I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Chronic Pain Management Research Program

Translational Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-21-CPMRP-TRA

**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 30, 2021

- **Invitation to Submit an Application:** September 24, 2021

- **Application Submission Deadline:** 11:59 p.m. ET, November 12, 2021

- **End of Application Verification Period:** 5:00 p.m. ET, November 17, 2021

- **Peer Review:** January 2022

- **Programmatic Review:** March 2022

*This program announcement must be read in conjunction with the General Application
Instructions, version 605. The General Application Instructions document is available for
downloading from the Grants.gov funding opportunity announcement by selecting the
"Package" tab, clicking "Preview," and then selecting "Download Instructions."*

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II.   DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A.   Program Description

Applications to the Fiscal Year 2021 (FY21) Chronic Pain Management Research Program (CPMRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP). The CPMRP was initiated in 2019 to provide support for research of exceptional scientific merit with the potential to make a significant impact on improving the health and quality of life of those living with chronic pain. Appropriations for the CPMRP from FY19 through FY20 totaled $25 million (M). The FY21 appropriation is $15M.

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.

Per the FY19 CPMRP congressional appropriation, chronic pain is defined as pain that occurs on at least half the days for 6 months or more, and which can be caused by issues including, but not limited to, combat- and training-related physical or mental stress and trauma, migraines and chronic headaches, traumatic brain injury (TBI), arthritis, muscular-skeletal conditions, neurological disease, tick and vector-borne disease, other insect-transmitted or tropical disease, and cancer. The CPMRP encourages alignment of research projects with the Federal Pain Research Strategy for maximizing the impact of chronic pain research outcomes. Applications from investigators within the military Services and applications involving multidisciplinary collaborations among academia, industry, the military Services, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged.

II.A.1. FY21 CPMRP Translational Research Award (TRA) Focus Areas

To meet the intent of the award mechanism, ***applications must address at least one of the FY21 CPMRP TRA Focus Areas***. Selection of the appropriate focus area is the responsibility of the applicant.

- Implementation science (for evidence-based, efficacious interventions to manage or prevent chronic pain)

  - Unique barriers in military populations and environments, including at-risk subpopulations

  - Self-management and service-of-care models

  - Interventions to prevent chronification of pain

- Comparative effectiveness (for evidence-based, efficacious interventions to manage or prevent chronic pain)

- o Multimodal and combination therapies

- o Relationships between comorbidities and pain

- o Preventing chronification of pain

- Observational studies related to chronic pain

- o Predictor studies of poor outcomes from long-term opioid use

- o Predictors of pain chronification

- o Evaluation of health care use patterns (e.g., systems, interventions, treatments, self-care)

- o Relationships between comorbidities and pain

II.A.2. Award History

The CPMRP TRA mechanism was first offered in FY19. Since then, 24 TRA applications have been received, and 3 have been recommended for funding for a 13% funding rate.

II.B. Award Information

The intent of the FY21 CPMRP TRA is to support translational research that will accelerate the movement of evidence-based ideas in chronic pain management research into clinical applications, such as healthcare products, technologies, clinical practice guidelines, and/or models of care. TRA applications should explain how the proposed work will inform the development, refinement, and/or revision of existing standards of care, recommendations, or guidelines for managing chronic pain. ***Studies seeking to advance new and novel opioid-based therapeutic interventions do not meet the intent of the award mechanism and may be withdrawn. Studies seeking to understand and reduce opioid utilization in chronic pain management within the context of current prescribing practices are acceptable.***

The critical components of this award mechanism are:

- **Translation:** The proposed study should demonstrate how the research findings will translate to the application of non-opioid non-addictive approaches to chronic pain management and prevention in the diverse setting of regular patient care, taking into consideration the specific needs of at-risk populations, such as active-duty Service Members and Veterans. The research should be geared toward near-term clinical applicability with the potential of making an immediate impact on the identified target population. Translational research will, if successful, accelerate the movement of promising ideas into clinical applications.

- **Preliminary Data:** Applications ***must include preliminary data*** (e.g., published works by the investigators, pilot data, peer-reviewed literature) to support feasibility of the study. Any unpublished preliminary data provided should originate from the laboratory of the Principal Investigator (PI) or a member(s) of the research team. The TRA is intended to support

translational investigations that improve: patient care through the characterization of the chronic pain experience and treatment practices, the application of known efficacious treatments of chronic pain by identifying and eliminating barriers to implementation, and pairing patients with treatment regimens based on relative measures of effectiveness. Given the strong clinical focus, the TRA is not intended for basic research to generate preliminary data.

- **Biopsychosocial Model of Assessment:** Studies including prospective subject evaluation are encouraged to incorporate an established biopsychosocial model of pain assessment that includes pain interference in emotional and physical functioning. Applications are encouraged to consider the six core outcomes domains for a chronic pain clinical trial recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) in Dworkin RH, Turk DC, Farrar JT, et al. 2005. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain* 113(1-2):9-19. The six core outcomes domains are: (1) pain, (2) physical functioning, (3) emotional functioning, (4) participant ratings of improvement and satisfaction with treatment, (5) symptoms and adverse events, and (6) participant disposition.

- **Relevance to Military Health:** The CPMRP seeks to support research that is relevant to the healthcare needs of military Service Members, Veterans, and/or their families. Relevance may arise by addressing high incidence rate within a population of interest, or significant debilitating effects on focused subpopulations. The application must articulate the potential translational impact the proposed project will have on Service Members, Veterans, and/or their family members or beneficiaries living with chronic pain. Investigators are *encouraged* to consider the following characteristics as examples of how a project may demonstrate relevance to military health:

    o Use of military or Veteran populations, biospecimens, or data/databases in the proposed research.

    o Collaborations that include the Department of Defense (DOD) Military Health System (MHS), Military Treatment Facilities (MTFs), and/or VA investigators and facilities.

    o Research projects that integrate and/or align with DOD and/or VA research laboratories and programs. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 2.

    o Research projects that integrate techniques/approaches/pathways that fill an unmet requirement in patient care and are feasible for deployment within the existing Defense Health Agency (DHA) or Veterans Health Administration (VHA) healthcare systems.

    o Explanation of how the project addresses an aspect of chronic pain management that has direct relevance to military Service Members, Veterans, and/or other MHS beneficiaries.

- **Stakeholder Engagement:** Applicants are strongly encouraged to consider the views, opinions, and priorities of stakeholders at various ecological levels of patient care. This includes consideration of patient expectations, preferences, and goals of treatment at point of

care. Stakeholder engagement should be considered during both study design and research conduct.

- **Partnering PI Option:** The FY21 CPMRP TRA encourages applications that include meaningful and productive collaborations between two investigators. Electing to submit to the Partnering PI Option does not influence the total direct cost limit as outlined in [Section II.D.5 Funding Restrictions](#). One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. The PIs may have expertise in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application. The application should clearly demonstrate that both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project. It is expected that funding will be balanced between both PIs unless appropriately justified. The application is expected to describe how the PIs' unique expertise combined as a partnership will better address the research question, how the unique expertise that each individual brings to the application is critical for the research strategy and completion of the SOW, and why the work should be done together rather than through separate efforts. ***To meet the intent of the Partnering PI Option, applicants are discouraged from being named as a Partnering PI on multiple applications unless they are clearly addressing distinct research questions. Applications in which a mentor and their current postdoctoral fellow or junior investigator are named as Initiating and Partnering PIs do not meet the intent of the Partnering PI Option.*** If recommended for funding, each PI will be named to an individual award within the recipient organization. For individual submission requirements for the Initiating and Partnering PI, refer to [Section II.D.2, Content and Form of the Application Submission](#).

Collaborations with researchers at military or Veteran institutions and non-military institutions are strongly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations, ultimately advancing chronic pain management research that is of significance to the Warfighter, military families, and/or the American public.

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a "thing of value" to a "state, local government," or "other recipient" to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the DOD during project performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed

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

The anticipated direct costs budgeted for the entire period of performance for an FY21 CPMRP TRA will not exceed **$1.4M**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information refer to Section II.F.1, Federal Award Notices.

The CDMRP expects to allot approximately $4.48M to fund approximately two TRA applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is **not** required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

The FY21 CPMRP TRA mechanism supports implementation and/or comparative effectiveness research. ***Clinical trials are allowed under these focus areas but should be restricted to pain management interventions that have already been shown to be efficacious in some clinical settings. Studies seeking to evaluate new therapies or approaches, either pharmacological or non-pharmacological, do not meet the intent of the award mechanism.*** Supported research can include studies using human subjects data and/or prospectively enrolling clinical studies. For more information on clinical trials and clinical research, a Human Subject Resource Document is provided at https://ebrap.org/eBRAP/public/Program.htm.

A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Funded trials are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in Code of Federal Regulations, Title 32, Part 219 (32 CFR 219).

Clinical research is defined as: (1) patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research. ***Note:*** Studies that meet the requirements for IRB Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

An implementation science study is defined as the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health. Studies that examine barriers/facilitators to implementation and those investigating strategies that address barrier/facilitators are acceptable under the FY21 CPMRP TRA.

An ***evidence-based, efficacious intervention*** should be consistent with the standards established in [Flay BR, Biglan A, Boruch RF, et al. 2005. Standards of evidence: Criteria for efficacy, effectiveness and dissemination. *Prevention Science* 6(3):151-175.](#) It should have been tested in at least two rigorous trials that (1) involved defined samples from defined populations, (2) used sound measures and data collection procedures, (3) analyzed the data with rigorous statistical approaches, (4) showed consistent positive effects (without serious iatrogenic effects), and (5) reported at least one significant long-term follow-up.

The Office of the Army Surgeon General established a Pain Management Task Force whose [final report (http://www.dvcipm.org/site/assets/files/1070/pain-task-force-final-report-may-2010.pdf)](http://www.dvcipm.org/site/assets/files/1070/pain-task-force-final-report-may-2010.pdf) was published in May 2010. In the report, a list of Tier 1 ***complementary and integrative health treatment modalities*** were identified based on efficacy, safety, and widespread use or acceptance. Applicants are encouraged to consider modalities identified by the DOD and VA as a priority for development and implementation.

Use of DOD or VA Resources: If the proposed research involves access to active-duty military or Veteran patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full Application Submission Components,](#) for detailed information. Refer to the General Application Instructions, Appendix 1, Section C, for additional detailed information.

Research Involving Animals: All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. *Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.* Refer to the General Application Instructions, Appendix 1, for additional information.

Studies utilizing animals as a model system to replicate chronic pain conditions are prohibited under the TRA mechanism. Studies including service animals that provide support to human subject participants are permissible.

Prospective Human Studies and the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System: The DOD requires that awardees make TBI research data generated by this award mechanism available to the research community through the FITBIR Informatics System. The FITBIR Informatics System is a free resource designed to accelerate research progress by allowing the storage, re-analysis, integration, and rigorous comparison of multiple datasets. *Currently, FITBIR-eligible research includes all studies generating prospectively collected human TBI subject data (e.g., clinical, demographic, phenotypic, imaging, genomic).* Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and to collaborate with others engaged in similar research. While there is no direct charge to users of the FITBIR Informatics System, a project estimation tool (https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp) is available to help estimate costs and manpower needs that may be associated with data submission. FITBIR guidance and policies, as well as the considerable advantages of FITBIR participation to the researcher, are detailed at https://fitbir.nih.gov/.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

Government Agencies Within the United States: Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

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

Intramural DOD Organization: A DOD laboratory, DOD MTF, and/or DOD activity embedded within a civilian medical center. *Intramural Submission: Application submitted by*

a DOD organization for an intramural investigator working within a DOD laboratory or MTF or in a DOD activity embedded within a civilian medical center.

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Investigators at or above the level of Assistant Professor (or equivalent) may be named by the organization as the PI or Partnering PI on the application.

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

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at https://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

Submission of applications that are essentially identical or 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).

Extramural Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.

- Full application packages must be accessed and submitted at Grants.gov.

Intramural DOD Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.

- Full application packages must be accessed and submitted at eBRAP.org.

Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.

II.D.1. Address to Request Application Package

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in Section II.G, Federal Awarding Agency Contacts.

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

Submission is a two-step process requiring both ***pre-application*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to Table 1, Full Application Guidelines).

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

Partnering PI Option: The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified of the pre-application submission separately by email. ***The Partnering PI must follow the link in the notification email in order to associate their full application package with that of the Initiating PI. After following the link, the Partnering PI must verify their contact information, organization, and designation as an extramural or intramural submission within eBRAP.*** If not previously registered, the Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI. Applicants are urged to complete these steps as soon as possible. If they are not completed, Partnering PIs will not be able to view and modify their application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI's required full application package components to eBRAP.

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the Initiating PI through eBRAP (https://eBRAP.org/). Because the invitation to submit an 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.

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

PIs with an ORCID identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

  Submission of application information includes assignment of primary and secondary research classification codes, which may be found at https://ebrap.org/eBRAP/public/Program.htm. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

  Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

  Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on "Add

Organizations to this Pre-application." The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

  Enter the name, organization, and role of all collaborators and key personnel associated with the application.

  FY21 CPMRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

  The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

  Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

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

    The Preproposal Narrative should include the following:

    – **Rationale:** State the hypothesis and reasoning on which the proposed research project is based. Briefly describe how preliminary data, scientific rationale, and referenced literature support the research hypothesis. Clearly demonstrate that there is sufficient rationale for the project.

    – **Focus Area:** State the FY21 CPMRP TRA Focus Area(s) that the proposed study seeks to address.

- **Specific Aims and Study Design:** Clearly describe the type of research study being proposed. Concisely state the project's objectives, specific aims, and ultimate endpoints. As applicable, briefly describe the proposed recruitment strategies and methods, how they will accomplish the project's aims, as well as the outcomes measures that will be used.

- **Research Team:** Provide a description of the research team that clearly demonstrates the appropriate background and experience to accomplish the proposed work.

- **Impact and Relevance to Military Health:** Describe how the proposed work will impact healthcare and quality-of-life needs for military Service Members, Veterans, and/or family members or beneficiaries living with chronic pain.

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

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

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

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

- **Tab 6 – Submit Pre-Application**

  This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) and the CPMRP, pre-applications will be screened based on the following criteria:

  ○ **Rationale:** How well the hypothesis is stated and supported through preliminary data, scientific rationale, and referenced literature.

  ○ **Focus Area:** How well the proposed study addresses one or more of the FY21 CPMRP TRA Focus Areas.

- **Specific Aims and Study Design:** To what degree the objectives and specific aims support the research idea, how well the outcome measures and endpoints are defined and are appropriate for the proposed study, and whether the proposed recruitment strategies (if applicable) and methodology are appropriate for accomplishing the research aims.

- **Research Team:** Whether the background and experience of the PI and key personnel are appropriate to perform the proposed research.

- **Impact and Relevance to Military Health:** To what degree the proposed work will impact healthcare and quality-of-life needs for military Service Members, Veterans, and/or family members or beneficiaries living with chronic pain.

- **Notification of Pre-Application Screening Results**

Following the pre-application screening, Initiating PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated in Section I, Overview of the Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

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

Applications will not be accepted unless notification of invitation has been received by the Initiating PI.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (https://www.grants.gov/) for extramural organizations or through eBRAP (https://ebrap.org/) for intramural organizations. See Table 1 below for more specific guidelines.

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

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the ***same version*** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the "Apply For Grants" page of

Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Do not password protect any files of the application package, including the Project Narrative.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for W81XWH-21-CPMRP-TRA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-21-CPMRP-TRA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.

Extramural Submissions	Intramural DOD Submissions
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. *Note:* If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID *prior to* the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.***
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified *with the exception of the Project Narrative and Research & Related Budget Form*.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI(s) will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified *with the exception of the Project Narrative and Research & Related Budget Form*. Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.

Extramural Submissions	Intramural DOD Submissions
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

Partnering PI Option: The CDMRP requires separate full application package submissions for the Initiating PI and the Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique eBRAP log number. ***Note: All associated applications (Initiating PI's and the Partnering PI's) must be submitted by the full application submission deadline.***

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

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

- **Extramural Applications Only**

  SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

  Attachments:

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

  For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full application package may not exceed 200 MB.

○ **Attachment 1: Project Narrative (10-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

– **Background:** State the relevance of the proposed research and applicability of the anticipated findings to one or more of the [FY21 CPMRP TRA Focus Areas](). Present the scientific rationale behind the proposed work and cite relevant literature. Present pilot or preliminary data. Describe any stakeholder engagement that was performed and how it helped to formulate the hypothesis/objective and research strategy. Provide a summary of relevant prior clinical and preclinical work and distinguish how the proposed study differs from other relevant or recently completed research. Include a discussion of any current clinical use of the interventions under investigation and/or details of its study in clinical research for other indications (if applicable).

– **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be achieved.

– **Specific Aims:** Concisely explain the project's specific aims. The aims should agree with the primary aims and associated tasks described in the SOW ([Attachment 5]()).

– **Research Strategy:**

  ▪ Describe the study design, methods, models, and analyses in sufficient detail for assessment of the application. Explain how the research strategy will meet the project's goals and milestones within the proposed period of performance.

  ▪ Address potential pitfalls and problem areas and present alternative methods and approaches.

  ▪ For studies performing prospective human subject recruitment or observation:

    ❖ Describe the population(s) of interest.

    ❖ For studies utilizing a biopsychosocial model of pain assessment, describe the model that will be used; *provide relevant research data collection instruments in [Attachment 9]()*.

  ▪ Describe any stakeholder engagement that will be performed during the course of the study.

  ▪ Describe how data will be reported.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

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

– **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

– **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

– **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

– **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

– **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- **Intellectual Property:** Information can be found in 2 CFR 200.315, "Intangible Property."

  - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

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

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

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

  Technical abstracts should be written using the outline below. The technical abstract should provide an appropriate description of the project's key aspects; clarity and completeness within the space limits of the technical abstract are highly important.

  - **Background:** State how the proposed research addresses one or more of the FY21 CPMRP TRA Focus Areas. Present the scientific rationale behind the proposed work.

  - **Objective/Hypothesis:** State the objective to be reached or the hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

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

  - **Study Design:** Briefly describe the study design.

- **Impact and Relevance to Military Health:** Briefly explain how the project will have an immediate or potential long-term impact on the health and well-being of Service Members, Veterans, and/or family members or beneficiaries living with chronic pain.

○ **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information***. ***Do not duplicate the technical abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community.

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

  - Describe the ultimate applicability of the research.

  - Describe the types of patients that will be helped by the research and how it will help them. Include currently available statistics to the related injury/condition.

  - Describe potential clinical applications, benefits, and risks.

  - Describe the projected timeline to achieve the expected patient-related outcome.

  - Describe how the proposed project will impact the health and well-being of Service Members, Veterans, and/or family members or beneficiaries living with chronic pain.

○ **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). Recommended strategies for assembling the SOW can be found at https://ebrap.org/eBRAP/public/Program.htm.

For the FY21 CPMRP TRA mechanism, refer to either the "***Suggested SOW Strategy Clinical Research***" or "***Suggested SOW Strategy Generic Research***", whichever format is most appropriate for the proposed effort, and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

  - For FITBIR-eligible (human prospective TBI studies) research, also include:

    ▪ FITBIR investigator and study registration within the first 30 days of the award

- ▪ Sharing of draft data collection forms with FITBIR

- ▪ Annual FITBIR data submissions

For applications choosing the Partnering PI Option: Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.

○ **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Describe the short- and/or long-term impact of this study on the field of chronic pain research, patient care, and/or quality of life, including an assessment of the likelihood that a successful outcome of the proposed research project will lead to a practical application in individuals living with chronic pain. Describe the degree to which the research may improve standards of care for chronic pain management. Describe how the research will contribute to the development or validation of evidence-based policy or guidelines for patient evaluation and care. Address the impact on one or more of the FY21 CPMRP TRA Focus Areas.

○ **Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as "Military.pdf".** Demonstrate how the proposed research project is applicable to the healthcare needs and quality of life of military Service Members, Veterans, and/or family members or beneficiaries living with chronic pain. Provide evidence that the chronic pain condition under investigation is either prevalent in military or Veteran general populations or presents a significant healthcare burden on a vulnerable sub-population. If active-duty military, Veteran, or military family member population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research, and the feasibility of using the population. Identify any collaborations within the military Services and the proposed use of the MHS or an MTF. If applicable, discuss how the research study will fill an unmet requirement in patient care within the DHA and/or VHA and is feasible for deployment within the existing healthcare systems. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., Service Members or Veterans).

○ **Attachment 8: Clinical Strategy Statement (no page limit): Upload as "Clinical.pdf".**

   – Describe the rationale for the proposed clinical study, and the clinical endpoints to be measured. If applicable, provide a description of the proposed intervention and provide a brief summary of the relevant clinical setting where the intervention was shown to be efficacious to gauge maturity.

   – Describe potential challenges and alternative strategies where appropriate.

   – Provide detailed plans for initiating the clinical study within the first year, including U.S. Food and Drug Administration (FDA) Investigational New Drug (IND)/ Investigational Drug Exemption (IDE) application submission plans within 60 days of the award, if applicable.

- Demonstrate access to the study population. Describing any collaboration, integration, and/or alignment with military and/or VA research laboratories and programs, if applicable. Include recruitment plans.

- Indicate inclusion/exclusion criteria and provide justification and the rationale for how they were determined.

- 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/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- For studies prospectively recruiting subjects, provide a draft consent form.

- If the proposed research is cooperative (i.e., involving more than one institution), describe the plan for single IRB review. Identify the lead institution that will serve as the single point of contact for regulatory submissions.

- If applicable, describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled, pragmatic) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe the data management plans. If the proposed clinical study was initiated using other funding prior to this application, explain the history and background of the clinical study and declare the source of prior funding. Specifically identify the portions of the study that would be supported with funds from this award.

- 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.

- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

○ **Attachment 9: Research Data Collection Instruments, if applicable (no page limit): Upload as "Instruments.pdf".** The Research Data Collection Instruments attachment should include a copy of the most recent version of data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the

information collected is related to the objectives of the study. Describe how and when the instrument(s) will be administered. Describe how the instrument(s) will be adapted to the subject population, if applicable.

- ○ **Attachment 10: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** *(Attachment 10 is <u>required</u> for all applications addressing the implementation science or comparative effectiveness focus areas and <u>optional</u> for applications solely addressing the observational studies related to chronic pain focus area.)* Include the components listed below and provide supporting documentation as applicable.

    – State the product/intervention name.

    For products/interventions that do not require regulation by the FDA or an international regulatory agency:

    – State the rationale for why the product/intervention is exempt from FDA oversight. Provide a copy of the confirmation in writing from the IRB of record, the FDA, or the international regulatory agency for clinical trials conducted at an international site(s) *that the proposed intervention is exempt or the proposed investigational device qualifies for an abbreviated IDE.*

    For products that require regulation by the FDA:

    – State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the U.S.

    – If the product is marketed in the U.S., state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).

    – If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.

- ○ **Attachment 11: Transition Plan (two-page limit): Upload as "Transition.pdf".** Provide information on the methods and strategies proposed to advance the anticipated research outcomes to the next phase of development or delivery to the military or civilian market after successful completion of the award. The Transition Plan attachment should include the components listed below.

- Details of the strategy, schedule, and milestones to transition to the next level of development and/or commercialization (e.g., partners, internal/external funding opportunities to be pursued).

- 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, modes, simulations, and applications. (A "knowledge product" is a non-materiel product that addresses an identified need, topic area, or capability gaps, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support materiel solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities], and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)

- Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.

- If applicable, a risk analysis for cost, schedule, manufacturability, and sustainability.

o **Attachment 12: Partnership Statement (one-page limit): Upload as "Partnership.pdf".** *(Attachment 12 is only applicable and <u>required</u> for applications submitted under the Partnering PI Option.)* Describe the partnership and combined expertise of the Initiating and Partnering PIs that are critical for the research strategy and completion of the SOW. Explain how the partnership will better address the research question and why the work should be done together rather than through separate individual efforts. Explain how both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project. Explain how funding will be balanced between both PIs or otherwise provide appropriate justification.

o **Attachment 13: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

o **Attachment 14: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as "MFBudget.pdf".** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using "Suggested Collaborating DOD Military Facility Budget Format", available for download on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per

year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

  To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

  Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

  Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

  - PI Biographical Sketch (six-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health (NIH) Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

  - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

    - For extramural submissions, refer to the General Application Instructions, Section III.A.4 for detailed information.

    - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

  - Key Personnel Biographical Sketches (six-page limit each): Upload as "Biosketch_LastName.pdf".

  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

  Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf". The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for the Partnering PI even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

    Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

    ○ **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

    ○ **Intramural DOD Collaborator(s):** Complete the "Suggested Collaborating DOD Military Facility Budget Format" and upload to Grants.gov attachment form as Attachment 14. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

    Suggested DOD Military Budget Format: A military facility collaborating in the performance of the project (but not participating as a Partnering PI) should be treated as a subaward for budget purposes. *Note:* Applicants should complete a separate military budget using "Suggested Collaborating DOD Military Facility Budget Format" (available for download on the eBRAP "Funding Opportunities & Forms" web page [https://ebrap.org/eBRAP/public/Program.htm]) (Attachment 14) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

Application Components for the Partnering PI

The Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate their full application package with that of the Initiating PI.

For the Partnering PI, the Initiating PI must identify if the Partnering PI will be named on an extramural or intramural application (in accordance with the guidelines in [Section II.C.1.a, Organization](#)) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). The Partnering PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their application.

The application submission process for the Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

  Attachments:

  - **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** Refer to the General Application Instructions, Section III.A.2, for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.

  - **Attachment 13: Representations (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

  - **Attachment 14: Suggested Collaborating DOD Military Facility Budget Format: Upload as "MFBudget.pdf".** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

  Research & Related Personal Data: For extramural submissions (via Grants.gov) refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

  Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

  - PI Biographical Sketch (six-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.

  - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

- For extramural submissions, refer to the General Application Instructions, Section III.A.4 for detailed information.

- For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

○ Key Personnel Biographical Sketches (six-page limit each): Upload as "Biosketch_LastName.pdf".

○ Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section III.A.5, and for intramural submissions, refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf".

Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  Research & Related Subaward Budget Attachment(s) Form:

  ○ **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.)

  ○ **Intramural DOD Collaborator(s):** Complete a separate DOD military budget, using Suggested Collaborating DOD Military Facility Budget Format (available for download on the eBRAP "Funding Opportunities & Forms" web page [https://ebrap.org/eBRAP/public/Program.htm]), and upload to Grants.gov attachment form as Attachment 14. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Verify the status of the applicant organization's Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination as a basis for making a federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

For Both Extramural and Intramural Applicants: eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

Intramural DOD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

Single PI Option:

The maximum period of performance is **4** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **$1.4M.** If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **$1.4M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

Partnering PI Option:

The maximum period of performance is **4** years.

The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI's and the Partnering PI's applications will not exceed **$1.4M**. 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. The combined budgeted direct costs approved by the government will not exceed **$1.4M** or use an indirect cost rate exceeding each organization's negotiated rate.

A separate award will be made to each PI's organization.

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly, unless otherwise warranted and clearly justified.

The applicants may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years. The duration of the period of performance for the Initiating PI and Partnering PI should be the same.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Travel in support of multidisciplinary collaborations.

- Costs for the PI(s) to travel to up to two DOD-sponsored meetings (e.g., MHS Research Symposium) during the lifetime of the award. For budget purposes, it is suggested that these costs be included in year 2 of the award.

- Costs for the PI(s) to travel to one scientific/technical meeting per year in addition to the meetings described above. The intent of travel costs to scientific/technical meeting(s) is to present project information or disseminate project results of the FY21 CPMRP TRA.

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. ***For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.***

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Research Strategy and Feasibility**

  ○ To what extent the relevance and applicability of the proposed research and anticipated findings will address at least one of the FY21 CPMRP TRA Focus Areas.

  ○ How well the preliminary data and scientific rationale support the research project.

  ○ To what extent stakeholder engagement was performed, and to what degree it helped formulate the projects hypothesis/objective and research strategy, if applicable.

  ○ How well the hypotheses or objectives, specific aims, study design, methods, and analyses are developed and integrated into the project.

  ○ How well the application acknowledges potential problems and potential pitfalls, and addresses alternative approaches.

  ○ Whether the research can be completed within the proposed period of performance.

  ○ To what degree stakeholder engagement will be performed during the course of the proposed study, if applicable.

  ○ How well the application outlines a plan for management and sharing of research data, as appropriate, for the type of study.

  ○ *For studies performing prospective human subject recruitment or observations:*

    – How well the application describes the population(s) of interest.

    – Whether the proposed biopsychosocial model of assessment is appropriate to the research study.

    – How relevant the research data collection vehicles, along with the accompanying rating scales, interview guides, and other instruments are to the objectives of the study.

    – Whether the implementation plan for administration of the data collection instruments is appropriate.

- **Impact**

  ○ How likely it is that the proposed research will make an important short- and/or long-term impact on the field of chronic pain management research, patient care, and/or quality of life that will lead to practical application in the management of chronic pain.

  ○ Whether the research has the potential to improve standards of care for chronic pain management.

  ○ To what degree the research will contribute to the development or validation of evidence-based policy or guidelines for patient evaluation and care.

- How well the proposed research project addresses one or more of the [FY21 CPMRP TRA Focus Areas](#).

- **Clinical and Regulatory Strategy**

  - How well the application describes the rationale for the proposed clinical study. Whether the clinical endpoints are appropriate to meet the objectives of the study.

  - If applicable, whether the proposed interventions have established efficacy in relevant clinical settings and are significantly mature to meet the requirements of the FY21 CPMRP TRA.

  - How thoroughly the potential challenges and alternative strategies for the proposed clinical trial are described.

  - How well the plan for initiation of the clinical study within the first year is described, including FDA IND/IDE application submission plans within 60 days of the award, if applicable.

  - If applicable, whether a strategy for single IRB regulatory submission was described.

  - How well the applicant describes access to the study population and presents feasible recruitment plans.

  - To what degree the applicant provides a strong justification and rationale for the proposed inclusion/exclusion criteria.

  - Whether a strategy for the inclusion of women and minorities was provided and to what degree it is appropriate to meet the study objectives.

  - If applicable, whether a description of the proposed clinical trial to be performed (e.g., prospective, randomized, controlled, pragmatic) is provided and whether the proposed methodology provides sufficient detail to show a clear course of action.

  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

  - To what degree the statistical models and data analysis plans, are appropriate with respect to the study objective.

  - Whether a complete power analysis demonstrates that the sample size is appropriate to meet study objectives.

- **Transition Plan**

  - Whether the strategy, schedule, and milestones described are appropriate to bring the anticipated research outcome(s) to the next level of development and/or delivery to the military or civilian market.

- ○ Whether appropriate collaborations and other resources for providing continuity of development are established and/or well-described.

- ○ If applicable, how well-developed the risk analysis is for cost, schedule, manufacturability, and sustainability.

- ○ How well the application identifies intellectual property ownership, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement.

- **Personnel**

  - ○ How the background and experience of the PI and other key personnel demonstrate their ability to perform the proposed research.

  - o Whether the levels of effort by the PI and other key personnel are appropriate to ensuring the success of the project.

- **Partnership (only applicable to Partnering PI Option applications)**

  - o How well the partnership and combined expertise of the Initiating and Partnering PIs contribute to the research strategy and completion of the SOW.

  - o To what degree the partnership will better address the research question together rather than through separate individual efforts.

  - o How well the application reflects that both PIs contribute equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project.

  - o Whether funding will be balanced between both PIs or is otherwise appropriately justified.

In addition, the following **unscored** criteria will also contribute to the overall evaluation of the application:

- **Budget**

  - ○ Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.

  - ○ Whether the budget is appropriate for the proposed research.

- **Environment**

  - ○ To what degree the scientific environment and the accessibility of institutional/ organizational resources support the proposed research.

- Whether the quality and extent of institutional support are appropriate for the proposed project.

- **Application Presentation**

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

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers

- Relevance to the mission of the DHP and FY21 CPMRP, as evidenced by the following:

  - Adherence to the intent of the award mechanism

  - Program portfolio composition

  - Relative impact

  - Relevance to military health

II.E.2. Application Review and Selection Process

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

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the

evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, 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 Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

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.

II.E.4. Anticipated Announcement and Federal Award Dates

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

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY21 funds are anticipated to be made no later than September 30, 2022. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

Pre-Award Costs: An institution of higher education, hospital, or other non-profit 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. Refer to the General Application Instructions, Section III.A.5.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds. 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.**

Federal Government Organizations: Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

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

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 Partnering PI awards, an organizational transfer of an award supporting either the Initiating PI or Partnering PI is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants Officer.

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

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

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

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D General Terms and Conditions](); the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](); and the

[USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress reports with quad charts will be required. The Award Terms and Conditions will specify if more frequent reporting is required.

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

Inclusion Enrollment Reporting Requirement *(only required for clinical research studies)*: Enrollment on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final technical report. The suggested Inclusion Enrollment Report format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Awards resulting from this program announcement will incorporate 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 FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP

should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the "Synopsis" page for the program announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 605a. The program announcement numeric version code will match the General Application Instructions version code 605.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Preproposal Narrative exceeds page limit.

- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.

- Documents not requested will be removed.

II.H.2.c. Withdrawal

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

- An FY21 CPMRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY21 CPMRP Programmatic Panel members can be found at https://cdmrp.army.mil/cpmrp/panels/panels21.*

- The application fails to conform to this program announcement description.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.

- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The invited application proposes a different research project than that described in the pre-application.

- The application proposes a study seeking to advance a new or novel opioid-based therapeutic intervention.

- The application proposes a study utilizing animals as a model system to replicate the chronic pain condition.

- The Regulatory Strategy attachment (Attachment 10) is missing from an application addressing the Implementation Science or Comparative Effectiveness Focus Area.

- The PI(s) do not meet the eligibility criteria.

- *Partnering PI Option:* Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Single or Initiating PI Completed	Partnering PI Completed
SF424 Research & Related Application for Federal Assistance **(extramural submissions only)**	Complete form as instructed		
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	Complete tabs as instructed		
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"		
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"		
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"		
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"		
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"		
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"		
	Relevance to Military Health Statement: Upload as Attachment 7 with file name "Military.pdf"		
	Clinical Strategy Statement: Upload as Attachment 8 with file name "Clinical.pdf"		
	Research Data Collection Instruments: Upload as Attachment 9 with file name "Instruments.pdf" if applicable		
	Regulatory Strategy: Upload as Attachment 10 with file name "Regulatory.pdf" if applicable. (Required for applications addressing the implementation science or comparative effectiveness focus areas. Optional for applications solely addressing the observational studies related to chronic pain focus area.)		
	Transition Plan: Upload as Attachment 11 with file name "Transition.pdf"		
	Partnership Statement: Upload as Attachment 12 with file name "Partnership.pdf" if applicable		

Application Components	Action	Single or Initiating PI Completed	Partnering PI Completed
	Representations (extramural submissions only): Upload as Attachment 13 with file name "RequiredReps.pdf" if applicable		
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 14 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field		
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field		
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field		
Research & Related Budget **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field		
Budget **(intramural submissions only)**	Complete the Suggested DOD Military Budget Format, including justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form	Complete form as instructed		

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CPMRP	Chronic Pain Management Research Program
DHA	Defense Health Agency
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
MTF	Military Treatment Facility
NIH	National Institutes of Health
NPC	Non-Profit Corporation
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TBI	Traumatic Brain Injury

UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs
VHA	Veterans Health Administration

APPENDIX 2: DOD AND VA WEBSITES

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

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

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

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

Combat Casualty Care Research Program
https://ccc.amedd.army.mil

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

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

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

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

Military Health System Research Symposium
https://mhsrs.amedd.army.mil/SitePages/Home.aspx

Military Infectious Diseases Research Program
https://midrp.amedd.army.mil

Military Operational Medicine Research Program
https://momrp.amedd.army.mil

Naval Health Research Center
https://www.navy.mil/local/nhrc/

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

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

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

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

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

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

U.S. Army Medical Materiel Development Activity
https://www.usammda.army.mil/

U.S. Army Medical Research and Development Command
https://mrdc.amedd.army.mil/

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

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

U.S. Army Research Laboratory
https://www.arl.army.mil

U.S. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.amedd.army.mil/

U.S. Department of Veterans Affairs, Office of Research and Development
https://www.research.va.gov

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

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