I. OVERVIEW OF THE FUNDING OPPORTUNITY

Broad Agency Announcement for Extramural Research for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Military Burn Research Program

Technology/Therapeutic Development Award

Announcement Type: Initial

Funding Opportunity Number: HT942524SMBRP

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

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

This broad agency announcement must be read in conjunction with the General Submission Instructions, which are available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

TABLE OF CONTENTS

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

This funding opportunity announcement is a broad agency announcement (BAA) through the fiscal year 2024 (FY24) Military Burn Research Program (MBRP) for the Technology/Therapeutic Development Award (TTDA). For the remainder of the announcement, this BAA will be referenced as the MBRP TTDA. Specific submission information and additional administrative requirements can be found in the document titled "General Submission Instructions," available in Grants.gov along with this BAA.

This BAA for MBRP is intended to solicit extramural research and development ideas using the authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). This BAA is issued under the provisions of the Competition in Contracting Act (CICA) of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation (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.

This BAA is intended for extramural applicants only. **For definitions and additional information, see Section II.C.1, Eligible Applicants.** Intramural applicants applying through intramural organizations should use the separate funding opportunity announcement that is available through the electronic Biomedical Research Application Portal (eBRAP) at https://eBRAP.org/ under funding opportunity number HT942524MBRPTTDA. The North American Industry Classification System (NAICS) code for contracts under this announcement is 541715 - Research and Development in the Physical, Engineering, and Life Science (except nanotechnology and Biotechnology) with a small business size standard of 1,000 employees.

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) MBRP using delegated authority provided by 10 USC 4001. The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity.

Congress initiated the MBRP in 2011 to address combat-related and trauma-induced burn injuries as well as to improve health and performance outcomes for burn-injured Service Members. Appropriations for the MBRP from FY11 through FY23 totaled $110 million (M). The FY24 appropriation is $10M.

Burn injuries sustained by military Service Members while in the line of duty, whether on the battlefield or in a military training environment, represent a continuous health burden on both the injured Service Member and the Department of Defense health care systems in which they receive care. Historically, burn injuries afflicted some 5% to 20% of casualties during post-

World War II conflicts.[1] In recent years, burns sustained during Operation Enduring Freedom/ Operation Iraqi Freedom affected nearly 9% of combat-related casualties.[2] While thermal burns represent the most common mechanism of burn injury, other injurious mechanisms such as frostbite, high-voltage electrical, chemical, directed energy, and radiation/nuclear exposure represent an additional formidable threat to the health and well-being of Service Members. The Armed Forces Health Surveillance Division reports an increased number of cold-related injuries in recent years; high-voltage accidents occur on and off the battlefield; and the threat of chemical, nuclear, or directed energy weapons is an ever-present danger. Regardless of mechanism, combat-associated burn injuries are devastating due, in part, to the high incidence of concurrent severe traumatic injuries. In addition, burns sustained in a deployed environment more often lead to severe burns than those sustained in the civilian setting. The majority of combat burns sustained in recent conflicts resulted from explosive device detonation, leading to a greater Injury Severity Score, an increase in inhalation injuries, and a larger, full-thickness burn size.[3] It is anticipated that in future conflicts the explosive weaponry used against U.S. forces will be more powerful than that seen in the past, likely resulting in a higher number of casualties with significant injuries and larger, more severe burns. Furthermore, the care provided to Service Members in a combat environment where evacuation may be significantly delayed may impact clinical outcomes. Irrespective of the injury mechanism, prolonged delay to definitive care renders assessment and treatment of burn wounds at or close to the point of injury challenging to medical and non-medical first responders alike. There is an urgent need to develop, refine, or test novel burn therapies or technologies that would allow for better provision of care, particularly in resource-limited settings, and to improve both short- and long-term patient outcomes.

II.A.1. FY24 MBRP Focus Areas

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

---

[1] Kauvar DS, Wade CE, and Baer DG. 2009. Burn hazards of the deployed environment in wartime: Epidemiology of noncombat burns from ongoing United States military operations. *Journal of the American College of Surgeons* 209(4):453-460.

[2] Escolas SM, Archuleta DJ, Orman JA, et al. 2015. Postdischarge cause-of-death analysis of combat-related burn patients. *Journal of Burn Care and Research: Official Publication of the American Burn Care Association* 38(1):e158-e164.

[3] Kauver DS, Cancio LC, Wolf SE, et al. 2006. Comparison of combat and non-combat burns from ongoing U.S. military operations. *The Journal of Surgical Research* 132:195-200.

- **Atypical Burns:** Development and/or validation of methods to assess, treat, and/or prevent the progression of burns resulting from cold exposure, radiation, directed energy, chemical, or high voltage/combat-related electrical injuries.

- **Burn Knowledge Products:** Research to innovate best practices in the acute burn care continuum.

- **Burn Injury-Related Complications:** Development and/or validation of methods to prevent, assess, and/or treat burn injury-related complications including:

    - Over/under fluid resuscitation to include limited or low volume resuscitation

    - Acute respiratory distress syndrome (ARDS)

    - Sepsis

    - Inhalation injuries

    - Peripheral neuropathy

    - Chronification of pain (prevention only)

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

Areas of Encouragement:

- Development of a combination burn wound care product that prevents infection, burn progression, and pain; enhances healing through replacement or repair of the epidermis or dermis; is usable at the point-of-injury or soon thereafter.

- Development or refinement of point-of-injury and/or early acute burn wound care products that can be used in delayed care scenarios for at least 5 days.

- Expanded, novel indications for U.S. Food and Drug Administration (FDA)-approved medical products to achieve burn relevance.

- Development of therapeutics that mitigate burn-associated acute respiratory distress syndrome (ARDS) and/or refractory hypoxemia.

- Development of novel high fidelity burn simulation training aides.

- Studies that test the safety and efficacy of frostbite treatment in a delayed evacuation field environment.
- Development of treatments for burn wounds and/or burn lung injury from closed-space fires.
- Development of medical countermeasures to prevent, or reduce the severity of, cold, steam, radiation, or directed energy burns (excludes clothing, or clothing-like products).
- Advanced, shelf-stable allografts for large surface area burns to be used and stored in austere conditions.
- Advanced allografts or skin substitutes that reduce immunogenicity to eliminate or reduce autograft need.
- Development of donor site sparing technologies for autografting.
- Development of a treatment or technology to repair burn-related peripheral nerve damage associated with neuropathy, neuralgia, and/or pruritis.
- Collaborative studies that align civilian and military burn research.

II.A.2. Award History

The MBRP TTDA mechanism was first offered in FY22. Since then, 60 Technology/ Therapeutic Development Award applications have been received, and five have been recommended for funding.

II.B. Award Information

The MBRP TTDA is a product-driven award mechanism intended to provide support for the translation of promising preclinical findings into products for clinical application in resource-limited settings, particularly within the pre-hospital, or early, acute phase of care environments. Applications must address one or more of the critical gaps included in the FY24 MBRP TTDA Focus Areas. Products under development **must** address the needs of military Service Members, Veterans, their beneficiaries, and the American public.

The product(s) to be developed may be a tangible item such as a medical device or pharmacologic agent (including, but not limited to, drugs or biologics). Knowledge products may be considered, provided that the knowledge is applicable to a technology or therapeutic under development. (A "knowledge product" is a non-materiel product that addresses an identified need in one or more of the FY24 MBRP TTDA Focus Areas. 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 sustain medical solutions and capabilities], and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)

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 II).

Proof-of-concept AND a prototype/preliminary version of the proposed product demonstrating its potential utility must be 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 unpublished and/or from the published 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- or Investigational Device Exemption-enabling studies

Clinical trials and clinical research studies ARE NOT PERMITTED under this award mechanism. Projects involving limited use of commercially available human cells or anatomical specimens are permitted, provided that the use of such specimens is necessary for device or product development. Applicants interested in proposing clinical research should consider submitting to the FY24 MBRP Patient-Centered Research Award mechanism (HT942524MBRPPCRA).

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

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

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

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

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

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

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

Impact: The overall impact of the proposed research is a key component of this award mechanism. High-impact research will, if successful, lead to the development and translation of therapeutic or technologic advances for clinical application in the care of burn-injured casualties, such as detection, diagnosis, treatment, or burn complication prevention.

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

Use of DOD or Department of Veterans Affairs (VA) Resources: 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 clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Applicants are encouraged to integrate and/or align their research projects with DOD and/or VA research laboratories and programs. Collaboration with DOD or VA investigators is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in Appendix IV.

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., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit Attachment 8, Animal Research Plan, as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at https://arriveguidelines.org/arrive-guidelines.

The CDMRP expects to allot approximately $4.4M to fund approximately two MBRP Technology/Therapeutic Development Award applications. Funding of applications received

is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

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

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.

An ***"Other Transaction"*** will also be considered as a vehicle for award under this BAA, in accordance with 10 USC 4021 and 10 USC 4022. The OT authorities were created to give DOD the flexibility necessary to adopt and incorporate business practices that reflect commercial industry standards and best practices into its award instruments. When leveraged appropriately, OTs provide the government with access to state-of-the-art technology solutions from traditional and non-traditional defense contractors (NDCs), through a multitude of potential teaming arrangements tailored to the particular project and the needs of the participants. OTs can help to foster new relationships and practices involving traditional and NDCs, especially those that may not be interested in entering into FAR-based contracts with the government; broaden the industrial base available to government; support dual-use projects; encourage flexible, quicker, and cheaper project design and execution; leverage commercial industry investment in technology development and partner with industry to ensure DOD requirements are incorporated into future technologies and products; and collaborate in innovative arrangements. OTs are not FAR-based procurement contracts, grants, cooperative agreements, or cooperative research and development agreements.

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

The anticipated ***total costs*** budgeted for the entire period of performance for an FY24 MBRP Technology/Therapeutic Development Award should not exceed **$2.2M**. Refer to Section II.D.6, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025. For additional information refer to Section II.F.1, Federal Award Notices.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization:

Applications for this BAA may only be submitted by extramural organizations, including foreign or domestic institutions, for-profit and non-profit organizations, and public entities. Submissions from intramural DOD organizations to this BAA will be withdrawn.

Applications with Principal Investigators (PIs) employed by intramural DOD organizations may be submitted extramurally through a research foundation. It is also permissible for an intramural DOD investigator to be named as a collaborator on an application submitted through an extramural organization. In this case, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

In accordance with DoDI 5000.77 and FAR 35.017, Federally Funded Research and Development Centers (FFRDCs) are not eligible to directly receive awards under this 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.

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

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

Awards are made to eligible ***organizations***, not to individuals.

II.C.1.b. Principal Investigator:

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

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement for contracts or assistance agreements but may exist if research OT or prototype OT is the selected funding instrument. Cost-sharing requirements for OTs are stated in 10 USC 4021 for Research OTs and 10 USC 4022 for Prototype OTs.

II.C.3. Other

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

Use of the System for Award Management (SAM): To protect the public interest, the federal government ensures the integrity of federal programs by striving to conduct business only with responsible organizations. The 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. More information about SAM is available at https://sam.gov/SAM/. Refer to the General Submission Instructions, Section IV.A, for additional information.

Conflicts of Interest (COIs): Prior to award, applicants/offerors will be required to disclose all potential or actual 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.

Review of Risk: The following areas may be reviewed in evaluating the risk posed by an applicant: 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 non-federal entities; degree of institutional support; integrity; adequacy of facilities; and conformance with safety and environmental.

For general information on required qualifications for award recipients, refer to the General Submission Instructions, Appendix 1.

Subcontracting Plan: 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.

In addition to other information provided herein, by submitting an application and accepting an award, the organization is: (1) certifying that the applicants' credentials have been examined and (2) verifying that the applicants are qualified to conduct the proposed study and to use humans as research subjects, if proposed. Applicants include all individuals, regardless of ethnicity,

nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization.

Refer to Section II.H.1, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this BAA.

II.D. Application and Submission Information

II.D.1. Location of Application Package

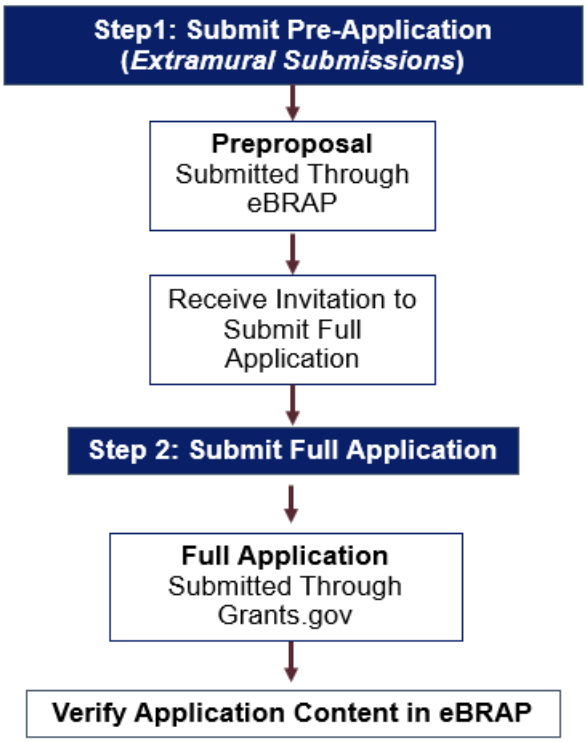
Submission is a two-step process requiring both a pre-application submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a full application (eBRAP.org or Grants.gov).

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

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

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

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD PI working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524SMBRP from Grants.gov (https://grants.gov). Full applications from extramural organizations must be submitted through Grants.gov.

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

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

Submitting applications that propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

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

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

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

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

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

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

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

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

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

- **Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Preproposal Narrative should include the following:

  - **Research Idea:** State the ideas and reasoning on which the proposed work is based. State how the research addresses an important problem relevant to military burn injuries. Describe the proposed product that will address an unmet need and briefly how the product advances upon existing technologies/therapeutics. Explain how the product meets the needs and requirements for the care of military-relevant burn injuries.

  - **Research Strategy:** State the hypothesis to be tested and/or the objective(s) to be reached. Briefly describe the study design and methodology to include animal models or human anatomical specimens to be used, if applicable. Concisely state the scientific

rationale, the preliminary findings that support the continued development of the proposed product, and a description of how proof-of-concept has been demonstrated.

- **Focus Area**: Describe how the proposed project addresses at least one of the FY24 MBRP Focus Areas and, if applicable, the Area(s) of Encouragement.

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

- **Impact:** The potential impact of the research, both short term and long term, in addressing one or more of the FY24 MBRP Focus Areas and Area of Encouragement (if applicable) should be clearly described. Describe how the research will result in the development and eventual translation of therapeutic or technologic advances for clinical application in the care of burn injuries, such as detection, diagnosis, treatment, or prevention of burn complications. 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 (1) how the project addresses military-relevant burn injury; (2) how the therapy, technology, or knowledge gained from the proposed research could be implemented to address a military need; and (3) the role(s) of care within which the proposed study intervention or product is intended (e.g., prolonged field care, pre-hospital, emergency department, full-service hospital).

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:

  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).

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

  - **Key Personnel Biographical Sketches (six-page limit per individual):** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

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

To determine the technical merits of the pre-application and the relevance to the mission of the 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

addressed the care of military-relevant burn injuries in the early, acute phase of care. Whether the proposed research is based on promising preclinical findings, sound scientific rationale, and demonstrated proof of concept.

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

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

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

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

Following the pre-application screening, PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section I, Overview of the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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

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

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

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

Each application submission must include the completed full application package for this BAA. See Section II.H.2 of this BAA for a checklist of the required application components.

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

(b) Attachments:

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

- **Attachment 1: Project Narrative (15-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

  - **Background:** Describe how the proposed research project addresses at least one of the FY24 MBRP Focus Areas. Describe the product to be developed. Present the scientific rationale behind the proposed work. 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 unpublished or from the published literature.

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

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

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

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

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

- 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.
- Clearly describe the statistical plan and the rationale for the statistical methodology, if applicable.
- Provide a sample size estimate and the method by which it was derived, including power analysis calculation, if applicable.
- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, or international regulatory agency, if applicable.
- 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 (https://arriveguidelines.org/arrive-guidelines). Further details of research involving animals will be required in Attachment 8, Animal Research Plan, as applicable.
- 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 datasets, 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 active-duty military and/or VA patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to the General Submission 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.

- **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.

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

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

- **Use of DOD Resources *(if applicable)*:** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

- **Use of VA Resources *(if applicable)*:** Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  The clarity and completeness within the space limits of the technical abstract are highly important for review of the application.

  Technical abstracts should be written using the outline below.

  - **Background:** Present the ideas and rationale behind the proposed research, including how it addresses one or more FY24 MBRP Focus Areas and, if applicable, the Area(s) of Encouragement.

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

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

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

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

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

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

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

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

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

  For the MBRP TTDA mechanism, refer to the "Example: Assembling a Generic Statement of Work", for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6: Impact and Military Relevance Statement (three-page limit): Upload as "Impact.pdf".**

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

  - 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, such as detection, diagnosis, treatment, or prevention of burn complications.

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

  - If available and applicable, provide military-specific information about the incidence and/or prevalence of the problem to be addressed, as well as the incidence in the general population.

  - Explain how the project addresses an aspect of military-relevant burn injury and the subsequent care provided in a resource-limited, military operational setting

  - Describe how the therapy, technology, or knowledge gained from the proposed research could be implemented to address a military need

- Describe the role(s) of care within which the proposed product is intended (e.g., prolonged field care, pre-hospital, emergency department, full-service hospital)

- **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 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, and Good Clinical Practice 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 the 2 CFR 200.315, "Intangible Property." Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

  - 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 II).

- 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: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Submission Instructions, Appendix 5, 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 performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Submission Instructions, Section IV.B.(g), for detailed information.

(c) Research & Related Personal Data: Refer to the General Submission Instructions, Section IV.B.(c), for detailed information.

(d) Research & Related Senior/Key Person Profile (Expanded): Refer to the General Submission Instructions, Section IV.B.(d), for detailed information.

- PI Biographical Sketch (six-page limit): Upload as "Biosketch_LastName.pdf".
- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".
- Key Personnel Biographical Sketches (six-page limit each): Upload as "Biosketch_LastName.pdf".
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

(e) Research & Related Budget: Refer to the General Submission Instructions, Section IV.B.(e), for detailed instructions.

- **Budget Justification (no page limit): Upload as "BudgetJustification.pdf".** Refer to the General Submission Instructions, Section IV.B.(e), for detailed instructions.

(f) Project/Performance Site Location(s) Form: Refer to the General Submission Instructions, Section IV.B.(f), for detailed information.

(g) Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Submission Instructions, Section IV.B.(g) for detailed information.

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

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

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

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

II.D.4. Submission Dates and Times

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

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

II.D.5. Funding Restrictions

The maximum period of performance is **3** years.

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

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

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

- Travel costs for the PI to present project information or disseminate project results at one DOD-sponsored meeting (the Military Health System Research Symposium or a MBRP-specific meeting) in year 2 or 3 of the period of performance. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Support for multidisciplinary collaborations, including travel.
- Travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/ technical meetings is to present project information or disseminate project results.

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

II.D.6. Other Submission Requirements

Refer to the General Submission Instructions, Appendix 2, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Research Strategy and Feasibility**
    - How well the scientific rationale supports the project, as demonstrated within the cited literature, preliminary data, promising preclinical findings, and demonstrated proof of concept.
    - How well the hypotheses, purpose statement, study design, and methods have been developed and how well they are supported by the study aims.
    - The degree to which the expected outcomes are specific and measurable.
    - To what extent the power analysis demonstrates that the sample size is appropriate to test the hypothesis and supports a meaningful outcome, if applicable.
    - The degree to which the research is appropriate and feasible and whether the application provides evidence of availability of and access to necessary study resources.
    - How well the study (or studies) is designed to achieve reproducible and rigorous results, including data handling and, if applicable, controls and randomization.

- The feasibility of the plan to access DOD and/or VA databases and maintain access throughout the research period.
- How well potential problems are identified and alternative approaches are addressed.
- Whether the research can be completed within the proposed period of performance.

- **Impact and Military Benefit**
  - How well the project addresses one or more of the FY24 MBRP Focus Areas.
  - How likely the proposed product will lead to the development and eventual translation of therapeutic or technologic advances in the care of burn-injured casualties, such as detection, diagnosis, treatment, or prevention of burn complication.
  - To what degree the proposed product promotes positive short-term and long-term outcomes for military health and medicine.
  - To what degree the project addresses an aspect of military-relevant burn injury and the subsequent care provided in a resource-limited, military operational setting.
  - To what degree the therapy, technology, or knowledge gained from the proposed research could be implemented to address a military need.
- **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, if applicable. 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.

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

- **Environment**
    - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
    - How the quality and extent of organizational support are appropriate for the proposed research.
    - Whether the scientific environment is appropriate for the proposed research.
- **Budget**
    - Whether the budget is appropriate for the proposed research.
- **Personnel**
    - Whether the expertise of the PI and key personnel is appropriate to perform the described research project.
    - How appropriate the levels of effort are for successful conduct of the proposed work. If applicable, to what degree the intellectual and material property plan is appropriate.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the Defense Health Program and FY24 MBRP, as evidenced by the following:

- Adherence to the intent of the funding opportunity
- Program portfolio composition
- Relative impact and military benefit

II.E.2. Application Review and Selection Process

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

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the DoDGARs, Section 22.415.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the MBRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

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

Only an appointed USAMRAA 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).***

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 support ***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 costs prior to contract award.

Refer to the General Submission Instructions, Section IV.B.(e), Pre-Award Costs section, for additional information about pre-award costs.

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

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

Unless otherwise restricted, changes in 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 assistance 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 F, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter 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 found in Appendix IV.

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 General Terms and Conditions and the USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions for further information.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local IACUC, Institutional Review Board, or Ethics Committee review. Refer to the General Submission Instructions, Appendix 6, for additional information.

II.F.3. Reporting

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

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

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan,"

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Submission Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@grants.gov

II.H. Other Information

II.H.1. Administrative Actions

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

II.H.1.a. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

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

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

II.H.1.b. Modification

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

II.H.1.c. Withdrawal

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

- An FY24 MBRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. ***A list of the FY24 MBRP Programmatic Panel members can be found at https://cdmrp.health.mil/mbrp/panels/panels24***.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government

organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The invited application proposes a different research project than that described in the pre-application.
- The PI does not meet the eligibility criteria.
- A clinical trial or clinical research is proposed.

II.H.1.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants/Contracting/ Agreements Officer for a determination of the final disposition of the application.

II.H.2. Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural 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 – 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 PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐

APPENDIX I: ACRONYM LIST

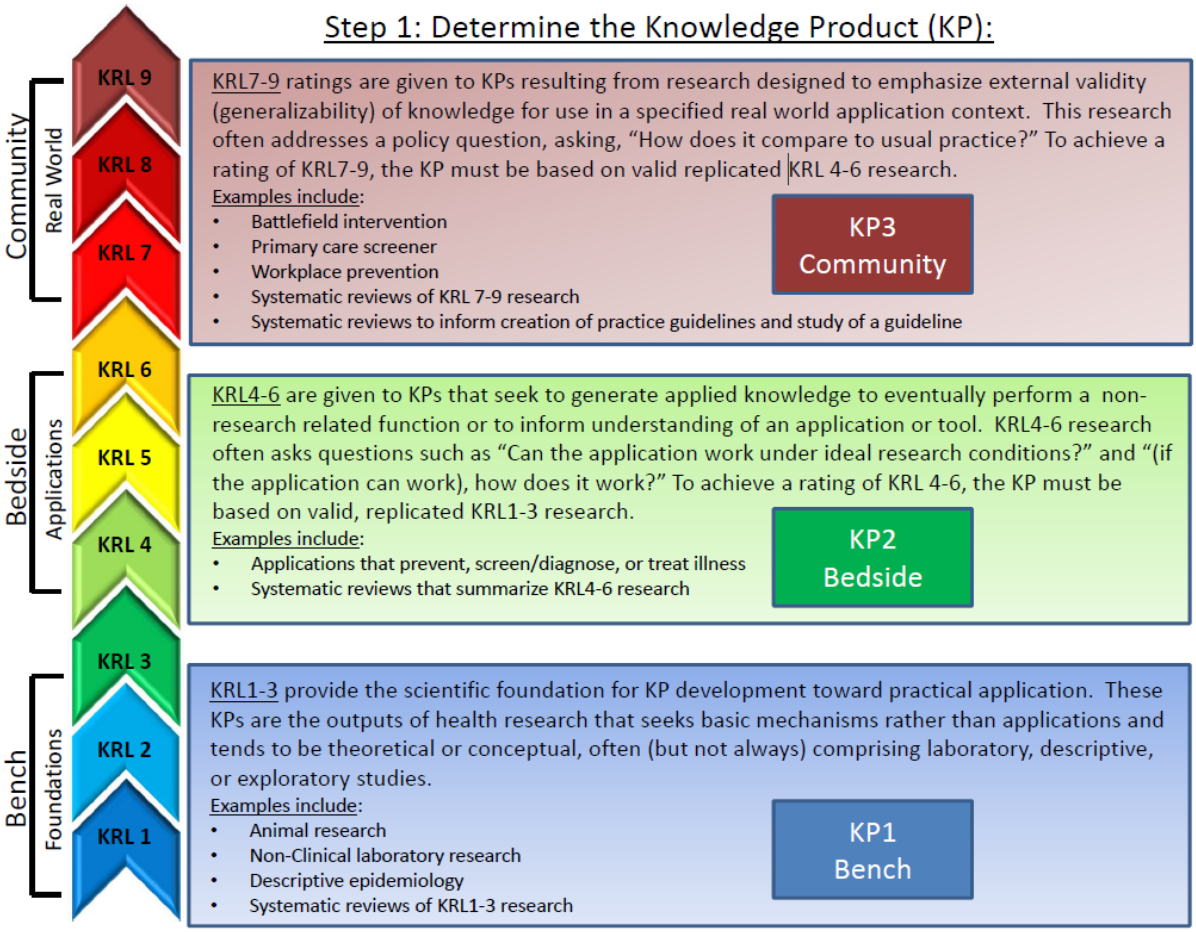
ACOS/R&D	Associate Chief of Staff for Research and Development
BAA	Broad Agency Announcement
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CICA	Competition in Contracting Act
COI	Conflict of Interest
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FFRDCs	Federally Funded Research and Development Centers
FY	Fiscal Year
GMP	Good Manufacturing Practice
IACUC	Institutional Animal Care and Use Committee
KRL	Knowledge Readiness Level
M	Million
MBRP	Military Burn Research Program
MIPR	Military Interdepartmental Purchase Request
NAICS	North American Industry Classification System
NDC	Non-traditional Defense Contractor
OT	Other Transaction
PDF	Portable Document Format
PI	Principal Investigator
SAM	System for Award Management
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

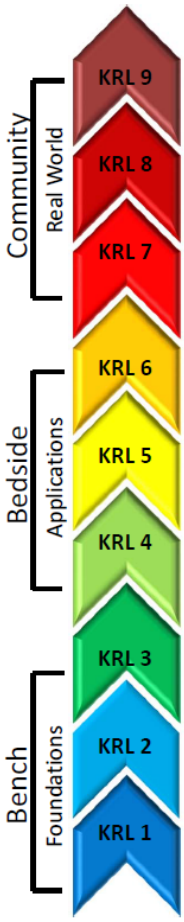
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs

APPENDIX II: 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 Report (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 III: DOD AND VA WEBSITES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Navy and Marine Corps Public Health Center
https://www.med.navy.mil/sites/nmcphc/Pages/Home.aspx

Office of Naval Research
https://www.nre.navy.mil/

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

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

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

U.S. Air Force 59th Medical Wing
https://wilfordhall.tricare.mil/

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

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

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

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

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

U.S. Army Medical Research and Development Command
U.S. Army Research Laboratory
https://www.arl.army.mil

U.S. Army Sharp, Ready and Resilient Directorate
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://www.wrair.health.mil/

APPENDIX IV: 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