Broad Agency Announcement for Extramural Research for the Department of Defense

Defense Health Program

Military Burn Research Program

Technology/Therapeutic Development Award

Funding Opportunity Number: HT942525MBRPTTDA

Pre-Application/Proposal Due: June 23, 2025

Application/Proposal Due: September 8, 2025

This BAA must be read in conjunction with the General Submission Instructions, version CD25_01.

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Before You Begin

- **Active SAM.gov, eBRAP.org, and Grants.gov registrations are required for application/proposal submission.** User registration for each of these websites can take several weeks or longer. Each applicant/offeror 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/proposal materials**. It is the responsibility of the applicant/offeror 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/proposal 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: The fiscal year 2025 (FY25) Military Burn Research Program (MBRP) Technology/Therapeutic Development Award (TTDA) is a burn-focused, product-driven award mechanism intended to provide support for the translation of promising preclinical findings into burn products for clinical application in an austere, resource-limited, distributed operational environment.

Distinctive Features: The technology or therapeutic product(s) to be developed must be product-oriented (e.g., medical device, drug, or clinical practice guidelines involving a therapeutic or technology). The product(s) to be developed may be tangible or knowledge supporting the development of a tangible product and must address one or more of the FY25 MBRP TTDA focus areas. Knowledge products are allowable, provided that the knowledge is applicable to a technology or therapeutic under development. (A "knowledge product" is a non-tangible, non-materiel product that results from research with the potential to improve individual or public health.)

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $3.4 million (M) to fund approximately 2 Technology/Therapeutic Development Award applications/proposals with total cost caps of $1.7M. The maximum period of performance is 3 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/Proposal (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 23, 2025
- **Invitation to Submit an Application:** July 18, 2025
- **Full Application/Proposal Submission Deadline:** 11:59 p.m. ET, September 8, 2025
- **End of Full Application/Proposal Verification Period:** 5:00 p.m. ET, September 15, 2025
- **Peer Review:** October 2025
- **Programmatic Review:** January 2025

Announcement Type: Initial

Funding Opportunity Number: HT942525MBRPTTDA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants/Offerors

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-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.

In accordance with Department of Defense Instruction (DoDI) 5000.77 and Federal Acquisition Regulation (FAR) 35.017, Federally Funded Research and Development Centers (FFRDCs) are not eligible to directly receive awards under this Broad Agency Announcement (BAA). However, teaming arrangements between FFRDCs and eligible organizations are allowed as long as they are permitted under the sponsoring agreement between the federal government and the specific FFRDC.

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.

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 for contracts or assistance agreements but may exist if Research Other Transactions (OTs) or Prototype OTs is the selected funding instrument. Cost-sharing requirements for OTs are stated in United States Code, Title 10, Section 4021 (10 USC 4021) for Research OTs and 10 USC 4022 for Prototype OTs.

2.3. Other

Awards are made to eligible ***organizations***, not to individuals. The U.S. Army Medical Research and Development Command (USAMRDC) uses the “Exclusions” within the Performance Information functional area of the SAM and the “Responsibility and Qualifications” within the Entity Information functional area of the SAM to verify that an organization is eligible to receive federal awards. Refer to the General Submission Instructions, Appendix 1, for additional recipient qualification requirements.

3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications/proposals to this funding opportunity using delegated authority provided by 10 USC 4001. The CDMRP at the 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 setting for the improvement of both short- and long-term burn 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.

3.1. Award History

The MBRP first offered the TTDA mechanism in FY22. Since then, the MBRP has received 101 TTDA applications/proposals, and recommended eight for funding.

3.2. Intent of the Technology/Therapeutic Development Award

The MBRP TTDA is a product-driven award mechanism intended to provide support for the translation of promising preclinical findings into burn products for clinical application in an austere, resource-limited, distributed operational environment, particularly within the pre-hospital, and/or early, acute phase of care.

The technology or therapeutic to be developed must be product-oriented (e.g., medical device, drug, or clinical practice guidelines involving a therapeutic or technology). The deliverable resulting from this research may be a tangible item such as a medical device or pharmacologic agent (including, but not limited to, drugs, or biologics) or it may be knowledge applicable to a technology or therapeutic under development. A “knowledge product” is a non-tangible, non-materiel product that results from research with the potential to improve individual or public health. A knowledge product is based on current evidence, aims to transition clinical practice standards, training, or tools into clinical practice, or supports materiel solutions [systems to develop, acquire, provide, and/or sustain medical solutions and capabilities], and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes. Tangible or knowledge products developed under the MBRP TTDA must address an identified need in one or more of the FY25 MBRP TTDA Focus Areas.

3.2.1. Focus Areas for the Technology/Therapeutic Development Award

The MBRP seeks to fund the research and development of technologies and/or therapeutics that enhance the ability to provide burn care in an austere, resource-limited, distributed operational environment. The program seeks to improve the ability of non-burn specialist military care providers to accurately assess burn severity, adequately treat burns, mitigate and/or treat burn-associated complications, and prevent progression of burn depth. Enhancing the ability to provide high-quality burn care at the point of injury and during the early, acute phase of care is expected to shorten the time to recovery and improve the long-term physical and psychological health and well-being among burn-injured Service Members, with the potential for benefit among Veterans, military beneficiaries, and the American public. Within this context, the MBRP is interested in research proposals that address specific gaps in the 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 an 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 Technology/Therapeutic Development Award

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 an austere, resource-limited, distributed operational environment. High-impact research will, if successful, lead to the development and translation of therapeutic or technologic advances such as detection, diagnosis, treatment, or burn complication prevention for clinical application in the care of combat burn-injured casualties at, or close to, the point of injury, or in the early acute phase of care within a prolonged field care combat environment.

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.

At the time of pre-application submission, the proposed product must have achieved a minimum technology readiness level (TRL) or knowledge readiness level (KRL) of 3 (Appendix 4).

Proof-of-concept AND a prototype/preliminary version of the proposed product demonstrating its potential utility must be well established at the time of pre-application submission. ***Applications must include relevant data that support the rationale for the proposed study.*** These data may be from published and/or unpublished literature.

This award mechanism is intended to facilitate progression of research that is supported by significant preliminary data but has not yet advanced to the level of clinical use. Examples of the types of research that may be supported include, but are not limited to:

- Testing new therapeutic or technologic modalities (e.g., agents, delivery systems, chemical modification of lead compounds, device testing and/or validation) using established or validated preclinical systems.
- Designing pilot or full-scale Good Manufacturing Practice (GMP) production of therapeutics and/or technologies for use in advanced preclinical studies.
- Developing pharmacologic agents through absorption, distribution, metabolism, excretion, and toxicity studies.
- Investigational New Drug-enabling or Investigational Device Exemption-enabling studies.

Clinical trials and clinical research studies ARE NOT PERMITTED under this award mechanism. Enrollment of human subjects is NOT PERMITTED under this award mechanism. Projects involving limited use of de-identified and/or commercially available human cells or anatomical specimens are permitted, provided that the use of such specimens is necessary for device or product development and human subject consent is not required. Applicants interested in proposing clinical research should consider submitting to the FY25 MBRP Patient-Centered Research Award mechanism (HT942525MBRPPCRA).

3.2.3. Other Important Considerations for the Technology/Therapeutic Development Award

This BAA is issued under the provisions of the Competition in Contracting Act (CICA) of 1984 (Public Law 98-369), as implemented in FAR 6.102(d)(2) and 35.016 and in Department of Defense Grant and Agreement Regulations (DoDGARs) 22.315. In accordance with FAR 35.016, projects funded under this BAA must be for *applied research* not related to the development of a specific system or hardware procurement. Research and development funded through this BAA is intended and expected to benefit and inform both military and civilian medical practice and knowledge.

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.

Use of DOD or U.S. Department of Veterans Affairs (VA) Resources: If the proposed research involves access to 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 1, for additional information.

Applications involving multidisciplinary collaborations among academia, industry, the military Services, the VA, and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique resources, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. PIs are encouraged to collaborate, integrate, and/or align their research projects with DOD

and/or VA research laboratories and programs. 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.

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 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.

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/proposals 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, including studies analyzing sex as a biological variable. 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 instruments for awards made under this BAA may be assistance agreements, contracts, or OTs. The type of instrument used to reflect the business relationship between the organization and the government is at the discretion of the government, in accordance with the Federal Grant and Cooperative Agreement Act of 1977, as amended, 31 USC 6301-6308, which provides the legal criteria to select a procurement contract or an assistance agreement. The USAMRDC will also consider the use of OTs as a vehicle for award, in accordance with the conditions in 10 USC 4021 and 10 USC 4022.

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.

A **contract** is required when the principal purpose of the instrument is to acquire property or services for the direct benefit or use of the U.S. government (31 USC 6303).

An **"OT"** is utilized for certain awards when the government determines execution of the project requires flexibility (10 USC 4021 and 10 USC 4022). Such flexibility may allow for incorporation of dynamic commercial industry standards and best practices or adjustment of project scope to evolving requirements of government use cases.

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 **3** years.

Cost Cap: The application's/proposal'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/offeror may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** 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 multidisciplinary collaborations, including travel.
- Costs for one investigator to 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 TTDA.
- 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 a MBRP-specific meeting) in year 2 or 3 of the period of performance. These travel costs may be in addition to those allowed for annual scientific/technical meetings.

Must not be requested for:

- Clinical trial or clinical research costs.
- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.
- Tuition.

4. Application/Proposal Contents and Format

4.1. Application/Proposal Overview

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

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

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

4.2. Step 1: Pre-Application/Proposal Components

Pre-application/proposal submissions must include the following components.

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

- **Pre-Application Narrative (three-page limit):** The Pre-Application 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 Pre-Application Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Pre-Application Narrative should include the following:

  - **Research Idea:** State the ideas and reasoning upon which the proposed work is based. State how the research addresses an important problem relevant to combat burn care in an austere, resource-limited, distributed operational environment. Describe the proposed product that will address an unmet need and briefly elucidate how the product will advance 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. Provide a description of how proof-of-concept has been established.
  - **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 development and translation of a therapeutic or technologic advancement for clinical application in the care of combat burn-injured casualties at, or close to, the point of injury, or in the very early acute phase of care within a prolonged combat care environment. Describe how the proposed project, if successful, will represent an improvement over currently available diagnostics, treatments, interventions, and/or standards of care.
  - **Military Relevance:** Describe how the proposed product is expected to be relevant to combat burn care, particularly in an austere, resource-limited 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 Narrative using a standard reference format the 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: *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/Proposal Components

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

Each application/proposal submission must include the completed full application/proposal package for this BAA. See Appendix 1 for a checklist of the full application/proposal components.

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

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

(b) Attachments:

Each attachment of the full application/proposal components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Submission 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/proposal.

  Describe the proposed project in detail using the outline below.

  - **Background:** Describe how the proposed research project addresses at least one of the FY25 MBRP focus areas. Describe the proposed product and how the product will advance combat burn care. Concisely state the scientific rationale. Cite relevant literature. Describe previous experience most pertinent to the project. Include relevant preliminary data and/or promising preclinical findings that demonstrate proof of concept of the product or prototype/preliminary version of the product; these data may be from published or unpublished literature. State how the research addresses

an important problem relevant to combat burn care in an austere, resource-limited, distributed operational environment.

- **Hypothesis/Objective:** Clearly state the hypothesis to be tested (if applicable), a purpose statement, and/or 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 analysis plan, including appropriate controls.
  - State the hypothesis to be tested and/or the objective(s) to be reached. Briefly describe the preliminary findings that support the proposed study.
  - Define the specific study outcomes and how they will be measured.
  - 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.
  - Address potential problems and present alternative methods and approaches.
  - Describe data collection and handling, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, and identification of primary endpoints/outcomes.
  - Describe the statistical plan and the rationale for the statistical methodology, if applicable.
  - If animal studies are proposed, briefly describe the key elements of the study/studies as they relate to the overall project. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and how it is optimal for addressing the study aims and facilitates rapid development and translation of solutions for the Warfighter. Describe how animal research will be conducted in accordance with the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments). Further details of research involving animals will be required in Attachment 8, Animal Research Plan, as applicable.
  - 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). ***Clinical research (including Clinical Trials) is not allowed under the Technology/Therapeutic Development Award.***
  - If the proposed research involves access to 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. Refer to the General Application Instructions, Appendix 4, for additional considerations.

- 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/proposal.

  - **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.

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource (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 performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to the CDMRP Policy on Data & Resource Sharing for more information about the 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 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. 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 ultimately 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 TTDA mechanism, refer to the "Example: Assembling a Generic Statement of Work" for guidance on preparing the SOW.

- **Attachment 6: Impact and Military Relevance Statement (three-page limit): Upload as "Impact.pdf".** Impact should be written in a manner that will be ***readily understood by readers without a background in science or medicine.***
  - Outline the expected short- or long-term impact of the proposed research on the care of combat burn casualties in an austere, resource-limited, distributed operational environment.
  - Describe how the proposed project addresses at least one of the FY25 MBRP focus areas.
  - Describe how the proposed product will lead to the development and eventual translation of therapeutic or technologic advances in the care of burn-injured casualties at, or close to, the point of injury, or in the early acute phase of care within a combat care environment.
  - Indicate whether the proposed burn care product will require minimal, moderate, or substantial training for use.
  - Describe how the proposed product will represent an improvement over currently available burn diagnostics, treatments, interventions, and/or standards of care.
  - Describe how the therapy, technology, or knowledge gained from the proposed research is usable in a combat health care environment.
  - If applicable, describe how the anticipated outcomes of the proposed study will make an impact on understanding health differences between sexes.

- **Attachment 7: Transition Plan and Regulatory Strategy (three-page limit): Upload as "Transition.pdf".**

  The transition plan should include the following components:

  - The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication (e.g., Target Product Profile). Describe in detail the U.S. Food and Drug Administration (FDA) regulatory strategy, including the number and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that have been held and/or will be held, the submission filing strategy, and considerations for compliance with GMP, Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) guidelines, if appropriate.

- Details of the funding strategy to transition the product(s) to the next level of development and/or commercialization (e.g., specific potential industry partners, specific 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, a description of collaborations and other resources that will be used to provide continuity of development, including 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 brief schedule and milestones for transitioning the product to the next phase of development (e.g., next-phase clinical trials, transition to industry, delivery to the civilian and/or military 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.
- Intellectual Property: Information can be found in 2 CFR 200.315, "Intangible Property".
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- A risk analysis for cost, schedule, manufacturability, and sustainability.

The regulatory strategy should include the following components:

- Describe the methods and strategies proposed to move the product or knowledge outcomes to the next phase of development (e.g., clinical trials, partnership with DOD advanced developers, commercialization, and/or delivery to the civilian or military market) after successful completion of the award.
- Demonstrate how the proposed product or knowledge outcome is currently at a minimum TRL or KRL of 3 and estimate the target TRL/KRL level expected upon completion of the proposed research (Appendix 4).
- Outline the regulatory strategy. 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, DOD advanced developers, and/or other funding agencies to facilitate moving the product into the next phase of development.

- **Attachment 8: Animal Research Plan *(if applicable)*: Upload as "AnimalPlan.pdf".**

  When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the Institutional Animal Care and Use Committee (IACUC) as the Animal Research Plan. The Animal Research Plan should address the following points 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/offerors must complete and submit the "Required Representations" document that is available on eBRAP. For more information, see the General Submission 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 Submission 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 Submission Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Submission 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 Submission Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Submission Instructions, Section V.B.(c).

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

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

- **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/Proposal 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/proposals recommended for funding.
- Prior to award, applicants/offerors will be required to disclose all potential or actual conflicts of interest (COIs) along with a plan to mitigate them. An award may not be made if it is determined by the USAMRAA Warranted Official that COIs cannot be adequately mitigated. Refer to the General Submission Instructions, Appendix 1, for additional information.
- If the resultant award is a contract that exceeds $750,000 and the offeror is other than a small business, the contractor will be required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7, Defense Federal Acquisition Regulation Supplement (DFARS) 219.7. A mutually agreeable plan will be developed during the award negotiation process and incorporated as part of the resultant contract.

5. Submission Requirements

5.1. Location of Application/Proposal Package

Download the application/proposal package components for HT942525MBRPTTDA from Grants.gov or eBRAP, depending on which submission portal will be used.

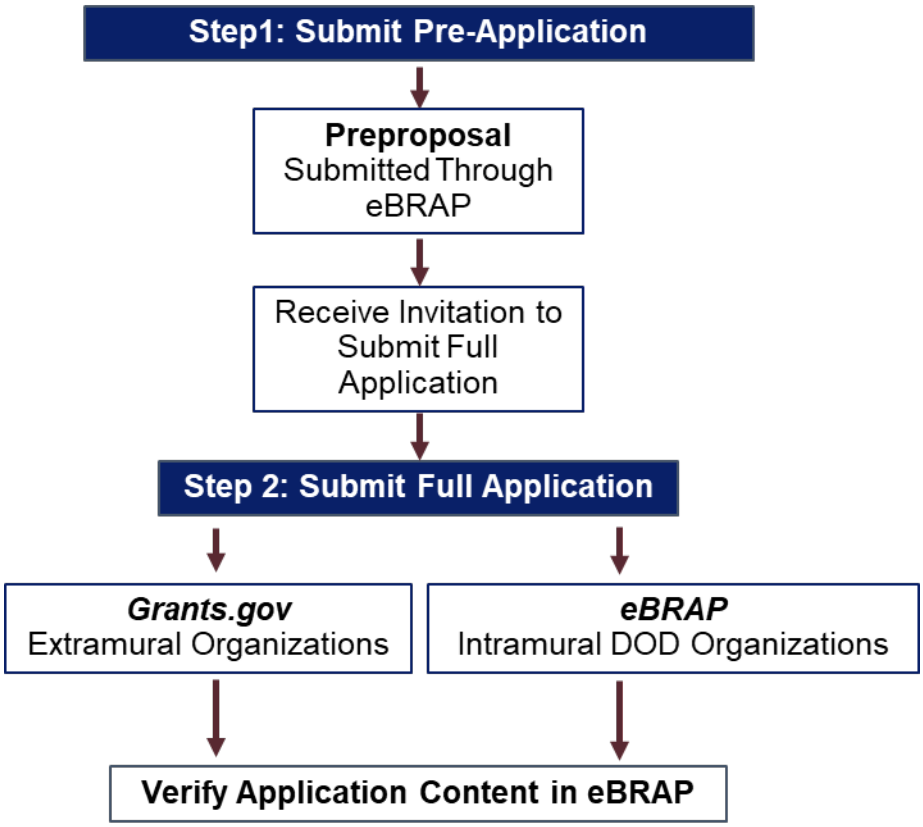
5.2. Unique Entity Identifier and System for Award Management

The applicant/offeror organization must be registered as an entity in the SAM, SAM.gov, and receive confirmation of an "Active" status before submitting an application/proposal through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications/proposals 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/proposal under consideration. More information regarding SAM registration can be found in the General Submission Instructions, Section IV.A.

5.3. Submission Instructions

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

Application Submission Workflow



5.3.1. Pre-Application/Proposal Submission

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

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

Refer to the General Submission Instructions, Section III.B, for considerations and detailed instructions regarding pre-application/proposal submission.

5.3.2. Full Application/Proposal Submission

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

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

5.3.3. Applicant/Offeror Verification of Full Application Submission in eBRAP

Independent of submission portal, once the full application/proposal is submitted, it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify and verify the full application/proposal submission. Verification is strongly recommended but not required. eBRAP will validate full application/proposal files against the specific BAA 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/offeror’s responsibility to review all application/proposal components and ensure the proper ordering as specified in the BAA. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application/proposal submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application/proposal package must be submitted through the appropriate portal prior to the full application/proposal submission deadline.*** Other application/proposal components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application/proposal verification period. The full application/proposal cannot be modified once the application/proposal verification period ends.

5.4. Submission Dates and Times

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

There are no grace periods for deadlines; failure to meet submission deadlines will result in application/proposal rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant/offeror.***

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/Proposal Review Information

6.1. Application/Proposal Compliance Review

Submitting applications/proposals 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)/proposal(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/proposal and/or proposing research that may produce classified outcomes or outcomes deemed sensitive to national security concerns, may result in application/proposal withdrawal. Refer to the General Submission Instructions, Appendix 7, Section B.

Members of the FY25 MBRP Programmatic Panel should not be involved in any pre-application/proposal or full application/proposal including, but not limited to, concept design, application/proposal 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/Proposal 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:

- **Technology/Therapeutic Development Product:** Whether the pre-application defines a product that will address an unmet need in burn care. Whether the proposed product addresses the care of combat-relevant burn injuries at the point of injury, or in the early, acute phase of combat care. Whether the proposed research is based on promising preclinical findings, sound scientific rationale, and demonstrated proof of concept.
- **Impact:** Whether the proposed research will lead to the development and translation of a therapeutic or technologic advancement for clinical application in the care of combat burn-injured casualties at, or close to, the point of injury, or in the early acute phase of care within a combat care environment. 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 military-relevant burn research and/or combat burn care as related to one or more of the FY25 MBRP focus areas. The degree to which the proposed product represents an improvement over currently available diagnostics, treatments, interventions, and/or standards of care.

- **Military Relevance:** How well the research addresses combat-relevant burn care; how well the therapy, technology, or knowledge gained from the proposed research could be implemented to address a burn-relevant combat health care need.

6.2.2. Peer Review Criteria

To determine technical merit, all applications/proposals will be individually evaluated according to the following **scored criteria**, which are of equal importance***:***

- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project, as demonstrated within the cited literature, preliminary data, and promising preclinical findings.
  - Whether proof of concept of the product or prototype/preliminary version of the product has been adequately demonstrated.
  - How well the hypotheses, purpose statement, study design, and methods have been developed and how well they are supported by the study aims.
  - To what degree the expected outcomes are specific and measurable.
  - How well the power analysis demonstrates that the sample size is appropriate to test the hypothesis and supports a meaningful outcome, if applicable.
  - To what degree the research is appropriate and feasible.
  - Whether the application provides evidence of availability of and access to necessary study resources, including access to DOD and/or VA databases, if applicable
  - How well the study is designed to achieve reproducible and rigorous results, including data handling and, if applicable, controls and randomization.
  - How well potential problems are identified, and alternative approaches are addressed.
  - Whether the research can be completed within the proposed period of performance.
  - 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 Benefit**
  - To what degree the proposed product promotes positive short-term and long-term outcomes related to the care of combat burn casualties in an austere, resource-limited, distributed operational environment.
  - How well the project addresses one or more of the FY25 MBRP focus areas.
  - How likely is the proposed product to lead to the translation of therapeutic or technologic advances in the care of burn-injured casualties at, or close to, the point of injury, or in the early acute phase of care within a combat care environment.
  - To what degree the proposed product requires training for use.
  - How well the proposed product represents an improvement over currently available burn diagnostics, treatments, interventions, and/or standards of care.
  - To what degree the therapy, technology, or knowledge gained from the proposed research is usable in a combat health care environment.

- If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

- **Transition Plan and Regulatory Strategy**
  - Whether the proposed product or knowledge outcome is currently at a minimum TRL/KRL of 3.
  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA or international regulatory agency. Whether the identified next level of development and/or plans for commercialization is realistic.
  - Whether the funding strategy described to bring the product to the next level of development (e.g., specific potential industry partners, specific funding opportunities to be applied for) is reasonable and realistic.
  - Whether the regulatory strategy and the development plan to support the proposed product label, if applicable, are appropriate and well-described.
  - If applicable, whether the proposed collaborations and other resources for providing continuity of development of knowledge products, including 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 are established and/or achievable.
  - Whether the schedule and milestones for bringing the anticipated product to the next level of development (clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA, or international regulatory agency, if applicable) are achievable. Whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
  - If applicable, to what degree the intellectual and material property plan is appropriate.

In addition, the following criteria will also contribute to the overall evaluation of the application/proposal, but will not be individually scored and are therefore termed **unscored criteria**:

- **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.
- **Budget**
  - Whether the budget is appropriate for the proposed research.
- **Personnel**
  - How appropriate the expertise and levels of effort are for successful conduct of the proposed work.
- **Application/Proposal Presentation**
  - To what extent the writing, clarity, and presentation of the submission components influence the review.

6.2.3. Programmatic Review

To make funding recommendations and select the application(s)/proposal(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 Areas
    - Program portfolio composition
    - Relative impact and military benefit

6.3. Application/Proposal Review and Selection Process

6.3.1. Pre-Application/Proposal

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 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/Proposal

All applications/proposals are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications/proposals against established criteria to determine technical merit, where each application/proposal is assessed for its own merit, independent of other applications/proposals. The second tier is **programmatic review**, a comparison-based process in which applications/proposals 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/proposals 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/proposals received is contingent upon the availability of federal funds for this program, the number of applications/proposals received, the quality and merit of the applications/proposals 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

The following areas may be reviewed in evaluating the risk posed by an applicant/offeror: financial stability; quality of management systems and operational controls; history of performance; reports and findings from audits; ability to effectively implement statutory,

regulatory, or other requirements imposed on nonfederal entities; degree of institutional support; integrity; adequacy of facilities; and conformance with safety and environmental.

Prior to making an 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/offeror that is available in SAM.

An applicant/offeror 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/offeror, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's/offeror'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 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/proposal 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/proposal and an information paper describing the application/proposal 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/proposal 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 awardee organization.

Only an appointed USAMRAA Warranted Official 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 USAMRAA Warranted Official is the official authorizing document (i.e., assistance agreement, contract, or other transaction 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 subawards/subcontracts*** 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.

For assistance agreement awards, 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 contract awards and OTs, an organization may request and negotiate pre-contract/pre-agreement costs prior to award.

Refer to the General Submission Instructions, Section I.D, Pre-Award Costs section, for additional information about pre-award costs.

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 BAA.

Applicable requirements in the FAR, found in 48 CFR, Chapter 1; and DFARS, found in 48 CFR, Chapter 2, apply to contracts resulting from this BAA. Refer to additional FAR and DFARS clauses as outlined in Appendix 5.

Refer to the General Submission Instructions, Appendix 7, for general information regarding administrative requirements.

Refer to the General Submission 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/offeror organization, no new awards will be issued to the applicant/offeror organization until all delinquent reports have been submitted.

Applications/proposals 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, Institutional Review Board (IRB), or Ethics Committee (EC) review. Refer to the General Submission 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).

If the award made under this funding opportunity announcement is a contract or OT, additional reporting requirements may apply.

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.

Awards resulting from this BAA may entail additional reporting requirements related to awardee integrity and performance matters. Awardee 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 awardees are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Submission 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 Submission Instructions, Appendix 7, Section H, for general information on organization or PI changes.

9. Other Information

9.1. Broad Agency Announcement and General Submission Instructions Versions

Questions related to this BAA should refer to the program name, the BAA name, and the BAA version code CD25_01Bc. The BAA numeric version code will match the General Submission Instructions version code CD25_01.

9.2. Administrative Actions

After receipt of pre-applications or full applications/proposals, 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/proposal:

- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter on invitation was not received.

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/proposal:

- 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/proposal or application/proposal processes.
- Applications/proposals 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/offeror 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/proposals from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications/proposals 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/proposal fails to conform to this BAA description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Application/proposal 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.
- A clinical trial or clinical research is proposed.
- The invited application proposes a different research project than that was described in the pre-application.

9.2.4. Withhold

Applications/proposals 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 Warranted Official for a determination of the final disposition of the application/proposal.

Appendix 1. Full Application/Proposal Submission Checklist

Full Application/Proposal 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 and Military Relevance Statement – Attachment 6, upload as "Impact.pdf"	☐
Transition Plan and Regulatory Strategy – Attachment 7, upload as "Transition.pdf"	☐
Animal Research Plan (if applicable) – Attachment 8, upload as "AnimalPlan.pdf"	☐
Representations *(Grants.gov submissions only)* – Attachment 9, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 10, 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

ARRIVE	Animal Research: Reporting In Vivo Experiments
BAA	Broad Agency Announcement
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CICA	Competition in Contracting Act
COI	Conflict of Interest
DFARS	Defense Federal Acquisition Regulation Supplement
DHP	Defense Health Program
DOD	U.S. Department of Defense
DoDI	Department of Defense Instruction
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FFRDC	Federally Funded Research and Development Centers
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
KRL	Knowledge Readiness Level
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
OT	Other Transaction
OUSD R&E	Office of the Under Secretary of Defense for Research and Engineering
PDF	Portable Document Format
PI	Principal Investigator
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
TRA	Technology Readiness Assessment
TRL	Technology Readiness Level
TTDA	Technology/Therapeutic Development Award
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/

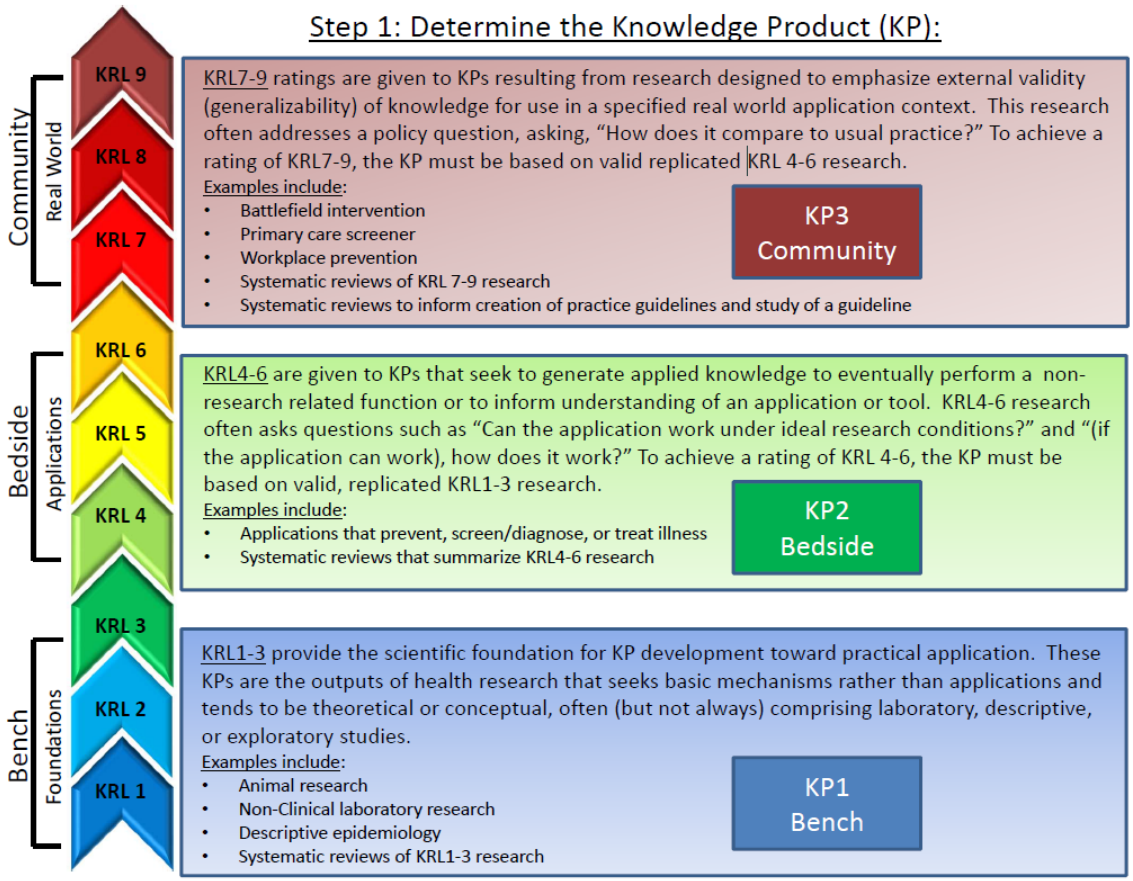
U.S. Naval Research Laboratory
https://www.nrl.navy.mil/

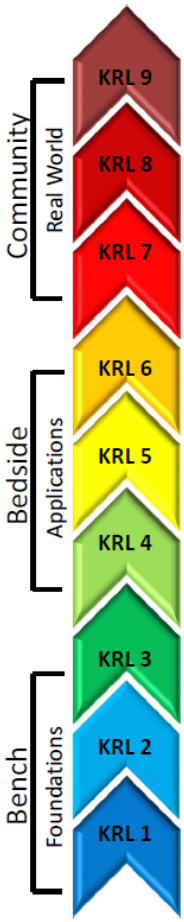
Walter Reed Army Institute of Research
https://wrair.health.mil/

Appendix 4. Technology Readiness Levels and Knowledge Readiness Levels

TRLs: TRLs are used to categorize the product maturity of materiel solutions. The DOD's Technology Readiness Assessment (TRA) Deskbook is a reference for systematic assessment of technical maturity of relevant materiel solutions. For biomedical applications, Biomedical TRL definitions and descriptions have been developed that account for regulatory context for technology maturity and *intended context of use*. Information on Biomedical TRLs can be found in Appendix E of the DOD TRA Deskbook (July 2009, https://apps.dtic.mil/sti/pdfs/ADA418881.pdf)

KRLs: The scientific maturity of knowledge products resulting from biomedical research is not assessed in the same manner as that of materiel solutions. At the request of the USAMRDC, the Rand Corporation developed and released a framework to assess the relative scientific maturity of knowledge products. This process is described in a 2019 Rand Corporation (https://www.rand.org/pubs/research_reports/RR2127.html). The figures below represent a quick reference guide for assessing KRLs for knowledge products.





Step 2: Determine the Knowledge Readiness Level (KRL)

KRL9 research replicates or reviews well-designed KRL7 and KRL8 studies (e.g., cost analyses to achieve desired effect; comparative effectiveness studies to aid context specific policy development or intervention decisions; systematic review to estimate effect size with average participants in a real world context, assess **"Does the application work?"** in a context, or determine for which participants or time period the application works in an identified context.)

KRL8 research expands on or replicates KRL7 studies to directly assess "Does the application work in the context of interest?" It uses valid designs with emphasis on external validity (generalizability) for an intended context. (e.g., multi-site to obtain average effects; generalizable analyses of real world, (e.g., administrative) data; usual or standard care (not placebo or contact time) controls; and average (not ideal) participants.)

KRL7 research comprises early studies adapting applications supported by KRL4-6 research for use in a military health context. (e.g., adaptation from a longer screener, feasibility and standardization for post-deployment use of a brief screener; initial multi-modal tests of combined KRL4-6 supported interventions to achieve improved outcomes in primary care; adaptation and initial study in military mental health settings of KRL4-6 support therapy for PTSD; adaptation and initial study of KRL4-6 supported protective gear for preventing TBI during deployment.)

KRL6 research replicates well-designed KRL5 studies. It adds nuance to answers from completed studies (e.g., not just "Can it work" and "How," but also "For whom," "Under what conditions," or "With what frequency?") It validates hypotheses that may suggest important application contexts (e.g., battlefield, primary care, emergency rooms, post-deployment screening). It includes systematic reviews of KRL4-5 studies to address "Can it work?" and "How?" questions.

KRL5 research tests *a priori* (pre-specified) hypotheses using rigorous scientific designs (e.g., RCTs for intervention efficacy) to directly assess "Can it work" and "If so, how?" It expands on or replicates a KRL4 finding and/or improves on the design of one or more KRL4 studies.

KRL4 research generates initial knowledge regarding a human health-related application or use. KRL4 findings require subsequent replication (e.g., descriptive human epidemiology or preliminary human studies, human studies that test a clinical hypotheses, pilot tests of an intervention, screening or diagnostic tool, and development of instrumentation needed to test an intended application (e.g., outcome measure).

KRL3 research validates hypotheses and hints at future applications, research that replicates or systematically reviews well-designed KRL1-2 studies or theory, descriptive studies, particularly involving animal research (e.g., tool for prediction, prognosis, screening, diagnosis, treatment, prevention)

KRL2 research expands on or replicates a KRL1 finding, including systematic review of KRL1 studies to formulate a theoretical model (e.g., animal studies that test a hypothesis or are the first true experiment on a nascent theory and human studies not based on animal study findings that are descriptive or hypothesis generating.

KRL1 research generates initial or very early scientific knowledge without regard to or indication of a specific health use. Its purpose is inferential, with the intention to generalize. Its findings require replication. (e.g., descriptive animal studies, or those that are hypothesis generating rather than hypothesis testing.)

Appendix 5. FAR/DFARS Clauses Applicable to Contracts Requirements

FAR/DFARS Provisions/Clauses: For purposes of illustration, the following provisions and clauses may be applicable to procurement contracts resulting from this Broad Agency Announcement. Additional clauses apply based upon contract type. USAMRAA reserves the right to include all relevant and current FAR or DFARS clauses in the final contract award.

# Provision	Clause
52.204-7	System for Award Management
52.204-13	System for Award Management Maintenance
52.204-16	Commercial and Government Entity Code Reporting
52.204-21	Basic Safeguarding of Covered Contractor Information Systems
52.204-24	Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment
52.204-26	Covered Telecommunications Equipment or Services-Representation
52.204-27	Prohibition on ByteDance Covered Application
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters
52.215-20	Requirements for Certified Cost and Pricing Data and Data Other than Certified Cost and Pricing Data
52.215-16	Facilities Capital Cost of Money
52.215-22	Limitations on Pass Through Charges - Identification of Subcontract Effort
52.216-1	Type of Contract
52.216-27	Single or Multiple Awards
52.217-4	Evaluation of Options Exercised at time of Contract Award
52.217-5	Evaluation of Options
52.217-9	Option to Extend the Term of the Contract
52.222-24	Preaward On-Site Equal Opportunity Compliance Evaluation (Applies if Exceeds $10M)
52.222-50	Combating Trafficking in Persons
52.222-56	Certification Regarding Trafficking in Persons Compliance Plan
52.223-6	Drug Free Work Place
52.226-2	Historically Black College or University and Minority Institution Representation
52.230-7	Proposal Disclosure - Cost Accounting Practice Changes
52.232-15	Progress Payments Not Included
52.233-2	Service of Protest
52.252-1	Solicitation Provisions Incorporated by Reference
52.252-3	Alterations in Solicitation
52.252-5	Authorized Deviations in Provisions
252.203-7005	Representation Relating to Compensation of Former DoD Officials
252.204-7007	Alternate A, Annual Representations and Certifications
252.204-7008	Compliance with Safeguarding Covered Defense Information Controls
252.204-7012	Safeguarding Covered Defense Information and Cyber Incident Reporting

# Provision	Clause
252.204-7018	Prohibition on the Acquisition of Covered Defense Telecommunications Equipment or Services
252.215-7003	Requirements for Submission of Data Other than Certified Cost or Pricing Data - Canadian Commercial Corporation
252.204-7000	Disclosure of Information
252.235-7010	Acknowledgement of Support and Disclaimer
252.235-7011	Final Scientific or Technical Report
252.204-7019	Notice of NIST SP 800-171 DoD Assessment Requirements
252.204-7020	NIST SP 800-171 DoD Assessment Requirements
252.219-7000	Advancing Small Business Growth
252.225-7048	Export Controlled Items
252.225-7055	Representation Regarding Business Operations with the Maduro Regime
252.225-7057	Preaward Disclosure of Employment of Individuals Who Work in the People's Republic of China
252.225-7058	Postaward Disclosure of Employment of Individuals Who Work in the People's Republic of China
252.225-7060	Prohibition on Certain Procurements from the Xinjiang Uyghur Autonomous Region
252.225-7966	Prohibition Regarding Russian Fossil Fuel Business Operations—Representation
252.225-7967	Prohibition Regarding Russian Fossil Fuel Business Operations