Program Announcement for the Defense Health Agency

Combat Readiness – Medical Research Program

Translational Research Award

Funding Opportunity Number: HT942526CRRPTRA

Pre-Application Due: August 17, 2026

Application Due: November 18, 2026

This program announcement must be read in conjunction with the General Application Instructions, version CD26_01.

Content

Before You Begin

- **Active SAM.gov, eBRAP.org and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read this funding opportunity announcement in the order it is written before beginning to prepare application materials.** It is the responsibility of the applicant to determine whether the proposed research meets the intent of this funding opportunity and that all parties meet eligibility requirements.
- **To support application preparation, additional resources are available** including an application process FAQ, a Guide for Intragovernmental & Intramural Applicants and a CDMRP Video Series detailing the application process.

Who to Contact for Support

eBRAP Help Desk

301-682-5507
help@eBRAP.org

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

Grants.gov Support Center

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

Questions regarding Grants.gov registration and Workspace.

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

Click ⓘ to be taken to additional guidance and instructions within the General Application Instructions (GAI).

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2026 (FY26) Combat Readiness – Medical Research Program (CRRP) Translational Research Award (TRA) supports hypothesis-driven innovative, high-impact translational research that will accelerate the movement of promising ideas and/or technologies in trauma care into solutions to maximize casualty survivability, improve patient care closer to the point of injury and/or trauma care guidelines. Preliminary data are required. Research using well-validated animal models is allowed.

Distinctive Features:

- **NEW for FY26** An investigator may be named as the Principal Investigator (PI) on only one FY26 CRRP TRA application.
- Research supported by the FY26 CRRP TRA must represent a mature, translational research effort with a minimum biomedical technology readiness level (TRL) of 4 or knowledge readiness level (KRL) of 4.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $4.37M to fund approximately three Translational Research Award applications with total cost caps of $2.45M per award, of which $1.45M of FY26 funds will be used for a base award. A $1.00M optional research effort (Option Phase) may be funded with future funds, if appropriated. The maximum period of performance is 2 years for the base award, with an optional research effort of 1 year. It is anticipated that awards made from this FY26 funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. Awards supported with FY26 funds will be made no later than September 30, 2027.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), August 17, 2026
- **Invitation to Submit an Application:** October 14, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, November 18, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, November 23, 2026
- **Peer Review:** January 2027
- **Programmatic Review:** March 2027

Announcement Type: Initial

Funding Opportunity Number: HT942526CRRPTRA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural U.S. Department of War (DOW) organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities*.**

2.1.2. Principal Investigator

Independent investigators at all career levels affiliated with an eligible organization are eligible to be named PI on the application, regardless of ethnicity, nationality or citizenship status.

An investigator may be named on only one FY26 CRRP application as a PI.

Individuals in a mentored position (e.g., postdoctoral fellows, clinical fellows) are not considered independent investigators.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the GAI for additional recipient qualification requirements.

3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the Combat Readiness – Medical Research Program (CRRP). The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. Congress initiated the CRRP in 2019 to focus on the medical needs of the Warfighter on the battlefield, with a focus on addressing life-threatening injuries closer to the point of injury. Appropriations for the CRRP from FY19 through FY24 totaled $55 million (M). The FY26 appropriation is $5M.

The CRRP vision is to increase survivability and readiness of the Warfighter. The program seeks to develop innovative high-impact solutions to increase medical readiness; triage, diagnose and treat life-threatening injuries; reduce morbidity and mortality; and promote positive long-term outcomes for the Warfighter. While the CRRP considers medical priorities that contribute to Warfighter readiness, innovations developed by CRRP-supported research may be applied proactively to enhance medical readiness ahead of deployment, in operational settings at the point of injury, during periods of prolonged care, or during transport/en route between roles of care. These solutions will not only help to minimize the morbidity and mortality of combat-related injuries sustained by the Warfighter but will often translate to civilian care.

A 2009 DOW mandate established a policy that Warfighters should be provided with lifesaving care within 60 minutes of injury, a time span that is referred to as the “golden hour.” Achieving this metric is supported through increased infrastructure enabling rapid transportation of battlefield casualties from the point of injury to forward surgical teams (Role of Care, Role 2) and combat support hospitals (Role 3), where medical assets and damage control capabilities could rapidly provide lifesaving treatment. Future combat scenarios may involve peer or near-peer adversaries in large-scale combat operations where evacuation capabilities are delayed or unavailable. Recent global military operations reflect combat operations in varied environments where medical and casualty care support is dispersed and sometimes isolated under difficult conditions (e.g., dense urban, subterranean, maritime, high-altitude, dust storm and extreme environments). When access to highly skilled providers under such conditions may be limited, the time-specific window of the golden hour may not be feasible. Therefore, it is essential to bring effective and efficient life-saving capabilities closer to the point of injury and sustain prolonged care (greater than 72 hours) where necessary. Innovations in technology and knowledge are critical to ensure front line provider skills sustainment to support rapid response in future operations. Advancement of clinical decision support tools and other automated technologies may support continued Force readiness and availability in combat environments and assist Warfighters in providing additional life-saving care where clinical capabilities are limited or non-existent. Casualty care must address not only the scope of these challenges, but also the scale of casualties projected. Mass casualty events that overwhelm immediately available medical capabilities, to include personnel, supplies, and/or equipment, present a significant obstacle to providing damage control interventions closer to the point of need.

3.1. FY26 CRRP Focus Areas

The program priorities described in past congressional intent for the CRRP are aligned to distinct focus areas that describe medical priorities to improve readiness and to deliver frontline care in combat situations. For FY26, the CRRP streamlined program research priorities into

three key focus areas aligned to distinct themes of medical readiness for the Warfighter. ***Research supported by the FY26 CRRP must address at least one of the program focus areas listed below.*** Selection of the appropriate FY26 CRRP Focus Area is the responsibility of the applicant.

- **Battlefield diagnostics, triage and decision aid tools:** Solutions to enhance identification and management of trauma in point of injury, austere resuscitative and surgical care, prolonged casualty care and en route care environments
- **Treatments:** Solutions to enhance delivery of care in point of injury, austere resuscitative and surgical care, prolonged casualty care and en route care environments
- **Battlefield readiness:** Solutions to address readiness with a focus on prehospital and operational environments

3.2. Award History

The CRRP Translational Research Award mechanism was first offered in FY23. Since then, 135 Translational Research Award applications were received, and seven were recommended for funding.

3.3. Intent of the Translational Research Award

The FY26 CRRP TRA intends to support mature high-impact translational research that will accelerate innovative ideas into clinical applications, including health care products, technologies and/or practice guidelines. Research funded under this award mechanism will be hypothesis-driven, high-impact applied research that is relevant to Service Members, with the potential for benefit among Veterans, military beneficiaries and the American public.

Submissions that propose solutions to advance civilian trauma care are not precluded. Trauma care in complex and austere environments is not unique to military contexts. Civilian emergency medical care provided in rural settings or during natural disasters, public health crises and mass-casualty events draws on lessons learned in battlefield medicine. Solutions addressing medical challenges during combat operations have potential for integration into civilian-based practices to address health security threats and support a goal of zero preventable deaths, regardless of environment. ***The CRRP expects the innovative approaches and technologies developed with CRRP funding to improve survivability of injuries sustained in both combat and civilian settings.***

Allowable Research: Applications to the FY26 CRRP TRA may include preclinical or clinical research. ***Proposal of animal studies is not a required element of this mechanism, but applications including animal studies must demonstrate the animal model is relevant and well-validated.***

The FY26 CRRP TRA may support a small scale, pilot clinical trial ***only during an optional research effort (Option Phase).*** Applications that include a pilot clinical trial require additional submission requirements and review criteria.

Applicants are encouraged to leverage existing resources in translational research to address essential research ideas or unmet needs to enable the delivery of life-saving care to the Warfighter during prolonged and en route care in austere and combat environments. ***For this award mechanism, the definition of "leveraging" is as follows: an investigator basing a research project on existing resources in order to amplify potential gains in knowledge or accelerate technical maturity.*** Research of interest may include knowledge products,

"knowledge resulting from research with the potential to improve individual or public health,"[1] and solutions that can accelerate the introduction of military-relevant health products or technologies into clinical and/or operational use. Projects should take into consideration the varied expertise levels of targeted medical providers, available resources and the possible diverse environmental conditions in combat situations. Application submissions are encouraged to include characteristics relevant to military use in the prehospital, combat operational setting.

3.3.1. Key Elements for the TRA

Impact and military relevance: Research supported by the TRA seeks to accelerate translational research relevant to military trauma care closer to the point of injury and/or clinical implementation. Applications must clearly demonstrate innovative qualities that will lead to translation of advances for medical readiness and life-saving care for the Warfighter aligned to at least one of the FY26 CRRP Focus Areas.

Preliminary data: Applications must include preliminary data relevant to the proposed study. Proposed research must clearly demonstrate a sound scientific approach based on the preliminary data and relevant scientific literature.

Research maturity: Research supported by the FY26 CRRP TRA must represent mature, translational research effort with a minimum biomedical TRL of 4 or KRL of 4. See Appendix 3 for more details.

3.3.2. Other Important Considerations for the TRA

Applications that consist of foundational research or a clinical trial during initial base award period of performance, or an advanced clinical trial in the Option Phase are not supported by the FY26 CRRP.

Funding from the FY26 CRRP may not be used to support studies requiring an exception from informed consent (EFIC).

In accordance with the National Defense Authorization Act for Fiscal Year 2026, Section 732, CDMRP does not support the conduct of painful research (U.S. Department of Agriculture pain category D or E) involving domestic cats or dogs, except for studies relating to military or service animals.

If the proposed research relies on access to unique resources, databases or populations, the application must describe access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research, such as those described in the STROBE, CONSORT, SPIRIT and ARRIVE 2.0 guidelines.

Applications from investigators within the DOW and applications involving multidisciplinary collaborations among academia, industry, the DOW, the U.S. Department of Veterans Affairs (VA) and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, their Families and the American Public. If the proposed research

[1]Charles C. Engel, Richard Silberglitt, Brain G. Chow, et al., "Development of a Knowledge Readiness Level Framework for Medical Research," 2019. Santa Monica, CA: RAND Corporation, RR-2127-OSD. https://www.rand.org/pubs/research_reports/RR2127.html.

relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. A list of websites that may be useful in identifying additional information about ongoing DOW and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 10 of the GAI.

3.4. Funding Instrument

The funding instrument for awards made under the program announcement will be assistance agreements. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of CDMRP during the project's period of performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial involvement" on the part of CDMRP is anticipated, a grant will be made (31 USC 6304). Conversely, if "substantial involvement" on the part of CDMRP is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement means that, after award, CDMRP staff will assist, guide, coordinate or participate in project activities to include but not limited to making recommendations for exercise of the Option Phase efforts based on: (a) overall study progress, including sufficient patient and/or data accrual; and/or (b) maintenance of a high quality of research.

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

3.5. Funding Details

3.5.1. Application Submissions to the CRRP TRA (no Option Phase)

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

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$1.45M.**

3.5.2. Application Submissions to the CRRP TRA With Option Phase

The CRRP TRA with Option Phase may be funded in two phases over the maximum period of performance listed below. Each phase must be a distinct but related research effort with a non-overlapping period of performance, research outcomes/milestones and budget. The Option Phase must clearly represent a follow-on effort stemming from the work completed during the base CRRP TRA. Research products from the CRRP TRA shall be leveraged in the subsequent Option Phase.

Period of Performance: The maximum period of performance for awards with an option phase is **3** years.

The first phase of performance of the CRRP TRA will be no greater than 2 years (base award). The Option Phase will be no greater than 1 year, maximum of 3 years in total (base award plus Option Phase).

Cost Cap: The application's total costs budgeted for the entire period of performance, including option period, should not exceed **$2.45M.**

The total costs budgeted for the first phase should not exceed $1.45M. Total costs budgeted for Option Phase year should not exceed **$1.00M.**

Awards funded under this mechanism may propose a base award, with a potential Option Phase (not required) to be considered for funding with a future appropriation, if available. **Applicants are required to select the appropriate funding option when applying.**

There is no guarantee of future appropriations for this program or that funds will be available in future years to implement the Option Phase of this award. The budget for the first phase should correspond to Budget Period 1 and 2 on the Research and Related Budget Attachment Form. The Option Phase should correspond to Budget Period 3 on the Research & Related Budget Attachment Form. The Budget Justification should clearly separate the first phase from the Option Phase and provide discrete totals for each phase.

Exercise of the Option Phase is contingent on the availability of sufficient future congressional appropriations to the CRRP, alignment of the proposed research during the Option Phase to that fiscal year's congressional language, acceptable performance under the base award (first phase) by the recipients and relevance to current program priorities. Evaluation of progress against the Statement of Work (SOW) will be conducted during a virtual milestone review meeting to be conducted on or about Month 18 of the period of performance.

3.5.3. For Both Options Within This Mechanism

If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **2 years for the CRRP TRA and 3 years for the CRRP TRA with Option Phase.**

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

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

Must be requested for:

- Travel costs for the PI to present project information or disseminate project results at a DOW-sponsored meeting (e.g., Military Health Systems Research Symposium) in Year 2 of the award. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Research subject compensation and reimbursement for trial-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving and resources/equipment to enable participation).
- Special purpose equipment.
- 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 to scientific/technical meetings should be to present project information or disseminate project results from the FY26 CRRP TRA.

Must not be requested for:

- Costs for travel to scientific/technical meetings beyond the limits stated above.
- Equipment (general).
- Tuition.

4. Application Contents and Format

4.1. Application Overview

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

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

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

4.2. Pre-Application Components

Pre-application submissions must include the following components.

Upload documents as individual PDF files unless otherwise noted. Files must comply with the formatting guidelines listed in the GAI.

- **Preproposal Narrative: Provide responses in the appropriate data fields for the following:**
  - Identify and explain how the proposed work will address at least one FY26 CRRP Focus Area. (750-character limit)
  - State the project's hypotheses, objectives and specific aims, and briefly describe the experimental approach. Describe the maturity of approach, to include technology and/or knowledge readiness level. (2,000-character limit)
  - Concisely state the scientific rationale on which the proposed work is based. Describe relevant preliminary data to support the approach. If the work includes animal research, briefly describe which well-validated animal model will be used in the work. (1,000-character limit)
  - How will the proposed research lead to a major advancement for the focus area. Identify how the proposed work will address specific challenges encountered in priority environments identified by the DOW, i.e., frontline, prolonged and/or enroute care in austere and combat environments. (1,000-character limit)
  - Is the proposed research translational? How will the proposed work lead to translation of advances for improving medical readiness, mitigating fatalities and/or optimally treating life-threatening injuries. How well the proposed work promotes positive long-term outcomes for military health and medicine, as well as the general product. (1,000-character limit)
  - ***For CRRP TRA with Option Phase including a clinical trial*:** Will the proposed research include a clinical trial? If yes, briefly state the intervention, subject population(s) and how the trial meets the definition of a small-scale or pilot clinical trial. (750-character limit)

- **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:
  - **Additional information that the PI can use, at their discretion to provide supporting data, rationale and/or references for the pre-application (one page limit):** References (including URLs if available) should be provided 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).
  - **Key Personnel (one page limit):** Provide a list of the PI and key personnel. Briefly describe roles, qualifications and expertise relevant to execution of the research project.

4.3. Full Application Components

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

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov submissions only)*:

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

(b) Attachments:

Each attachment of the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines in the GAI.

- **Attachment 1: Project Narrative (15-page limit): Upload as "ProjectNarrative.pdf".**

  Describe the proposed project in detail using **one** of the two outlines below, depending on whether or not a pilot clinical trial is included in the proposed research.

  Outline for projects without a small-scale or pilot clinical trial:

  - **Background:** Describe the problem, question, or knowledge gap related to at least one of the FY26 CRRP Focus Areas to be addressed by the proposed project. Present the current state of the field and scientific rationale on which the proposed work is based. Describe the current state of the science, preliminary studies and/or preclinical data that supports the proposed research. These data may be unpublished or from the published literature. Describe any existing resources that the proposed project will leverage. If the project is part of a larger study, articulate the information that establishes a framework for this study. The application must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project. Throughout the Project Narrative, describe how the proposed research is translational and has the potential for broadly applicable, cross-cutting advances that benefit military health and medicine as well as the general public.
  - **Hypothesis/Specific Aims/Hypotheses:** State the hypothesis to be tested and/or the objective to be reached. Detail the project's specific aims that will address the

hypothesis and/or research objective. If the proposed work is part of a larger study, present only aims that this CRRP award would fund.

- For applications to the CRRP TRA with Option Phase: Each phase should reflect a distinct (i.e., severable) research effort with a non-overlapping period of performance and research outcomes/milestones. Clearly demonstrate how the Option Phase follows on from the CRRP TRA.
- **Study Design and Feasibility:** Describe the experimental design, methods and analyses, including appropriate controls, in sufficient detail for evaluation. Explain how the research strategy will meet the project's goals and milestones within the proposed period(s) of performance. Provide a well-developed, well-integrated research strategy that supports the translational feasibility and promise of the approach. Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.
  - 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, is a well-validated animal model and how it is optimal for addressing the study aims and facilitates translation of solutions for the Warfighter. Describe how animal research will be conducted in accordance with appropriate preclinical research guidelines. Further details of research involving animals will be required in Attachment 8: Animal Research Plan, as applicable.
  - Describe the data collection instruments (e.g., research questionnaires, assays, assessment measures) that will be used, and to what degree they are appropriate to support the proposed study. Define the specific study outcomes/endpoints and how they will be measured. Address potential problem areas and present alternative methods and approaches.
  - If applicable, describe resources available for the development of sufficient quantities of critical reagents under Good Manufacturing Practice (GMP).
  - If human subjects will be used, briefly describe the study population and include a detailed plan for the recruitment of human subjects. Further details of clinical research components will be required in Attachment 7: Human Subject Recruitment and Safety Procedures for Clinical Research, as applicable.
  - If human-derived biological specimens or data will be used, describe the sourcing and/or acquisition of samples. If human-derived specimens will be obtained from military Service Members, military Families and/or Veteran population(s) or dataset(s), describe the feasibility of accessing the samples/dataset(s).
  - Provide information on the availability of, and access to, sufficient subjects to meet accrual goals for clinical studies. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, racial and ethnic group, and an accompanying rationale for the selection of subjects. Anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race and ethnicity should be provided as part of the application's Supporting Documentation (Public Health Service [PHS] Inclusion Attachment in Attachment 2).

- If the proposed research involves access to military and/or VA patient populations and/or DOW or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding or other agreements required to access and publish data. Refer to the GAI, Appendix 4, for additional considerations.

– **Statistical model and data analysis plan:** Clearly describe the statistical model and data analysis plan with respect to the study objectives. Demonstrate the proposed research is designed to achieve reproducible and rigorous results. If applicable, include power analysis calculations. If applicable, describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), or international regulatory agency. ***This is not the National Institutes of Health (NIH) Data Management and Sharing Plan.*** Further information describing the strategy for how sex will be considered as a biological variable will be requested in Attachment 2.

– **Research Team:** Describe how the background and expertise of the PI and other key personnel demonstrate their understanding of working in military populations or relevant trauma environments. Describe whether the composition of the research or study team is appropriate and complementary. If prospective clinical studies are included, the PI or research team must demonstrate appropriate expertise in conducting clinical studies.

***Outline for projects with a small-scale or pilot clinical trial (CRRP TRA with Option Phase only)*:**

– **Background:** Describe the problem, question or knowledge gap related to at least one of the FY26 CRRP Focus Areas to be addressed by the proposed project. Present the current state of the field and scientific rationale on which the proposed work is based. Describe the current state of the science, preliminary studies and/or preclinical data that supports the proposed research. These data may be unpublished or from the published literature. Describe any existing resources that the proposed project will leverage. If the project is part of a larger study, articulate the information that establishes a framework for this study. The proposal/application must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project. Throughout the Project Narrative, describe how the proposed research is translational and has the potential for broadly applicable, cross-cutting advances that benefit military health and medicine as well as the general public.

– **Hypothesis/Specific Aims/Hypotheses:** State the hypothesis to be tested and/or the objective to be reached. Detail the project's specific aims that will address the hypothesis and/or research objective. If the proposed work is part of a larger study, present only aims that this CRRP award would fund.

  For applications to the CRRP TRA with Option Phase: Each phase should reflect a distinct (i.e., severable) research effort with a non-overlapping period of performance and research outcomes/milestones. Clearly demonstrate how the Option follows on from the CRRP TRA.

– **Study Design and Feasibility:** Describe the experimental design, methods and analyses, including appropriate controls, in sufficient detail for evaluation. Explain how the research strategy will meet the project's goals and milestones within the

proposed period(s) of performance. Provide a well-developed, well-integrated research strategy that supports the translational feasibility and promise of the approach. Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.

- 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, is a well-validated animal model and how it is optimal for addressing the study aims and facilitates translation of solutions for the Warfighter. Describe how animal research will be conducted in accordance with appropriate preclinical research guidelines. Further details of research involving animals will be required in Attachment 8: Animal Research Plan, as applicable.
- *For clinical trials, describe the rationale for the proposed clinical trial during the Option Phase*. Identify the intervention, technology, or approach to be investigated. Describe the clinical trial approach and outline the proposed methodology in sufficient detail to show a clear course of action. Demonstrate the availability of the intervention, technology or approach, including Investigational New Drug/Investigational Device Exemption (IND/IDE) status (or other relevant Regulatory Agency approvals), as applicable. Provide detailed plans for initiating the clinical study, including FDA IND/IDE application submission plans before Month 18 of the period of performance, if applicable. Regulatory documentation should be provided as part of the application's Supporting Documentation (Attachment 2). Indicate who holds the intellectual property rights for conduct of the study, if applicable. Describe how the study addresses clinical needs and how it compares with what is currently available and/or standards of care. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- Describe the data collection instruments (e.g., research questionnaires, assays, assessment measures) that will be used, and to what degree they are appropriate to support the proposed study. Define the specific study outcomes/endpoints and how they will be measured. Address potential problem areas and present alternative methods and approaches.
- If applicable, describe resources available for the development of sufficient quantities of critical reagents under GMP.
- If human subjects will be used, briefly describe the study population and include a detailed plan for the recruitment of human subjects. Further details of clinical research components will be required in in Attachment 7: Human Subject Recruitment and Safety Procedures for Clinical Research, as applicable.
- If human-derived biological specimens or data will be used, describe the sourcing and/or acquisition of samples. If human-derived specimens will be obtained from military Service Members, military Families and/or Veteran population(s) or dataset(s), describe the feasibility of accessing the samples/dataset(s).
- Provide information on the availability of, and access to, sufficient subjects to meet accrual goals for clinical studies. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a

description of the composition of the proposed study population in terms of sex, racial and ethnic group, and an accompanying rationale for the selection of subjects. Anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race and ethnicity should be provided as part of the application's Supporting Documentation (PHS Inclusion Attachment in Attachment 2).

- If the proposed research involves access to military and/or VA patient populations and/or DOW or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding or other agreements required to access and publish data. Refer to the GAI, Appendix 4, for additional considerations.
- If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically, identify the portions of the study that would be supported with funds from this award.

– **Statistical model and data analysis plan:** Clearly describe the statistical model and data analysis plan with respect to the study objectives. Demonstrate the proposed research is designed to achieve reproducible and rigorous results. If applicable, include power analysis calculations. 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. ***This is not the NIH Data Management and Sharing Plan.*** Further information describing the strategy for how sex will be considered as a biological variable will be requested in Attachment 2.

– **Research Team:** Describe how the background and expertise of the PI and other key personnel demonstrate their understanding of working in military populations or relevant trauma environments. Describe whether the composition of the research or study team is appropriate and complementary. If prospective clinical studies are included, the PI or research team must demonstrate appropriate expertise in conducting clinical studies.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".**

There are no page limits for these components unless otherwise noted. Include only 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 in the Project Narrative using a standard reference format (include URLs, if available).

– **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; include 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 the original or present government award under which the facilities or equipment items are now accountable. There is not a standardized form for this information.

- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letters of Support (one-page limit per letter is recommended):** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOW collaborator(s) and/or access to military populations, databases or DOW resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.
- **Sex as a Biological Variable Strategy (two-page limit is recommended):** Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.
- **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Research Sharing Plan:** Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe the mechanism (e.g., direct sharing, repository, mixed mode) by which data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical research participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed study will be archived, if applicable. Identify and provide the rationale for any data or resources that will not be shared (e.g., for intellectual property, feasibility, cost or other considerations). The plan should also protect participant privacy, confidential and proprietary data, and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

  Do not submit a copy of the NIH Data Management and Sharing Plan or duplicate the Data Management Plan which will be requested only after a recommendation for funding is made.

Refer to the CDMRP Directive on Sharing Data and Research Resources for more information about the CDMRP's expectations for making data and research resources publicly available.

- **Quad Chart:** Provide a quad chart for the proposed project. The format for the quad chart is available on the eBRAP "Funding Opportunities & Forms" web page at (https://ebrap.org/eBRAP/public/Program.htm).

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".**

Write the technical abstract using the outline below. Clarity and completeness within the space limits are highly important.

- **Background:** Present the scientific rationale behind the proposed research project.
- **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Describe the study design, including appropriate controls.
- **Impact and Translation:** Describe the innovative qualities of the proposed work. State the FY26 CRRP Focus Area(s) that the research addresses. Indicate how the proposed work will lead to the translation of advances for improving medical readiness, mitigating fatalities, optimally treating life-threatening injuries and promoting positive long-term outcomes for Service Members, as well as the general public.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".**

The lay abstract should address the points outlined below ***in a manner that is readily understood by readers without a background in science or medicine.*** Avoid overuse of scientific jargon, acronyms and abbreviations. ***Do not duplicate the technical abstract.***

- Summarize the objectives and rationale for the proposed research.
- State the FY26 CRRP Focus Area(s) that the research addresses and describe how it will be addressed.
- Describe the problem or question to be addressed and the ultimate applicability to Warfighter health and impact of the research.
- How will the research increase survivability and readiness of the Warfighter in diverse operational settings?
  - How does the research increase medical readiness, mitigate fatalities, optimally treat life-threatening injuries and/or promote positive long-term outcomes?
  - How will the research improve delivery of medical damage control capability, assets and life-saving interventions?
  - What are the potential clinical applications, benefits and risks?
- Describe how the proposed project will benefit Service Members, Veterans, their Families and the American public.

- **Attachment 5: Statement of Work (3-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the Suggested SOW Format.

  For guidance on preparing the SOW, refer to either the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work or Example: Assembling a Generic Statement of Work, whichever is most appropriate for the proposed effort. Include milestones for data or research resource(s) sharing.

- **Attachment 6: Military Relevance/Impact Statement (two-page limit): Upload as "Impact.pdf".** The impact statement should be written with a broad audience in mind, including readers without a background in science or medicine.
  - Explain in detail how the research represents an accelerated and relevant approach for existing research and technologies, aligned to the FY26 CRRP Focus Area(s). If research is cross-cutting, describe how it may have the potential to benefit multiple DOW medical research program areas.
  - Describe how the proposed research will significantly improve the readiness of the Force in varied military environments. Clearly articulate how the proposed research can be applied and implemented in far-forward roles of care (e.g., in combat, at point of injury, en route) to optimize survival and recovery during future large-scale combat operations that feature delayed evacuation and austere environments. Describe how the anticipated outcomes will be translated into clinical practice and decrease morbidity and mortality of the Warfighter. Describe any potential issues or anticipated challenges that might limit the impact.
  - If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
  - Describe how the anticipated outcomes of the proposed project will advance operational performance, medical readiness or quality of life of Service Members. In addition, describe how the proposed research will benefit their Veterans, Families, caregivers and the American public, as applicable. Include the timeline to realize the anticipated short-term and long-term outcomes of the research. Explain how the knowledge, technologies or products gained from the research could be implemented in a capacity to benefit the civilian population and address the health care needs of military Service Members, Veterans and/or their beneficiaries, as appropriate.

- **Attachment 7: Human Subject Recruitment and Safety Procedures for Clinical Research (no page limit), if applicable; required for all studies that recruit human subjects (e.g., clinical research and clinical trials): Upload as "HumSubProc.pdf".** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below, where applicable.
  - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the PHS Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study, with the proposed enrollment distributed on the basis of sex/gender, race and ethnicity. Studies that utilize human biospecimens or datasets that cannot be linked to a specific individual, gender,

ethnicity or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement. ***Demonstrate that the research team has access to the proposed study population at each site and describe the efforts that will be made to achieve accrual goals***. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity or sex/gender. ***For clinical research that proposes to include military personnel, refer to Appendix 4 of the GAI, for more information.***

- **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical study. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.
- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them and what methods will be used to recruit them. Address the availability of human subjects for the clinical study at each enrollment site. If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan. Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study. Address any potential barriers to accrual and plans to address unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Identify any ongoing clinical studies that may compete for the same population and how they may impact the enrollment progress.
- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects. ***This PA may not be used to support studies requiring EFIC.***
  - ***For the proposed study, provide a draft, in English, of the Informed Consent Form.***
    - Applicants are also strongly encouraged to include language in consent forms to allow for optional passive follow-up via electronic health record.
  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the study.
  - Include information regarding the timing and location of the consent process.
  - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations or human subject age), if applicable.
  - Address how privacy and time for decision-making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
  - Consider the need to obtain ongoing consent or to re-assess capacity over the course of a long-term study, and describe any relevant procedures to assure continued consent.

- Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. ***Note:*** In compliance with 10 USC 980 (https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf), if the research will include an intervention or interaction with subjects for the primary purpose of obtaining data regarding the effect of the intervention or interaction, the proposal/application must describe a clear intent to benefit for all human subjects who cannot give their own consent to participate in the proposed clinical study. If applicable, refer to the GAI, Appendix 6, for more information.
- ***Assent:*** If minors or other populations that cannot provide informed consent are included in the proposed clinical study, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.

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

– **Risks/Benefits Assessment:**

- **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is exposed to as a result of participation in the clinical study. Consider psychological, legal, social and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
- **Risk management and emergency response:**
  - ❖ Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and Regulatory Agency (if applicable) will be managed - and conducted. Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values. Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care. Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting and pregnancy prevention). Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.

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

- **Attachment 8: Animal Research Plan (five-page limit): Upload as "AnimalResPlan.pdf".** ***(Attachment 8 is only applicable and required for applications proposing animal studies.)***

  If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the 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 Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

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

- **Attachment 9: Regulatory Strategy (no page limit):** ***(Attachment 9 is applicable and required for clinical research/trials.)*** **If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Address the following and provide supporting documentation as applicable.

  ***For FY26 CRRP TRA applications proposing clinical trials*:**

  - State the product/intervention name.
  - If none, state how the proposed study meets the definition of clinical research.

  ***For products/interventions that do not require regulation by a Regulatory Agency*:**

  - Provide evidence that the product/intervention does not require regulation by a Regulatory Agency. Note that this request includes, but is not limited to software applications, algorithms, nutraceuticals or behavioral health interventions. ***Submissions providing "not applicable," "none," or similar responses do not satisfy this request and may be administratively withdrawn.*** If the clinical study will be conducted at international sites, provide equivalent information relevant to the

host country(ies) regulatory requirements. No further information for this attachment is required.

***For products that require regulation by the FDA and/or an international regulatory agency*:**

- For investigator-sponsored regulatory exemptions (e.g., IND, IDE) provide evidence of institutional support. Provide evidence that the clinical study does not require regulation by the FDA. Clearly identify whether a member of the study team holds the regulatory exemption.
- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States.
- If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).
- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic or combination product. Indicate whether the FDA has confirmed the proposed classification.
- ***If an IND or IDE is required for the work proposed in the FY26 CRRP TRA period of performance, the IND/IDE application must be submitted to the FDA prior to the application submission deadline. If an IND or IDE is required to support a clinical trial during the Option phase, the IND/IDE must be submitted to the FDA no later than Month 18 of the period of performance.*** The IND or IDE should be specific for the investigational product, i.e., not a derivative or alternate version of the product, and indication to be tested in the proposed clinical trial. ***Provide the date of submission, the application number and a copy of the FDA letter acknowledging the submission.*** If there are any existing cross-references in place, provide the application number(s) and associated sponsor(s). Provide an explanation of the status of the application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold, on partial clinical hold). If the IND or IDE application has been placed on clinical hold or partial hold, explain the conditions that must be met for release of the hold. Provide a summary of any previous meetings with the FDA on development of this product. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application.
- If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
- If an active IND or IDE for the investigational product is in effect, but an amendment is needed to include the proposed clinical study, describe the type and nature of the amendment(s) and the timeline for submission. Indicate whether the amendment increases the risk of the intervention.
- Provide the current status for manufacturing development (manufacturer's name, GMP-compliant lots available, status of stability testing, etc.), nonclinical

development (test facility name, status of pivotal Good Laboratory Practice [GLP] toxicology studies to support phase 1 testing, etc.), and clinical development (clinical site name, safety profile, status of any completed or ongoing clinical trials, etc.).

- **Attachment 10: Transition Plan (three-page limit): Upload as "Transition.pdf".**

  Describe the methods and strategies proposed to enable the product or knowledge outcomes to move to the critical next phase of development (e.g., clinical trials, partnership with DOW 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 biomedical TRL or KRL of 4, and estimate the target TRL/KRL level upon completion of the proposed research (Appendix 3). Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to determine the TRL/KRL levels and to develop the transition plan. PIs are encouraged to explore developing relationships with industry, DOW advanced developers and/or other funding agencies to facilitate moving the product into the next phase of development. The transition plan should include the components listed below.

  - Discuss the significance of this development effort, when it can be anticipated and the potential commercial and/or field use for the technology being developed.
  - Provide a brief financial analysis to support transition and translation of 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 products intended for commercialization, discuss the significance of the development effort, market space to include strengths and weaknesses of the proposed product(s), competitors, barriers to market.
  - A brief schedule and milestones for transitioning the product(s) to the next phase of development (e.g., next-phase clinical trials, transition to industry, delivery to the civilian and/or military market, and/or incorporation into clinical practice).
  - Describe the current and 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 to be held; the submission filing strategy; and considerations for compliance with GMP, GLP and Good Clinical Practice (GCP) guidelines, if appropriate. For clinical research involving FDA-regulated products or that may lead to FDA-regulated trials, see Attachment 9 for the required regulatory strategy appropriate to the objectives of the study.
  - 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.
  - 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.

  - A risk analysis for cost, schedule, manufacturability and sustainability.

- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.

- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOW organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the Suggested Intragovernmental/Intramural Budget form available on eBRAP.

(c) Additional Application Materials:

The following are additional forms for application submission. Follow the instructions specific to the submission portal, as found within the GAI.

	Grants.gov	eBRAP.org
i. Research & Related Senior/Key Person Profile (Expanded)		
○ **Biographical Sketch**		
○ **Current/Pending Support** *Intragovernmental applicants must include their internally supported research and development programs.*		
ii. Research & Related Budget		
iii. Project/Performance Site Location(s)		
iv. Research & Related Subaward Budget Attachment(s) *(if applicable, Grants.gov submissions only)*		

4.4. Other Application Elements

If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DOW Instructions 3200.12 will be requested.

The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942526CRRPTRA from Grants.gov or eBRAP, depending on which submission portal will be used.

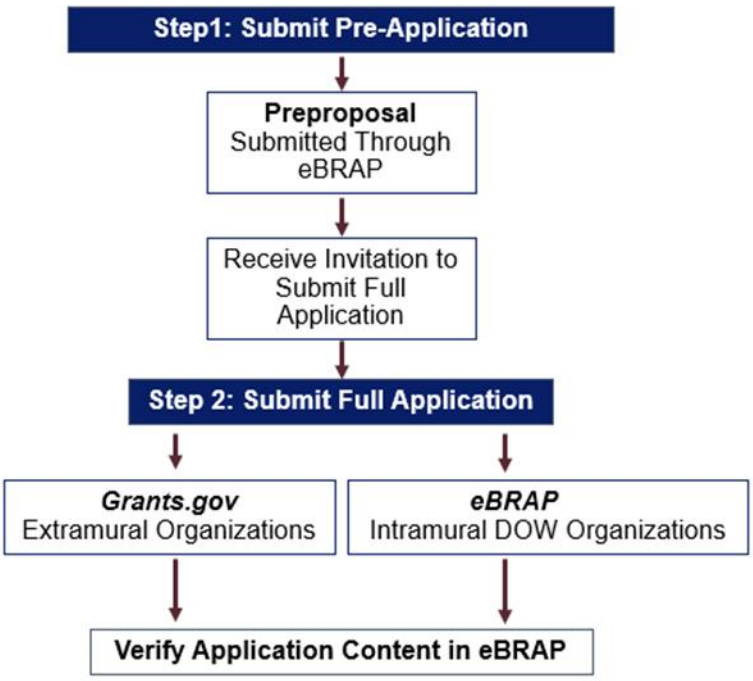
5.2. Unique Entity Identifier and System for Award Management

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

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions. The workflow below shows which portal system to use for pre- and full application submissions, respectively.

Application Submission Workflow



5.3.1. Pre-Application Submission

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

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

When starting the pre-application, PIs should select a Mechanism Option appropriate to their pre-application:

Application Includes:	Select Mechanism Option:
Translational Research Award	No Option
Proposed Optional Research Effort, but no pilot clinical trial	TRA With Option Phase
Proposed Optional Research Effort, with pilot clinical trial	TRA With Option Phase, Clinical Trial

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace.

eBRAP Submissions: Only intramural DOW organizations may submit full applications through eBRAP.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the application verification period ends. The full application cannot be modified once the application verification period ends.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The DHACA cannot make allowances/exceptions for submission problems encountered by the applicant.***

Submission dates and times are specified in Section 1, Basic Information.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

6. Application Review Information

6.1. Application Compliance Review

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

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

Including classified research data within the application and/or proposing research that may produce classified outcomes or outcomes deemed sensitive to national security concerns, may result in application withdrawal.

Members of the FY26 CRRP Programmatic Panel must not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members ***may*** provide letters to confirm PI eligibility and access to laboratory space, equipment and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). ***A list of the FY26 CRRP Programmatic Panel members can be found on the CDMRP website.***

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

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

To determine the merits of the pre-application and the relevance to the mission of the CRRP, pre-applications will be screened based on the following criteria:

- **Funding Mechanism and Alignment With Focus Areas:** How well the study adheres to the intent of the funding mechanism. To what extent the proposed work addresses at least one FY26 CRRP Focus Area.
- **Research Approach:** How well the scientific rationale (including relevant preliminary data), hypotheses, objectives, specific aims and experimental approach are described.
- **Translational Potential:** How well the project will accelerate promising research findings into clinical applications and move the field forward from where it is now to where it will be at the completion of the research project. Whether the next steps after completion of the work are articulated and reasonable.
- **Impact and Relevance to Military Health:** How well the research project will make important advancements towards improving medical readiness, mitigating fatalities, optimally treating life-threatening injuries and promoting positive long-term outcomes for military health and medicine, as well as the general public.

6.2.2. Peer Review Criteria

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

- **Translational Potential**
  - How well the application justifies how the proposed work is translational.
  - How well the application describes where the field is now, and whether the anticipated research outcome(s) are realistic given the state of the field and the proposed research approach.
  - To what extent the critical next step to take after completion of the proposed project is necessary and required to move the outcome of the research forward toward implementation.
  - How likely the research will move promising ideas into solutions for life-threatening injuries sustained by the Warfighter and overall medical readiness.
- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project as demonstrated by preliminary data, a critical review and analysis of published literature and completed/ongoing studies.
  - How well the hypothesis and/or objectives, specific aims, experimental design, methods and analyses are developed.
  - For clinical trials (*CRRP TRA with Option Phase*), to what degree the application includes preclinical and/or clinical evidence to support safety and stability (as appropriate) of the intervention, or to what degree the application includes a plan to generate this evidence prior to initiation of the clinical trial in the Option Phase.
  - How well studies are designed to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured.
  - For clinical trials (*CRRP TRA with Option Phase*) using a regulated product, whether the proposal includes a plan for obtaining an IND/IDE.
  - *For CRRP TRA with Option Phase*: To what extent the application reflects distinct, non-overlapping phases, where the Option Phase follows on from the initial research period.
  - To what extent the proposed research project is feasible as described.
  - How well the research strategy will meet the project's goals and milestones within the proposed period of performance.
  - How well the applicant demonstrates access to the relevant study resources.
  - If applicable, how well the animal study is (or studies are) designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used, and facilitate rapid development and solutions for the Warfighter.
  - How well the application acknowledges potential problem areas and addresses alternative methods and approaches.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single-sex study is sufficiently strong.

- How well the data and resources plan feasibly allows for data sharing.

- **Military Relevance/Impact**
  - To what extent the anticipated outcomes of the proposed study will make an impact in the field.
  - How well the proposed work represents an accelerated and relevant approach aligned to the FY26 CRRP Focus Area(s).
  - To what extent the proposed research will significantly improve the readiness of the Force.
  - How well the project outcomes will impact clinical practice and decrease morbidity and mortality of the Warfighter.
  - For clinical trials, to what degree the intervention addresses current clinical need(s), improves upon available interventions and/or standards of care, or addresses critical gaps relevant to the FY26 CRRP Focus Area(s).
  - To what extent the proposed research can be utilized in far-forward roles of care or austere environments, if applicable.
  - To what degree the anticipated outcomes of the proposed project will lead to improved operational performance, medical readiness or quality of life for Service Members.
  - To what degree the anticipated outcomes could be implemented in a capacity to benefit the civilian population and address the health care needs of military Service Members, Veterans and/or their beneficiaries, if applicable.
- **Clinical Strategy (for studies recruiting human subjects)**
  - How well the clinical research or clinical trial portion of the application is designed with appropriate study variables, controls, endpoints and data analysis plan.
  - How well the application demonstrates the availability of, and access to, the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.
  - Whether the strategy for the inclusion of women and minorities and the distribution of proposed enrollment are appropriate for the proposed research, including a description of the composition of the proposed study population in terms of sex, racial and ethnic group, and an accompanying rationale for the selection of subjects.
  - Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race and ethnicity is included.
- **Statistical and Data Analysis Plan**
  - How well the proposed research is designed to achieve reproducible and rigorous results, including controls, sample size estimation, randomization, statistical analysis and data handling.
  - How the statistical plan, including sample size projections and power analysis, is for achieving the study objectives and is appropriate to type and phase of study.
  - If applicable, how well the application identifies sampling methods to gain a representative sample from the population(s) of interest.
  - To what degree the research data collection instruments are appropriate to support statistical significance of the proposed study.

- **Ethical Considerations (for studies recruiting human subjects)**
  - How well the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.
  - Whether the population selected to participate in the clinical research stands to benefit from the knowledge gained.
  - To what degree privacy and confidentiality of study records are appropriately considered.
  - To what degree the processes for seeking informed consent are appropriate and whether safeguards are in place for vulnerable populations.
- **Regulatory Strategy and Transition Plan**
  - If applicable, whether evidence that the product/intervention does not require regulation by a Regulated Agency is provided and reasonable.
  - If applicable, how the overall regulatory strategy and product development plan will support the planned product indication or product label change.
  - As appropriate, whether the application includes evidence that the IND or IDE application (or international equivalent) has been submitted to the appropriate Regulatory Agency.
  - For investigator-sponsored investigational product regulatory exemptions (e.g., IND, IDE), whether there is evidence of appropriate institutional support.
  - Whether plans to comply with current GLP, GMP and GCP guidelines are appropriate.
  - Whether a member of the study team is the regulatory sponsor and holds the investigational product regulatory exemption (e.g., IND/IDE) for the proposed indication.
  - Whether the overall strategy described to transition the research to commercialization or clinical use is reasonable and achievable.
  - Whether the schedule and milestones for transitioning the research to a clinical product are achievable.
  - Whether the potential risk analysis for cost, schedule, manufacturability and sustainability is realistic and reasonable.
  - How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and commercialization.
  - If applicable, how well the application describes an appropriate intellectual and material property plan among participating organizations.
  - If applicable, how well the application addresses any impact of intellectual property issues on product development and the government’s ability to access such products or technologies in the future.
- **Research Team**
  - To what degree the background and experience of the PI and other key personnel demonstrate their ability to perform the proposed work.
  - To what degree the levels of effort by the PI and other key personnel are appropriate to ensuring the successful conduct of the project.

- How the PI's record of accomplishment demonstrates their ability to accomplish the proposed work.
- How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).

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:**

- **Research Sharing Plan**
  - To what extent the plan for sharing of project data and research resources is appropriate and reasonable and includes dissemination to affected communities, study participants and/or the scientific community. If applicable, whether specific repository(ies) are named where data and research resources arising from the project will be stored.
- **Budget**
  - Whether the budget is appropriate for the proposed research.
- **Environment**
  - To what extent the scientific environment and level of institutional support is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
- **Application Presentation**
  - To what extent the writing, clarity and presentation of the application components influence the review.

6.2.3. Programmatic Review

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

- Ratings and evaluations of peer reviewers
- Relevance to the priorities of the FY26 CRRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Relevance to military health
  - *Relative impact and translational potential*

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section 1, Basic Information about the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is

based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

6.3.2. Full Application

All applications are evaluated by scientists, clinicians and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are subject to review and approval by a designated official. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds.

6.4. Risk, Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in the Code of Federal Regulations, Title 2, Part 200.1 (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 the SAM.

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

In accordance with National Security Presidential Memorandum-33 and all associated laws, all fundamental research funded by the DOW must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

7. Federal Award Notices

For each compliant full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the application receipt and review process for the CRRP 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. After all awards are made, the CDMRP includes individual award information in a searchable database.

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 DHACA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. No commitment on the part of the government should be inferred from discussions with any other individual. ***The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).***

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

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

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award.

8. Post-Award Requirements

8.1. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

The GAI contain information regarding administrative requirements and national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the DHACA Terms and Conditions for further information.

If there are delinquencies in technical reporting requirements for any existing DHA or U.S. Army Medical Research and Development Command awards at the applicant organization, DHACA will not issue any new awards to the applicant organization until all delinquent reports have been submitted.

Applications recommended for funding that involve animals, human data, human specimens, human subjects or human cadavers must be reviewed for compliance with federal animal and/or human subjects protection requirements and must be approved by the DHA R&D Office of Research and Regulatory Compliance (ORRC), prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB or Ethics Committee (EC) review.

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Additionally, the CDMRP requires all funded clinical trials to register and submit study results on ClinicalTrials.gov.

8.2. Reporting

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

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

Inclusion Enrollment Reporting: ***(only required for clinical research studies and clinical trials)*:** Enrollment reporting on the basis of sex, race and/or ethnicity using the PHS Inclusion Enrollment Report will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on eBRAP.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to the SAM about certain civil, criminal and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with their 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.

8.3. Additional Requirements

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

For applications to the CRRP TRA with Option Phase, transition to the Option Phase will be based on the following criteria:

- Completion of the first phase research within the 2-year period of performance, with sufficient evidence of milestone completion, such as availability of any drugs/devices to be utilized during the Option, FDA IND/IDE filing (or other appropriate regulatory filing), commercialization or transition/translation of knowledge products to clinical practice or in a specific clinical environment, to include evaluation of clinical practice guidelines, if applicable.
- If a clinical trial is proposed in the Option SOW, communication from the FDA indicating the IND or IDE application is active/safe to proceed must be submitted to the CDMRP by Month 18 of the period of performance, if applicable.
- Timely submission of quarterly and annual progress reports and quad charts.
- Evaluation of progress against the proposed SOW during a virtual milestone review meeting to be conducted on or about Month 18 of the period of performance.
- Presentation of research at a minimum of one national research or military-relevant conference.
- Documented progress in making results available to the research community such as one or more documented publication submissions.

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

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

9. Other Information

9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26_01d.

9.2. Administrative Actions

After receipt of full applications, the following administrative actions may occur.

9.2.1. Rejection

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

- Preproposal Narrative is missing.

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

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

For applications involving animal research:

- The Animal Research Plan (Attachment 8) is missing.

For proposals/applications recruiting human subjects:

- The Human Subject Recruitment and Safety Procedures (Attachment 7) is missing.

9.2.2. Modification

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

9.2.3. Withdrawal

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

- A member of the FY26 CRRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.
- The federal government recipient organization (including an intramural DOW organization): (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or (b) cannot coordinate the use of contractual, assistance or other appropriate agreements to provide funds to collaborators.
- The application fails to conform to this program announcement description.
- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The invited application proposes a different research project than that described in the pre-application.
- The applicant is named as the PI on more than one application to the FY26 CRRP.
- The PI does not meet the eligibility criteria.
- The application requiring IND/IDE (or international equivalent) during the period of performance does not include documentation of submission in the Regulatory Strategy (Attachment 9).
- The application proposes EFIC research.
- A clinical trial is proposed under the CRRP TRA (without Option Phase).

9.2.4. Withhold

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

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance ***(Grants.gov submissions only)***	☐
Summary (Tab 1) and Application Contacts (Tab 2) ***(eBRAP submissions only)***	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Military Relevance/Impact Statement – Attachment 6, upload as "Impact.pdf"	☐
Human Subject Recruitment and Safety Procedures for Clinical Research ***(if applicable)*** **– Attachment 7, upload as "HumSubProc.pdf"**	☐
Animal Research Plan ***(if applicable)*** **– Attachment 8, upload as "AnimalResPlan.pdf"**	☐
Regulatory Strategy ***(if applicable)*** **– Attachment 9, upload as "Regulatory.pdf"**	☐
Transition Plan – Attachment 10, upload as "Transition.pdf"	☐
Representations ***(Grants.gov submissions only)*** **– Attachment 11, upload as "RequiredReps.pdf"**	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 12, upload as "IGBudget.pdf"**	☐
Additional Application Materials	
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)	☐
Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)	☐
Research & Related Budget	☐
Project/Performance Site Location(s)	☐
Research & Related Subaward Budget Attachment(s) ***(if applicable)***	☐

Appendix 2. Acronym List

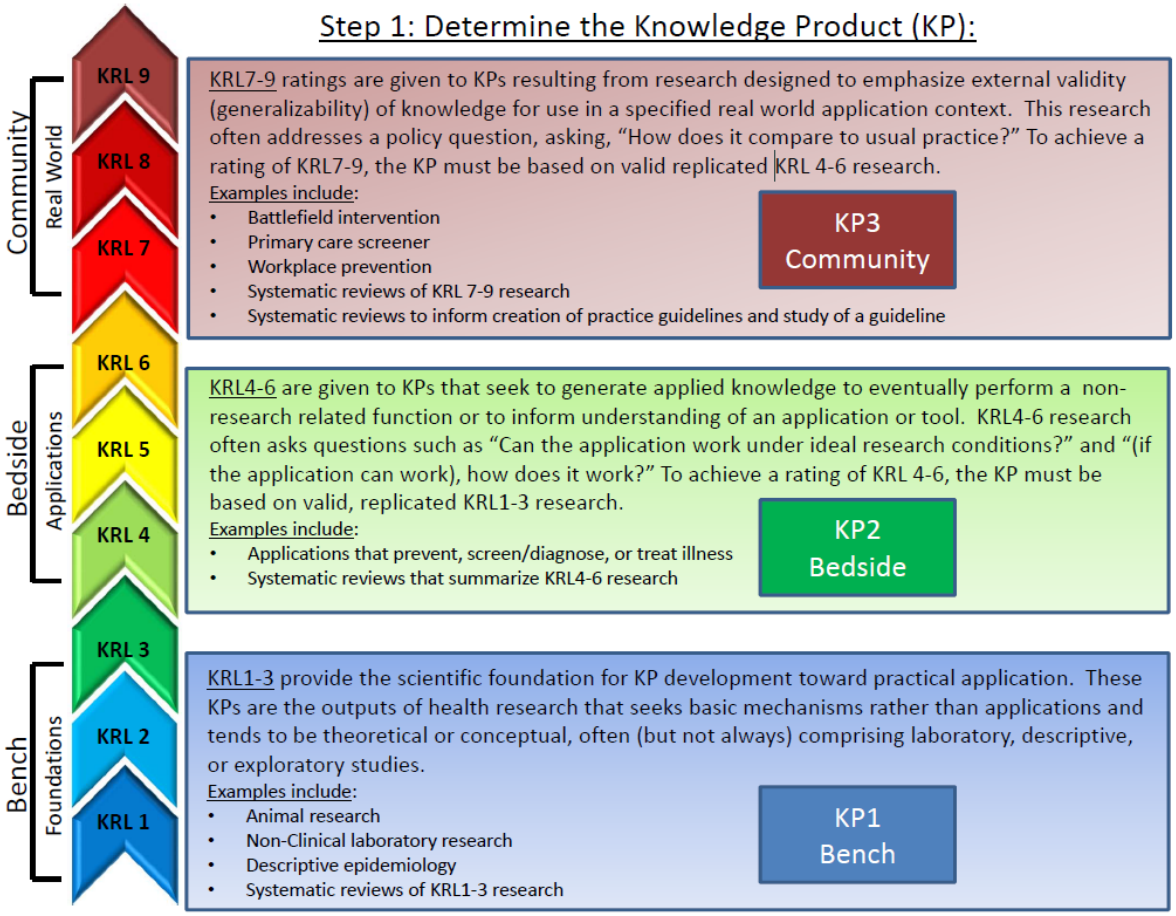
ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CRRP	Combat Readiness – Medical Research Program
DHA	Defense Health Agency
DHA R&D	Defense Health Agency Research and Development
DHACA	Defense Health Agency Contracting Activity
DOD	U.S. Department of Defense
DOWGARs	Department of Defense Grant and Agreement Regulations
DOW	U.S. Department of War
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
EFIC	Exception from Informed Consent
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
KP	Knowledge Product
KRL	Knowledge Readiness Level
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORRC	Office of Research and Regulatory Compliance
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
R&D	Research and Development
RPPR	Research Performance Progress Report
SAM	System for Award Management
SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
TRA	Translational Research Award

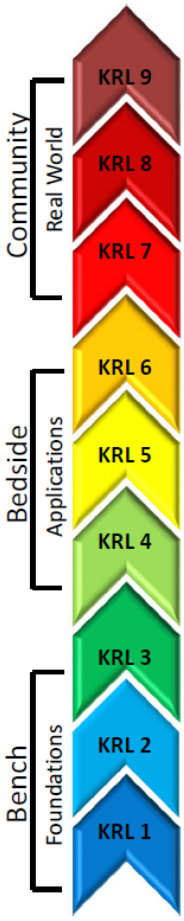
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs

Appendix 3. Technology Readiness Levels and Knowledge Readiness Levels

***Technology Readiness Levels*:** TRLs are used to categorize the product maturity of materiel solutions. The DOW's Technology Readiness Assessment 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 DOW Technology Readiness Assessment Deskbook (July 2009, https://apps.dtic.mil/sti/pdfs/ADA418881.pdf).

***Knowledge Readiness Levels*:** 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.)