

Program Announcement for the Department of Defense Defense Health Program

# Military Burn Research Program Discovery Award

Funding Opportunity Number: HT942525MBRPDA

Pre-Application Due: June 23, 2025

Application Due: September 8, 2025

# Content

	Before You Begin	3
1	Basic Information Contains a <u>summary of the funding opportunity</u> , <u>funding details</u> , and <u>submission/review dates</u>	4
2	Eligibility Details the factors that determine applicant organization and Principal Investigator eligibility	5
3	<b>Program Description</b> Describes the <u>program mission</u> and <u>intent of the Discovery Award</u> , provides <u>key award information</u> and <u>considerations</u> , and outlines <u>funding restrictions</u>	6
4	<b>Application Contents</b> Introduces the two-step <u>application process</u> and provides instructions for preparing a <u>preapplication</u> and <u>full application</u>	11
5	<b>Submission Requirements</b> Provides <u>locations for application packages</u> , instructions for submitting <u>pre-applications</u> and <u>full applications</u> , and describes <u>application verification</u>	19
6	Application Review Information Outlines the processes associated with application compliance review, pre-application and full application selection/notification, and risk assessment. Also details the complete review criteria for pre-application screening and both tiers of the CDMRP's application review process, Peer Review and Programmatic Review	22
7	Federal Award Notices Outlines what a successful applicant can expect to receive if recommended for funding	26
8	Post-Award Requirements References policy requirements for funded research, outlines reporting requirements, and restrictions related to Principal Investigator changes or institutional award transfers	27
9	Other Information Outlines criteria for administrative actions including application <u>rejection</u> , <u>modification</u> , <u>withdrawal</u> and <u>withhold</u>	29
	Appendix 1 Includes a checklist for all full application components to facilitate application submission	31
	Appendix 2 Acronym List	32
	Appendix 3 DoD and VA Websites	33

# **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.

<u>Basic Information</u> | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

# 1. Basic Information About the Funding Opportunity

**Summary:** The fiscal year 2025 (FY25) Military Burn Research Program (MBRP) Discovery Award (DA) Supports innovative, untested, groundbreaking research that provides new insights and explores early concepts in combat-relevant burn care that provides the foundation for future translational and/or clinical research. The proposed project may be exploratory, hypothesis-driven, or hypothesis-generating research but must be novel and must be based on a strong scientific rationale and a well-developed study design.

**Distinctive Features:** The focus of this award mechanism is innovation. Proposed research should lay the groundwork for future avenues of scientific investigation or product development in the area of combat-relevant burn care. The outcome of research supported by this award should be the generation of robust preliminary data that can be used as a foundation for groundbreaking future research projects.

**Funding Details:** The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$800,000 to fund approximately 4 Discovery Award applications with total cost caps of \$200,000. The maximum period of performance is 2 years. It is anticipated that awards made from this fiscal year 2025 (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: HT942525MBRPDA

**Assistance Listing Number: 12.420** 

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

# 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 all academic levels (or industry equivalent) 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.

Basic Information | Eligibility | <u>Program Description</u> | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

# 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 \$120 million (M). 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. In more recent conflicts, burn injury affected 9% to 10% of combat casualties, <sup>2,3,4</sup> and 20% of those burn injuries are characterized as severe. <sup>4</sup> 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 setting for the improvement of both short- and long-term outcomes.

<sup>&</sup>lt;sup>1</sup>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.

<sup>&</sup>lt;sup>2</sup>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.000000000000319.

<sup>&</sup>lt;sup>3</sup>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.

<sup>&</sup>lt;sup>4</sup>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.

<sup>&</sup>lt;sup>5</sup>"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.

Basic Information | Eligibility | <u>Program Description</u> | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

#### 3.1. Award History

This is the first release of the Discovery Award mechanism by the MBRP.

#### 3.2. Intent of the Discovery Award

The FY25 MBRP Discovery Award is intended to support innovative, untested, non-incremental, groundbreaking research that provides new insights, paradigms, technologies, or applications in combat-relevant burn care. The proposed project may be exploratory, hypothesis-driven, or hypothesis-generating research but must be **novel** and must be based on a strong scientific rationale and logical reasoning with a well-developed study design, methodology, and data analysis plan. The MBRP expects studies supported by this award to lay the groundwork for future avenues of scientific investigation or product development for burn care delivered in an austere, resource-limited, distributed combat operational environment. The outcome of research supported by this award should be the generation of robust preliminary data that can be used as a foundation for groundbreaking future research projects.

This award is not intended to support or validate ongoing research; therefore, **inclusion of preliminary data is not required**. The presentation of preliminary data beyond those offering initial insights and supporting new hypotheses suggests that the proposed research project would be more appropriately submitted to a different award mechanism. Applicants seeking funding for research to further an existing research project should consider either the FY25 MBRP Technology/Therapeutic Development Award (HT942525MBRPTTDA) or the Patient-Centered Research Award (HT942525MBRPPCRA).

#### 3.2.1. Focus Areas for the Discovery Award

The MBRP seeks to fund research that enhances the ability to provide burn care in an austere, resource-limited, combat environment. The program seeks to enhance 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. 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 area of military-relevant burns. 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

Basic Information | Eligibility | <u>Program Description</u> | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- 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 Discovery Award

- Innovation: The Discovery Award supports high-risk/high-reward research, and, as such, innovation is the most important review criterion. Innovative research may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, introduce novel concepts or agents, or exhibit other highly creative qualities. Research that represents an incremental advancement on previously published work is not considered innovative.
- Impact: The Discovery Award is designed to lay the groundwork for critical discoveries or
  major advancements in the care of burn-injured combat casualties both short term and long
  term. The application must clearly demonstrate the project's potential to impact the care
  provided to burn casualties in an austere, resource-limited, distributed operational setting.
  The research is expected to result in the development and eventual translation of scientific
  advances in combat-relevant burn care.
- **Relevance to Military Health:** Relevance to the care of burn-injured military Service Members in an austere, resource-limited setting is a key feature of this award.

#### 3.2.3. Other Important Considerations for the Discovery Award

This award mechanism may not be used to conduct clinical trials; however, noninterventional clinical research studies are allowed.

Applicants seeking funding for clinical trials should consider applying to the FY25 MBRP Patient-Centered Research Award program announcement (HT942525MBRPPCRA).

**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.

Basic Information | Eligibility | <u>Program Description</u> | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- (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, <a href="https://doi.org/10.1038/nature11556">https://doi.org/10.1038/nature11556</a>. 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.

**Use of DOD or VA Resources:** Applications involving multidisciplinary collaborations among academia, industry, and the DOD are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families.

If the proposed research 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 <a href="Section 4.3">Section 4.3</a>, <a href="Full Application Submission Components">Full Application Submission Components</a>, for detailed information. Refer to the General Application Instructions, Appendix 4, for additional information.

Pls are encouraged to integrate and/or align their research projects with DOD and/or VA research laboratories and programs. Collaboration with the DOD and/or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in <a href="https://documents.com/appendix3">Appendix 3</a>.

#### 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 funding instrument for awards made under the program announcement will be grants (31 USC 6304).

Basic Information | Eligibility | <u>Program Description</u> | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

#### 3.5. Funding Details

**Period of Performance:** The maximum period of performance is **2** years.

**Cost Cap:** The application's total costs budgeted for the entire period of performance should not exceed **\$200,000**. 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 **2** 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):

Costs for one investigator to travel to one scientific/technical meeting in year two. The intent
of travel to one scientific/technical meeting should be to present project information or
disseminate project results from the FY25 MBRP DA.

Must not be requested for:

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

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

# 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 (<u>eBRAP</u>) 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 elements:

- Innovation: State the ideas and reasoning on which the proposed work is based. Concisely state how the proposed research provides new insights, paradigms, technologies, or applications in combat burn care. State how the research addresses a previously unexplored problem relevant to combat burn care. Describe how the proposed research addresses an unmet need in combat burn care.
- **Research Strategy:** State the hypothesis to be tested and/or the objective(s) to be reached.
- Focus Area: Describe how the proposed project addresses at least one of the FY25 MBRP focus areas.
- Impact: The potential impact of the research, both short term and long term, in addressing one or more of the FY25 MBRP focus areas should be clearly described.
   Describe how the research is expected to result in the development and eventual translation of scientific advances in combat-relevant burn care.
- Military Relevance: Describe (1) how the project addresses military-relevant burn injury; (2) how the knowledge gained from the proposed research addresses a military need; and (3) how the proposed study is relevant to burn care provided in a combat setting.
- 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:

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

 List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

#### 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 <a href="Appendix 1">Appendix 1</a> 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 (four-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.

Describe the proposed project in detail using the outline below.

- Rationale: Clearly articulate the scientific rationale for the proposed research project. Cite relevant literature supporting your rationale. Explain how the project will lead to a new paradigm, challenge current paradigms, look at existing problems from new perspectives, and introduce novel concepts or agents in combat burn care.

  Preliminary data are allowed but not required. The presentation of preliminary data beyond those offering initial insights and supporting new hypotheses suggests that the proposed research project may be more appropriately submitted to a different award mechanism.
- Hypothesis: State concisely the new insights, paradigms, technologies, or applications as related to one or more of the FY25 MBRP focus areas. State if the research is hypothesis-generating rather than hypothesis-driven. If the research is hypothesis-driven, state the hypothesis to be tested. If the research is hypothesis-generating, state the expected hypothesis to be generated if the project is successful.
- Specific Aims: Concisely explain the project's specific aims and the objective(s) to be reached. The aims described in this section should agree with the primary aims and associated tasks described in the Statement of Work (SOW).
- Research Strategy and Feasibility: Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for scientific evaluation. Address potential problem areas and present alternative methods or

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

approaches. If cell lines or animals are to be used, justify why the proposed cell line(s) or animal model(s) were chosen. Describe how the proposed project will be completed within the proposed performance period.

- If animal studies are proposed, describe how they will be conducted in accordance with the <u>ARRIVE guidelines 2.0</u> (Animal Research: Reporting *In Vivo* Experiments).
- If human subjects, human biological samples, or datasets will be used, describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples/datasets. Describe the availability of the proposed study population and past successes in recruiting similar populations. If active-duty military, military Families, and/or Veteran population(s) or dataset(s) will be used in the proposed research project, describe the feasibility of accessing the population(s)/dataset(s). This award may not be used to conduct clinical trials.
- 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 applicable. 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 is recommended): 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

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

VA Facility Director(s), or individual designated by the VA Facility Director(s), confirming access to VA patients, resources, and/or VA research space.

- 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 <a href="CDMRP Directive on Sex as a Biological Variable in Research">CDMRP Directive on Sex as a Biological Variable in Research for additional information.</a>
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Inclusion Enrollment Plan (only required if clinical research is proposed): Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the "Public Health Service (PHS) Inclusion Enrollment Report", a three-page fillable PDF form, that can be downloaded from eBRAP. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race, and ethnicity. 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.
- Use of DOD Resources or VA Resources (if applicable): If the proposed research involves access to military and/or VA patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding, or other agreements required to access and publish data. Refer to the General Application Instructions, Appendix 4, for additional considerations.
- 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.
- Innovation: Briefly describe how the proposed project is innovative and will lead to a new paradigm, challenge current paradigms, look at existing problems from new perspectives, introduce novel concepts or agents, or exhibit other uniquely creative qualities.

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- Impact and Military Relevance: State briefly how the proposed project, if successful, will have an impact on the burn research field and/or the care of burn-injured combat casualties and how the research will ultimately improve the lives of combat burn casualties. Clearly describe the project's potential to impact the care provided to combat burn casualties in an austere, resource-limited, distributed operational setting. 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 ultimately benefit burninjured Service Members, Veterans, and/or the general public.
- Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf". Refer to eBRAP for the "Suggested SOW Format".
  - For the FY25 MBRP Discovery Award, refer to either the <u>"Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work"</u> or <u>"Example: Assembling a Generic Statement of Work"</u>, whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW.
- Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf". The
  Impact Statement should be written in a manner that will be readily understood by
  readers without a background in science or medicine.
  - Describe the FY25 MBRP focus area that is addressed in the proposed research.
  - Outline the potential short- or long-term impact of the proposed research on the care
    of burn-injured combat casualties and how the proposed research will impact the
    care provided to combat burn casualties in an austere, resource-limited, distributed
    operational setting.
  - Describe how the research has the potential to generate preliminary data that can be used as a foundation for future scientific advances in combat-relevant burn care.
  - If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as "MilRel.pdf"
  - Describe how the proposed study is responsive to the health care needs of combat burn-injured military Service Members.

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- If active-duty military, military Families, and/or Veteran population(s) or dataset(s) will be used in the proposed research project, describe the population(s)/dataset(s) and the appropriateness of the population(s)/dataset(s) for the proposed study. If a nonmilitary population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military Service Members, Veterans, and/or their Families).
- If applicable, show how the proposed research project aligns with DOD and/or VA areas of research interest. Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population and address a military need, as appropriate.
- Attachment 8: Animal Research Plan (three-page limit): Upload as "AnimalResPlan.pdf". (Attachment 8 is only applicable and required for applications proposing animal studies.)

If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the <u>ARRIVE guidelines</u> <u>2.0</u> to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why
  the animal species, strain, and model(s) being used can address the scientific
  objectives and, where appropriate, the study's relevance to human biology.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- Attachment 9: 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 10: 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.

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- (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 <a href="SciENcv">SciENcv</a> 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 <u>conflicts of commitment</u> 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.

Basic Information | Eligibility | Program Description | <u>Application Contents and Format</u> | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

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, <u>DoD Instructions 3200.12</u> will be requested.
- The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

Basic Information | Eligibility | Program Description | Application Contents and Format | <u>Submission Requirements</u> Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

# 5. Submission Requirements

#### 5.1. Location of Application Package

Download the application package components for HT942525MBRPDA from <u>Grants.gov</u> or <u>eBRAP</u>, 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), <u>SAM.gov</u>, 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.

# Step1: Submit Pre-Application Preproposal Submitted Through eBRAP Receive Invitation to Submit Full Application Step 2: Submit Full Application Grants.gov Extramural Organizations Verify Application Content in eBRAP

Basic Information | Eligibility | Program Description | Application Contents and Format | <u>Submission Requirements</u> Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

#### 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 preapplication 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.

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

Basic Information | Eligibility | Program Description | Application Contents and Format | <u>Submission Requirements</u> Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

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.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements **Application Review Information** | Federal Award Notices | Post-Award Requirements | Other Information

# 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 <u>CDMRP's full position on research duplication</u>.

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 <u>Section 9.2</u>, <u>Administrative Actions</u>.

#### 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:

- Innovation: The extent to which the proposed research provides new insights, paradigms, technologies or applications in combat burn care. How well the research addresses a previously unexplored problem relevant to combat burn care. Whether the proposed research addresses an unmet need in combat burn care.
- Impact: To what degree the research will result in improvements in the care of burn-injured combat casualties in an austere, resource-limited, distributed operational setting. Whether the potential short-term and long-term outcomes of the proposed research, if successful, will impact the field of burn research and/or combat burn care as related to one or more of the FY25 MBRP focus areas. Whether the research findings are expected to result in the development and eventual translation of scientific advances in combat-relevant burn care.
- Military Relevance: How responsive the proposed research is to the health care needs of burn-injured military Service Members.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements **Application Review Information** | Federal Award Notices | Post-Award Requirements | Other Information

#### 6.2.2. Peer Review Criteria

To determine technical merit, all applications will be individually evaluated according to the following **scored criteria**, which are of listed in decreasing order of importance:

#### Innovation

- To what extent the proposed research will lead to a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or introduce novel concepts or agents in combat burn care.
- Whether the proposed research represents more than an incremental advancement, studies a new avenue of research, and/or addresses new concepts beyond ongoing research.

#### Impact

- To what extent the proposed research addresses one or more <u>FY25 MBRP Focus</u> Areas.
- To what extent the proposed research has potential for short- or long-term impact on the care of burn-injured combat casualties in an austere, resource-limited setting.
- o To what extent the research has the potential to generate preliminary data that can be used as a foundation for future scientific advancement in military-relevant burn care.
- If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

#### Research Strategy and Feasibility

- How well the scientific rationale supports the proposed research project.
- How well the hypothesis, experimental design, methods, and analyses support the feasibility of completing the aims.
- How well the potential problems are identified, and alternative methods or approaches are addressed.
- Whether the proposed research project can be completed within the proposed performance period.
- o If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research. 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.
- 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.
- How well the study is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.
- How well the study is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

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

 How appropriate the expertise and levels of effort are for successful conduct of the proposed work.

#### Budget

Whether the budget is appropriate for the proposed research.

#### Environment

- To what extent the scientific environment and level of institutional support is appropriate for the proposed research project.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources.

#### 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
  - 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, 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 <a href="Section 1">Section 1</a>, Basic Information About the <a href="Funding Opportunity">Funding Opportunity</a>. 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

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements **Application Review Information** | Federal Award Notices | Post-Award Requirements | Other Information

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

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 <a href="mailto:limited time-period">limited time-period</a> 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 <a href="OUSD R&E Decision Matrix">OUSD R&E Decision Matrix</a> must decrease risk of foreign influence in accordance with the abovementioned laws and guidance prior to award.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

#### 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.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

### 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 <u>DoD R&D Terms and Conditions</u> and the <u>USAMRAA Research</u> 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 Human and Animal Research Oversight (OHARO), prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB, or Ethics Committee (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 <u>Award Expiration Transition Plan</u>, 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 <u>PHS Inclusion Enrollment Report</u> 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).

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | <u>Post-Award Requirements</u> | Other Information

#### 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.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

#### 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 issued.

#### 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 preapplication 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 on 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.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- 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 invited application proposes a different research project other than that described in the pre-application.
- The PI does not meet the eligibility criteria.
- A clinical trial is proposed.

#### 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.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

# **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"		
Impact Statement - Attachment 6, upload as "Impact.pdf"		
Relevance to Military Health Statement – Attachment 7, upload as "MilRel.pdf"		
Animal Research Plan – Attachment 8, upload as "AnimalResPlan.pdf"		
Representations (Grants.gov submissions only) – Attachment 9, upload as "RequiredReps.pdf"		
<u>Suggested Intragovernmental/Intramural Budget Form</u> (if applicable) – Attachment 10 upload as "IGBudget.pdf"		
Research & Related Personal Data		
Research & Related Senior/Key Person Profile (Expanded)		
Attach <u>Biographical Sketch</u> 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)		

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

# **Appendix 2. Acronym List**

ARRIVE Animal Research: Reporting In Vivo Experiments

CDMRP Congressionally Directed Medical Research Programs

CFR Code of Federal Regulations

DA Discovery Award

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

FY Fiscal Year

IACUC Institutional Animal Care and Use Committee

IRB Institutional Review Board

M Million

MBRP Military Burn Research Program

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)

OUSD R&E Office of the Under Secretary of Defense for Research and Engineering

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

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

# **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 <a href="https://cccrp.health.mil/">https://cccrp.health.mil/</a>

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 <a href="https://www.dtic.mil/">https://www.dtic.mil/</a>

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.navv.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 <a href="https://www.med.navy.mil/Naval-Medical-Research-Command/">https://www.med.navy.mil/Naval-Medical-Research-Command/</a>

Office of Naval Research <a href="https://www.onr.navy.mil/">https://www.onr.navy.mil/</a>

Office of the Under Secretary of Defense for Acquisition and Sustainment <a href="https://www.acq.osd.mil/">https://www.acq.osd.mil/</a>

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 <a href="https://www.army.mil/devcom">https://www.army.mil/devcom</a>

U.S. Army Institute of Surgical Research <a href="https://usaisr.health.mil/">https://usaisr.health.mil/</a>

U.S. Army Medical Materiel Development Activity

https://usammda.health.mil/

U.S. Army Medical Research and Development Command <a href="https://mrdc.health.mil/">https://mrdc.health.mil/</a>

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

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

U.S. Army Research Institute of Environmental Medicine <a href="https://usariem.health.mil/">https://usariem.health.mil/</a>

U.S. Army Research Laboratory <a href="https://www.arl.army.mil/">https://www.arl.army.mil/</a>

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 <a href="https://www.research.va.gov/">https://www.research.va.gov/</a>

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

Walter Reed Army Institute of Research <a href="https://wrair.health.mil/">https://wrair.health.mil/</a>