sure to select the correct option appropriate to your pre-application:

Application Includes:	Select Option:
Observational Clinical Research (or similar)	Patient-Centered Research Award
Clinical Trial with at least one intervention	Patient-Centered Research Award – Clinical Trial

Refer to the General Application Instructions, Section III.A, for considerations and detailed instructions regarding pre-application submission.

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding Grants.gov submissions.

eBRAP Submissions: Only intramural DOD organizations may submit full applications through eBRAP. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding eBRAP submissions.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. 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 the 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 through the appropriate portal 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.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in 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.***

All submission dates and times are indicated in Section 1, Basic Information above.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

6. Application Review Information

6.1. Application Compliance Review

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).

While it is allowable to propose similar research projects to different programs within CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the CDMRP's full position on research duplication.

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.

Members of the FY25 MBRP Programmatic Panel should not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members ***may*** provide letters of support to confirm PI eligibility and access to laboratory space, equipment, and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). ***A list of the FY25 MBRP Programmatic Panel members can be found on the CDMRP website.***

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program 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 FY25 MBRP focus areas. How well the pre-application addresses an important problem relevant to combat burn care in an austere, resource-limited, distributed operational environment and addresses an unmet need in combat burn care. Whether the project is based on promising preliminary findings and sound scientific rationale.
- **Impact:** To what degree the proposed research will lead to the advancement of combat burn care at, or close to, the point of injury, or in the early acute phase of care within a prolonged combat care environment. How well the proposed project, if successful, will represent an improvement over currently available standards of burn care. Whether the potential short-term and long-term outcomes of the proposed research, if successful, will impact a critical problem or question in the field of burn research and/or combat burn care.
- **Military Relevance:** How well the results of the proposed research are expected to be relevant to combat burn care, particularly in an austere, resource-limited environment.

6.2.2. Peer Review Criteria

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 preliminary studies and/or preclinical data that led to the development of the proposed study.
  - 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 proposal 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.
  - To what degree a feasible plan is presented for initiating the clinical research within six months of award.
  - 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.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single-sex study is sufficiently strong.
- **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 FY25 MBRP Focus Areas.
  - How well the proposed study would impact the care of combat burn casualties in the short and long term.
  - To what degree the proposed research will lead to the development of knowledge to support the broad dissemination and implementation of burn-specific therapeutics, technologies, tools, policies, or clinical practice guidance into combat burn care.
  - To what degree the proposed product or burn-care solution requires training for use (if applicable).
  - How well the product or intervention represents an improvement over currently available interventions and/or standards of care.
  - To what degree the proposed research will lead to the advancement of combat burn care at, or close to, the point of injury, or in the early acute phase of care within a resource-limited, prolonged combat care environment.

- To what degree the proposed research improves upon current standards of burn care and addresses an important problem relevant to combat burn care in a resource-limited, combat environment.
- If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

- **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 represents burn care that can be provided in an austere, resource-limited, distributed operational environment, and endpoints are feasible and clinically meaningful and relevant to patient outcomes.
  - To what degree the intervention addresses the clinical need(s) described in the application.
  - To what degree the intervention addresses combat burn care and how it compares with currently available interventions and/or standards of care.
  - To what degree preliminary evidence is provided to support the safety and stability (if applicable) of the intervention.
  - How clearly delineated the research procedures are from routine clinical procedures.
  - Whether the clinical monitoring plan is appropriate and well-described.
- **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 a product indication or product label change, if applicable, are appropriate and well-described.
  - Whether the plan for IND or IDE application submission to the FDA or equivalent international regulatory agency are appropriate, if applicable.
  - Whether the application includes documentation that the study is exempt from regulation by the FDA or the equivalent international regulatory agency, if applicable.
  - 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.
  - 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 criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **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.
- **Budget**
  - Whether the budget is appropriate for 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).

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

6.2.3. 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 FY25 MBRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity, including alignment to at least one FY25 MBRP Focus Area
  - Program portfolio composition
  - Relative impact and military relevance

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, Initiating 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 1, Basic Information about 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 nor research objectives after the pre-application is submitted.

6.3.2. Full Application

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 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

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.

6.4. Risk, 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.

In accordance with National Security Presidential Memorandum and all associated laws, all fundamental research funded by the DoD must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the OUSD R&E Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

7. Federal Award Notices

For each full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. 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 application receipt 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 additional information about pre-award costs for Grants.gov submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section; and for eBRAP submissions, refer to the General Application Instructions, Section 1.D, Pre-Award Costs section.

8. Post-Award Requirements

8.1. 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.

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.

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 Office of OHARO, prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), IRB, or EC review. Refer to the General Application Instructions, Appendix 6, for additional information.

8.2. Reporting

Annual technical progress reports as well as a final technical progress report 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, using the template available on eBRAP, must be submitted with the final progress report.

PHS Inclusion Enrollment Reporting ***(Required for research proposing clinical research)***: Enrollment reporting on the basis of sex, race, and ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on 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).

8.3. Additional Requirements

Unless otherwise restricted, changes in the PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

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 H, for general information on organization or PI changes.

9. Other Information

9.1. 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 CD25_01c. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

9.2. Administrative Actions

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

9.2.1. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.

The following will result in administrative rejection of the full application:

- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.
- Intervention (Attachment 6) is missing*, for applications proposing clinical trials*.
- Human Subjects Recruitment and Safety Procedures (Attachment 7) is missing.
- Regulatory Strategy (Attachment 9) is missing.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

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

- A member of the FY25 MBRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY25, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website.
- 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) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- 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.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- The proposed project includes animal research.
- The invited application proposes a different research project other than that described in the pre-application.

9.2.4. 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.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance ***(Grants.gov submissions only)***	☐
Summary (Tab 1) and Application Contacts (Tab 2) ***(eBRAP 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 *(if applicable)* – Attachment 6, upload as "Intervention.pdf"	☐
Human Subjects 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 *(Grants.gov 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 Biographical Sketch for PI and Senior/Key Persons ("Biosketch_LastName.pdf")	☐
Attach Current/Pending Support for PI and Senior/Key Persons ("Support_LastName.pdf")	☐
Research & Related Budget **Include Budget Justification**	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐

Appendix 2. Acronym List

ACOS/R&D	Associate Chief of Staff for Research and Development
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DOD	U.S. 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
IACUC	Institutional Animal Care and Use Committee
ICH E6	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
LAR	Legally Authorized Representative
MBRP	Military Burn Research Program
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NSF	U.S. National Science Foundation
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
OUSD R&E	Office of the Under Secretary of Defense for Research and Engineering
PCRA	Patient-Centered Research Award
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
QWERTY	First six letters of the second row of a standard English-language keyboard

RPPR	Research Performance Progress Report
SAM	System for Award Management
SciENcv	Science Experts Network Curriculum Vitae
SF424	Standard Form 424 (Application for Federal Assistance, Research & Related)
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 3: DOD and VA Websites

Collaboration with DOD and/or VA investigators is encouraged. Below is a list of websites that may be useful in identifying additional information about DOD and VA areas of research interest, ongoing research, or potential opportunities for collaboration.

Air Force Office of Scientific Research
https://www.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/

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

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

Defense Health Agency
https://www.dha.mil//

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 Force Health Protection Command
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.onr.navy.mil/

Office of the Under Secretary of Defense for Acquisition and Sustainment
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 Directorate of Prevention, Resilience and Readiness
https://www.armyresilience.army.mil/

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/