

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

Pain Management Collaborative Clinical Research Award

Announcement Type: Initial

Funding Opportunity Number: HT9425-23-CPMRP-PMCCRA

**Assistance Listing 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), August 21 2023
- **Invitation to Submit an Application:** September 25, 2023
- **Application Submission Deadline:** 11:59 p.m. ET, November 9, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, November 14, 2023
- **Peer Review:** January 2024
- **Programmatic Review:** March 2024

This program announcement must be read in conjunction with the General Application Instructions, version 803. 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 2023 (FY23) 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 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). 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 FY22 totaled \$55 million (M). The FY23 appropriation is \$15M.

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

Congressional language for the CPMRP defines chronic pain 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. Congressional intent for the program emphasizes collaboration with non-military research entities and 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. FY23 CPMRP Pain Management Collaborative Clinical Research Award (PMCCRA) Focus Areas

To meet the intent of the award mechanism, ***applications must address at least one of the FY23 CPMRP PMCCRA 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 for Service Members, Veterans, and beneficiaries, 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)
 - Multimodal, integrative, and combination therapies
 - Relationships between comorbidities and pain
 - Preventing chronification of pain

II.A.2. Award History

The CPMRP Pain Management Collaborative Clinical Research Award (PMCCRA) mechanism is being offered for the first time in FY23. In 2017 the National Institutes of Health (NIH), Department of Defense (DOD), and the VA sponsored an interagency initiative, the NIH-DOD-VA [Pain Management Collaboratory](#) (PMC), dedicated to the study of nonpharmacological approaches for the management of pain and common co-occurring conditions in Military and Veteran health care systems. The PMC is comprised of a central coordinating center and 12 multi-site pragmatic clinical trials. The FY23 CPMRP PMCCRA will support a new clinical trial that will participate in the PMC, leveraging the infrastructure, experience, and expertise thus far established by the Pain Management Collaboratory Coordinating Center (PMC3). The PMC3 will provide technical expertise and support to investigators conducting efficient, large-scale pragmatic or implementation clinical trials to evaluate evidence-based nonpharmacological interventions, either alone or in combination with pharmacotherapies, to improve the health of U.S. Service Members, Veterans, and/or their families, prioritizing integrative approaches that address the whole person.

II.B. Award Information

The intent of the FY23 CPMRP PMCCRA is to support large-scale pragmatic comparative effectiveness and implementation science clinical trials that will facilitate the acceptance and utilization of evidence-based chronic pain management clinical applications, such as health care products, technologies, clinical practice guidelines, and/or models of care. PMCCRA 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. Military and Veterans health care systems and other health care entities that provide services to Service Members, Veterans, and their families are the targeted organizations for this program. Research conducted in partnership with eligible VA and Military Health System (MHS) providers is essential for obtaining meaningful and relevant research results in “real world” health care delivery systems serving Veterans, Service Members, and their beneficiaries. Applications to the FY23 CPMRP PMCCRA are aligned with appropriations specifically intended for chronic pain research, therefore, all ***applications to the funding opportunity must address chronic pain*** either alone or in the context of common comorbidities. Applications primarily focused on comorbid conditions (e.g., TBI, depression, posttraumatic stress disorder [PTSD]) are not appropriate for the FY23 CPMRP PMCCRA. ***Studies seeking to advance new and novel opioid-based therapeutic interventions do not meet the intent of this***

award mechanism and will not be selected for funding. Studies seeking to understand and reduce opioid utilization in chronic pain management within the context of current prescribing practices are acceptable.

Funding from this award mechanism must support a clinical trial. 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. For more information, a Human Subject Resource Document is provided at <https://cdmrp.health.mil/pubs/pdf/Human%20Subjects%20Resource%20Document.pdf>.

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

The FY23 CPMRP PMCCRA mechanism supports implementation science and/or comparative effectiveness research. ***Clinical trials under these Focus Areas 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.*** Applicants seeking funding for a clinical trial of novel treatments or untested approaches to chronic pain management are encouraged to consider the FY23 Clinical Exploration Award.

The FY23 CPMRP PMCCRA is designed to be a phased award comprised of a 15-month planning phase award performance period intended for the completion of activities required to initiate the planned clinical trial (e.g., obtaining regulatory approvals, finalizing of collection tools and common data elements (CDEs), study site onboarding and activation). Execution of the full-scale clinical trial will be considered an optional second phase research effort.

Important tasks to consider under the Planning Phase with Clinical Trial include, but are not limited to:

- Planning for appropriate regulatory approvals (e.g., IRB submissions, U.S. Food and Drug Administration [FDA] submissions such as Investigational New Drug [IND]/ Investigational Device Exemption [IDE] applications, and DOD Office of Human Research Oversight [OHRO] submissions)
- Developing or refining the clinical protocol
- Establishing access to appropriate patient populations or resources
- Developing and implementing training procedures

Within the 15-month period of performance of the planning phase award, recipients are expected to submit an IND/IDE application to the FDA, if required, and obtain an FDA acknowledgment letter (or equivalent), to include submission date and receipt date, and a statement that the FDA did not raise concerns and/or did not place the clinical trial on hold. Exercise of the clinical trial option phase is contingent on the availability of all necessary regulatory milestones obtained under the planning phase award, accomplishment of research

milestones and goals as determined by the CPMRP and USAMRAA Grants Officer, and availability of funds under future appropriations and alignment to that year's congressional appropriations language.

The following research milestones are required for consideration of exercising the clinical trial option phase (for additional details refer to [Attachment 1: Project Narrative](#)):

- A copy of the FDA acknowledgment letter, to include submission date and receipt date, and a statement that the FDA did not raise concerns and/or did not place the clinical trial on hold, or
- A copy of the FDA acknowledgment letter and meeting minutes (pre-IND/pre-IDE and/or Type C) that ascertain the FDA's concurrence with the proposed regulatory approach if a technical or a protocol amendment to an active IND/IDE is necessary to complete the clinical trial, or
- A copy of the relevant national regulatory agency approval if the clinical trial will be conducted at an international site(s), or
- Evidence of Institutional Review Board (IRB) review of the clinical protocol for all sites. Where applicable, evidence should be available demonstrating IRB of record, or the FDA, has determined whether the proposed investigational therapy (e.g., techniques, approaches, drugs, agents, devices) is exempt or the proposed investigational device qualifies for an abbreviated IDE.
- Evidence of collaboration that leverages expertise across relevant PMC working groups.
- Research milestones to be accomplished by the end of the planning phase must be clearly defined in the project Statement of Work (SOW) and will be finalized during negotiations. The Principal Investigator (PI) will be required to present an update on progress toward accomplishing research milestones and goals of the project at a Virtual Milestone Meeting. Milestone Meetings will be held nearing the conclusion of the planning phase and will be attended by members of the CPMRP Programmatic Panel, CDMRP staff, and the USAMRAA Grants Officer.

The critical components of this award mechanism are:

- **Collaboration:** The NIH-DOD-VA PMC is designed to be a network of research studies dedicated to addressing the pain management needs of U.S. Service Members, Veterans, and/or their families, in relevant health care systems. While each investigator will lead a research study of their own design, they are expected to participate in working groups and cross project initiatives led by the PMC3. The PMC3 has working groups supporting topic areas including but not limited to Electronic Health Records, Stakeholder Engagement, Phenotypes & Outcomes, Ethics & Regulatory, Study Design & Biostatistics, Data Sharing, and Implementation Science. For full details of the working groups and their activities, please visit the [PMC3 working group website](#). It is anticipated that members of each study team will participate in centrally coordinated efforts and contribute to a community that

works collectively to address common challenges and broader cross project research initiatives that span common lines of investigation.

- **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 PI or a member(s) of the research team. The CPMRP PMCCRA is intended to support investigations that improve patient care through 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. Due to the strong clinical focus, the CPMRP PMCCRA 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 \(IMMPACT\)](#).¹ 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 health care 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:
 - Use of military or Veteran populations, biospecimens, or data/databases in the proposed research.
 - Collaborations that include the DOD MHS, Military Treatment Facilities (MTFs), and/or VA investigators and facilities.
 - 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](#).

¹ Dworkin RH, Turk DC, Farrar JT, et al. 2005. IMMPACT. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain* 113(1-2):9-19. doi: 10.1016/j.pain.2004.09.012

- 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) health care systems.
- 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. Stakeholder engagement should be considered during both study design and research conduct. This includes consideration of patient expectations, preferences, and goals of treatment at point of care. *At least two key stakeholders must be included as members of the research team that participate in the development of the research question, project design, oversight, and evaluation, as well as other significant aspects of the proposed projects. For the FY23 CPMRP PMCCRA, key stakeholders are defined as patients, immediate caregivers (not medical providers), patient advocates, or community leaders. Key stakeholders must be identified by the pre-application submission deadline.* Broader stakeholder engagements with clinicians, hospital/health system administrators, and health care policy and decision makers are also encouraged.

Applicants seeking information regarding considerations for stakeholder inclusion in participatory research and current practices for patient engagement during research planning and execution are encouraged to review resources available from the:

- [FDA Patient Engagement Advisory Committee](#)
- [Patient-Centered Outcomes Research Institute \(PCORI\)](#)

Clinical studies conducted in DOD MTFs have distinct stakeholders whose support are critical for project success. Onsite collaborators and co-investigators play an essential role in helping extramural partners navigate the unique considerations required when performing research in the MHS and facilitating stakeholder engagement with local commanders, senior military leaders, and potential study participants. Extramural applicants are encouraged to consider the challenges for clinical research in military settings described in Rhon et al., 2021.²

- **Research Representation of Military-Relevant Populations:** The CPMRP is dedicated to ensuring clinical studies are consistent with federal efforts for population diversity in research outcomes. Further, the CPMRP seeks to ensure outcomes from funded research appropriately reflect and address health care needs of and disparities in chronic pain management in, particularly, the Service member and Veteran communities.

² Rhon DI, Oh RC, and Teyhen DS. 2022. Challenges with engaging military stakeholders for clinical research at the point of care in the U.S. Military Health System. *Mil Med* 187(7-8):209-214. doi: 10.1093/milmed/usab494.

Disparities in medical research, health care delivery, access, and quality, and health outcomes are apparent in the Service members and Veteran populations.^{3,4} Chronic pain affects over 20% of the U.S. adult population, with even higher rates of occurrence observed among active-duty Service Members, ranging from 31% to 44%. The scope of chronic pain across social, economic, gender, racial, and cultural demographics may be significantly impacted by availability and access to effective treatments.⁵ Promising approaches to pain management should demonstrate equity in efficacy, acceptance, and implementation across population demographics.

Applications to the CPMRP are expected to include recruitment strategies in accordance with the [CDMRP policy on inclusion of women and minorities](#) in clinical research that strives for appropriate levels of representation among human subject participants. For example, female Service members represent 18.8% of the total DOD military force and 10% of the Veteran population, but traditionally women are underrepresented in research.^{6,7} Similarly, minority and other populations are underrepresented in research outcomes. Applications seeking to eliminate health disparities and improve chronic pain outcomes for at-risk, vulnerable, and underserved populations must identify the community that is the focus of their investigation. Additionally, applications must articulate the medical burden the named population faces compared to the greater public, and if applicable, describe the barriers that may be eliminated or circumvented by the proposed research to establish more equitable pain management access and care.

- **Multiple PI Option:** The FY23 CPMRP PMCCRA encourages multicenter applications and will allow for up to three partnering PIs to be named. Studies conducted across several clinical settings can alleviate potential regional biases with respect to the race and ethnicity of study participants and improve overall rates of recruitment. They also allow for the evaluation of interventions in different health care settings supporting the overall translatability of research findings. Electing to submit to the Multiple 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 PIs will be identified as Partnering PIs. All PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, 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. ***To meet the intent of the Multiple 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 PI do not meet the intent of the Multiple PI Option.*** If recommended for funding, each PI will be named to an individual award within the recipient organization. For

³ <https://www.dol.gov/agencies/vets/womenveterans>

⁴ Mancuso JD et al. 2023. Advancing health equity in the US military. *J Health Dispar Res Pract* 16(1):Article 3.

⁵ Dahlhamer J et al. 2018. Centers for Disease Control and Prevention *Morbidity and Mortality Weekly Report* 67(36).

⁶ <https://demographics.militaryonesource.mil/>

⁷ https://www.va.gov/vetdata/veteran_population.asp

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 FY23 CPMRP PMCCRA should not exceed **\$500,000** for the 15-month planning phase award and **\$3.0M** for the full-scale clinical trial optional effort for a combined total direct cost of **\$3.5M**. ***Exercise of the clinical trial option phase is contingent on the availability of sufficient future congressional appropriations to the CPMRP, alignment of the proposed research during the Option period to that fiscal year’s congressional appropriations language, attainment of regulatory approvals, and acceptable performance by the recipients in completing milestones of the approved SOW.*** Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2024. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The CDMRP expects to allot approximately \$5.6M to fund approximately one Pain Management Collaborative Clinical Research Award application. 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 the 15-month planning phase award made from this FY23 funding opportunity will be funded with FY23 funds, which will expire for use on September 30, 2029.

Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human data, human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), OHRO, prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of application submission is *not* required; however local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of *all required and complete* documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the OHARO web page https://mrhc.health.mil/index.cfm/collaborate/research_protections/hrpo for additional information.

As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research *must* rely on a single IRB to review and approve the portion of the research conducted at domestic sites Code of Federal Regulations, Title 45, Part 46.114(b) (45 CFR 46.114[b]). If the proposed, non-exempt research involves more than one U.S.-based 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.

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 FY23 CPMRP PMCCRA.

An *evidence-based, efficacious intervention* should be consistent with the standards established in Flay et al., 2005.⁸ 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 report⁹ was published in May 2010. The report identifies a list of Tier 1 *complementary and integrative health treatment modalities* 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 and/or VA patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed

⁸ Flay BR, Biglan A, Boruch RF, et al. 2005. Standards of evidence: Criteria for efficacy, effectiveness and dissemination. *Prev Sci* 6(3):151-175. doi: 10.1007/s11121-005-5553-y

⁹ <https://www.dvcipm.org/site/assets/files/1070/pain-task-force-final-report-may-2010.pdf>

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, for additional information.

Research Involving Animals: All research funded by the FY23 CPMRP PMCCRA involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO 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 PMCCRA 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 any traumatic brain injury (TBI) focused 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, reanalysis, 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 and genetic). Consult the FITBIR website at <https://fitbir.nih.gov> for additional information. Elements that must be included in the proposed research can be found in Appendix 3.

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 organizations other than the DOD, and research institutes.

Intramural DOD Organization: A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission:*** *An application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.*

The 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(s) on the application.

Investigators are discouraged from being named as the partnering-PI on multiple pre-applications to the PMCCRA unless they are clearly addressing distinct research questions.

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

The CDMRP strongly 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).

Inclusion of classified research data within the application and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns

may result in application withdrawal. Refer to the General Application Instructions Appendix 2, Section E.

II.D.1. eBRAP and Grants.gov

The electronic Biomedical Research Application Portal (eBRAP) (<https://ebrap.org>) is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov (<https://grants.gov>), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

Grants.gov is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Contact information for the eBRAP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

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.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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

Multiple PI Option: The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will then be notified of the pre-application submission separately by email. *Each 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, each 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(s) must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI(s). Applicants are urged to complete these steps as soon as possible. If they are not completed, the Partnering PI(s) 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 eBRAP 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 PIs 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 eBRAP 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.

When starting the pre-application, PIs should ensure that they have selected the appropriate application option:

- PMCCRA – Single PI Option
- PMCCRA – Multiple PI Option

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(s). Enter the organization’s Business Official(s) 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(s) will perform the proposed work) and the contracting organization (organization[s] submitting on behalf of the PI[s], 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.

At least two [key stakeholders](#) (e.g., patients, immediate caregivers [not medical providers], patient advocates, community leaders) that will be members of the research team must be named; failure to do so may result in administrative withdrawal of the application. Including any relevant details regarding their experience with chronic pain conditions and/or organizational/advocacy affiliations. The key stakeholders’ roles in the project should be independent of their employment, and they cannot be employees of any of the organizations participating in the application. Service Members can support studies conducted within the DOD, provided their role in the project is different from their current duty assignment. (For administrative purposes, please use the label “Consumer” when assigning the community partners’ roles in eBRAP).

[FY23 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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

For the Multiple PI Option, the Initiating PI must enter the contact information for each 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[s] has/have 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 (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Alignment to CPMRP Intent:** Describe how the proposed research meets the intent of the FY23 CPMRP PMCCRA mechanism as described in [Section II.B, Award Information](#), including adherence to restrictions on allowable and prohibited research categories. State the [FY23 CPMRP PMCCRA Focus Area\(s\)](#) the study seeks to address.
- **Scientific Rationale and Approach:** State the background and scientific rationale for the proposed research project. Provide preliminary data, referenced literature, and evidence of intervention efficacy (as applicable). Describe the type of research study being proposed and the target patient population. Concisely state the project’s objectives, specific aims, outcome measures, and ultimate endpoints. Describe the research approach, including recruitment strategies and methods (as applicable), and how it will accomplish the project’s aims. Briefly describe any stakeholder engagement that informed the research question or study design and planned involvement during the course of the project.
- **Impact:** Describe how the proposed work will impact health care and quality of life needs of individuals living with chronic pain. Describe potential benefits to military Service Members, Veterans, and/or their family members or beneficiaries.
- **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 CPMRP, pre-applications will be screened based on the following criteria:

- **Alignment to CPMRP Intent:** How well the proposed research meets the intent of the FY23 CPMRP PMCCRA mechanism. Whether the study addresses one or more of the [FY23 CPMRP PMCCRA Focus Areas](#). Whether the proposed research adheres to the research restrictions and does not include prohibited studies. Whether two key stakeholders with relevant experience are identified as members of the research team.
- **Scientific Rationale and Approach:** How well the background, scientific rationale, preliminary data, referenced literature, and evidence of intervention efficacy (as applicable) demonstrate sufficient support for the proposed research project. Whether the objectives and specific aims are reasonable and appropriate for the type of study proposed. Whether the outcome measures and endpoints are defined and suitable for the proposed study. The degree to which the research approach is adequate to meet the specific aims and whether the proposed patient population, recruitment strategies (if applicable), and methodology are appropriate. Whether [stakeholder engagement](#) was conducted to inform the research question and study design and is planned during the proposed project.
- **Impact:** Whether the research will impact the health care and quality of life needs of individuals living with chronic pain. Whether the proposed project will benefit military Service Members, Veterans, and/or their family members or beneficiaries.

- **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://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	
<p>Download application package components for HT9425-23-CPMRP-PMCCRA from Grants.gov (https://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.</p>	<p>Download application package components for HT9425-23-CPMRP-PMCCRA from eBRAP (https://ebrap.org).</p>
Full Application Package Components	
<p>SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.</p>	<p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • 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 	<p>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:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>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.</p>
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>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</p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>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. <i>Do not password</i></p>

Extramural Submissions	Intramural DOD Submissions
<p>to correct any potential technical issues that may disrupt the application submission.</p> <p>Note: If either the Project Narrative or the budget fails eBRAP validation or 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 <i>prior to</i> the application submission deadline. Do not password protect any files of the application package, including the Project Narrative.</p>	<p><i>protect any files of the application package, including the Project Narrative.</i></p>
<u>Application Verification Period</u>	
<p>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 <i>with the exception of the Project Narrative and Research & Related Budget Form.</i></p>	<p>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 <i>with the exception of the Project Narrative and Research & Related Budget Form.</i> 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.</p>
Further Information	
<p>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.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

Multiple PI Option: The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Initiating and each Partnering PI 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 each 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 megabytes (MB), and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (24-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Planning Phase Award (eight-page limit): Describe activities that will be pursued to support initiation of the planned clinical trial including any projected engagement of the PMC3 working groups as appropriate (e.g., Electronic Health Records, Stakeholder Engagement, Phenotypes & Outcomes, Ethics & Regulatory, Study Design & Biostatistics, Data Sharing, and Implementation Science).

- Outline the plan for obtaining IND/IDE status (or other FDA approvals) during the 15-month or less period of performance if an IND or IDE is required. 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, as defined in 21 CFR 312.2 (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.3>), and commitment to oversee execution of the study.

- If applicable, describe how the planning phase will enable finalization or completion of the Study Procedures and/or Clinical Monitoring Plan.
- If applicable, describe how the planning phase will enable finalization or completion of Study Population, Inclusion/Exclusion Criteria, Recruitment Process, Informed Consent Process, and/or Screening Procedures.
- If applicable, describe how the planning phase will enable finalization or completion of selecting CDEs and Research Data Collection Instruments.
- If applicable, describe how the planning phase will enable finalization or completion of Organizational Chart, Study Personnel Description, and/or Study Management Plan.
- If applicable, describe how the planning phase will enable finalization or completion of Data Management procedures.
- If applicable, describe how the planning phase will enable finalization or completion of the Regulatory Strategy and Transition Plan to support the planned product indication.
- If applicable, describe how the planning phase will enable finalization or completion of the Stakeholder Engagement Plan.
- Describe plans for other administrative approvals (e.g., IRB, DOD OHRO).

Clinical Trial, Optional Research Effort (16-page limit):

- **Background:** State the relevance of the proposed research and applicability of the anticipated findings to one or more of the [FY23 CPMRP PMCCRA 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. 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. 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.
- **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 [Attachment 5: Statement of Work](#).
- **Research Strategy:**
 - Describe the study design, methods, models, and analyses in sufficient detail for assessment of the application. Identify the type of clinical trial to be performed and outline the proposed methodology in sufficient detail to show a clear course of action. Explain how the research strategy will meet the project’s goals and milestones within the proposed period of performance.
 - Define the primary and any secondary or interim endpoints/outcome measures, outline why they were chosen, and describe how and when they will be measured. Include a description of appropriate controls. Outline the timing and procedures planned during the follow-up period.
 - Identify the target population(s) that the study seeks to benefit. Describe and justify the study population and the inclusion and exclusion criteria that will be used to meet the needs of the proposed clinical study.
 - If proposing a study seeking to address health disparities related to chronic pain, articulate the additional medical burden and challenges Service Member and/or Veteran populations, to include vulnerable, at-risk, or underserved communities, face compared to the general public. If applicable, describe how the work will overcome barriers related to equitable levels of pain management access and care.
 - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random; refer to [Attachment 8: Clinical Strategy Statement](#) for additional details).
 - Define each arm/study group of the proposed trial, if applicable. Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, other procedures). Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
 - Outline whether subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.
 - 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: Research Data Collection Instruments](#).***
 - Describe potential problem areas and discuss alternative methods/approaches that may be employed to overcome them. Estimate the potential for subject loss to follow-up, and how such loss will be handled/mitigated.

- **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 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 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.
- **Chronic Pain Community Key Stakeholder Letters of Commitment:** Provide a letter signed by each [key stakeholder](#) from the chronic pain community confirming their role and commitment to participate on the research team.

- **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 demonstrates 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 the 2 CFR 200.315, “Intangible Property.”
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **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.
- **Quad Chart:** Provide a Quad Chart for the proposed project. The format for the quad chart is available on the eBRAP “Funding Opportunities & Forms” web page at (<https://ebrap.org/eBRAP/public/Program.htm>).
- **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 non-profit corporation 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 [FY23 CPMRP PMCCRA 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 their 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 their family members or beneficiaries living with chronic pain.
- **Attachment 5: Statement of Work (eight-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 FY23 CPMRP PMCCRA mechanism, refer to the “*Suggested SOW Strategy Clinical Research_Clinical Trial*” and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks related to the major tasks and milestones within the period of performance. *Two SOWs should be uploaded as a single attachment: The first (three-page limit) should describe the major tasks for the planning phase award, and the second (five-page limit), beginning on a new page, should describe the major tasks for the proposed clinical trial, optional research effort.* The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
- Indicate the number of research subjects and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., IND and IDE applications) by the FDA or other government agency.
- 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

- **Multiple PI Option:** Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and each 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 [FY23 CPMRP PMCCRA 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 health care 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 health care burden on an at-risk, vulnerable, or underrepresented subpopulation(s). 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 need in patient care within the DHA and/or VHA and is feasible for deployment within the existing health care 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”.**
 - **Study Procedures:** Describe the interaction with the human subject, including any study intervention(s) that they will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Clearly delineate research procedures from routine clinical procedures. Describe monitoring plans, including the types of monitoring visits to be conducted, the intervals (based on level of risk), how corrective actions will be reported to the sponsor and PI, and how they will be corrected and prevented by the clinical trial site/PI.
 - Describe potential challenges and alternative strategies where appropriate.

- 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.
- Identify the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible populations at the study site(s). Provide a table of anticipated enrollment counts at each study site, as applicable. Demonstrate access to the study population or data, describing any collaboration, integration, and/or alignment with military and/or VA research laboratories and programs, if applicable.
- **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed study, as applicable. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.
- **Women and Minorities in the Study:** Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research.
 - Describe the strategy for the inclusion of women and minorities in the clinical research appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, 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 Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
- For studies prospectively enrolling human subjects:
 - Include recruitment plans and describe efforts that will be made to achieve accrual goals. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical studies. Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Identify ongoing clinical studies that may compete for the same patient population and how they may impact enrollment progress. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. For clinical studies proposing to include military personnel, refer to the General Application Instructions, Appendix 1, for more information.

- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification).
 - ❖ Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
 - ❖ If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan.
 - ❖ Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.
 - ❖ For the proposed study, provide a draft, in English, of the Informed Consent Form.
 - ❖ Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
 - ❖ Include information regarding the timing and location of the consent process.
 - ❖ Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
 - ❖ Address how privacy and time for decision-making will be provided and whether the potential human subject will be allowed to discuss the study with anyone before making a decision.
 - ❖ Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
 - ❖ Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. **Note:** In compliance with 10 USC 980 (<https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>), the application must describe a

clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial. If applicable, refer to the General Application Instructions, Appendix 1, for more information.

- ❖ Assent. If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- **Risks/Benefits Assessment:**
 - ❖ **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is exposed to as a result of participation in the clinical study. Consider psychological, legal, social, and economic risks as well as physical risks. Consider how the proposed clinical study might affect the daily lives of the individual human subjects participating in the study (e.g., will human subjects still be able to take their regular medications while participating in the clinical study? Are human subjects required to stay overnight in a hospital?). If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
 - ❖ **Risk management and emergency response:**
 - Appropriate to the study's level of risk, describe how safety monitoring and reporting to the IRB and FDA (if applicable) will be managed and conducted.
 - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
 - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.
 - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
 - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.

- ❖ **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.
- **Data Management:** Describe all methods used for data collection, including the following:
 - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
 - **Confidentiality:**
 - ❖ Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
 - ❖ Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DOD are eligible to review study records.
 - ❖ Address requirements for reporting sensitive information to state or local authorities.
 - **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process. For FDA-regulated studies, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) are required.
 - **Data reporting:** 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.
 - **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

- **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”.** 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. 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. Provide detailed plans for initiating the clinical study within 15 months, including FDA IND/IDE application submission plans within 60 calendar days of the award. The IND/IDE should be specific for the product (i.e., the

- product should not represent a derivative or alternative version of the investigational agent described in the IND/IDE application) and indication to be tested in the proposed clinical trial.
- **Attachment 11: Transition Plan (three-page limit): Upload as “Transition.pdf”.** Describe/discuss the methods and strategy 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. Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. 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). Include a description of collaborations and other resources that will be used to provide continuity of development.
 - For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, 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, or 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.)
 - A brief schedule and milestones for transitioning the intervention (e.g., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by the FDA).
 - 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.
 - **Attachment 12: Stakeholder Engagement Plan (three-page limit): Upload as “Stakeholder.pdf”.** Describe the plan that will be pursued to perform meaningful stakeholder engagement that will help shape and inform the research study.
 - Provide the names of at least two [key stakeholders](#) from the chronic pain community that will participate as members of the research team and their affiliation (if applicable) with a relevant organization(s). Formal letters of commitment from the key stakeholders should be provided in [Attachment 2: Supporting Documents – Chronic Pain Community Key Stakeholder Letters of Commitment](#). The key stakeholders’ role in the project should be independent of their employment, and they

cannot be employees of any of the organizations participating in the application. Service Members can support studies conducted within the DOD, provided their role in the project is different from their current duty assignment.

- Describe how the stakeholders’ personal experience is relevant to the study’s target patient profile and will provide insight into that group’s opinions and priorities.
 - Describe the benefits the stakeholders hope to obtain from participation on the research team. Explain the benefits the research team hopes to obtain through engagement of the chronic pain community (e.g., enhanced study recruitment and retention, foster stronger partnerships, develop a better appreciation of the views, perspectives, and priorities of the patient population).
 - Describe any stakeholder engagement activities that occurred prior to application that helped to formulate the research question, study hypothesis, or project objectives.
 - Describe the roles that the [key stakeholders](#) will play in the planning, design, implementation, and evaluation of the research. Describe how the stakeholder will be integrated into the research team.
 - Provide details on any orientation or training that has occurred or is planned to prepare the stakeholders for their roles on the research team. Explain the overall engagement structure including scheduled meetings and frequency, and methods of communication and information sharing. Explain how the stakeholders’ perspectives and input will be captured and integrated into the research project. Describe any metrics or methods that will be used to assess the effectiveness and benefit of the engagement activities.
 - Describe any broader engagement that will occur with individuals outside of the research team, including clinicians, hospital/health system administrators, and health care policymaking stakeholders.
- **Attachment 13: Study Personnel and Organization (10-page limit): Start each document on a new page. Combine into one document and upload as “Personnel.pdf”.** The Study Personnel and Organization attachment should include the components listed below.

If Study Personnel and participating Organization are not fully identified, describe how the planning phase will enable finalization or completion of the components listed below.

- **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments and name each person’s position on the project. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate. Identify and provide justification for the inclusion of international sites, as appropriate. If applicable, identify the FDA regulatory sponsor and any external consultants or other experts who will assist with FDA applications.

While there is no specified format for this information, a table(s) or diagram is recommended. **Note:** This item may be made available for programmatic review.

- **Study Personnel Description:** Briefly describe the composition of the study team, including roles of the individuals listed in the organizational chart on the project. Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed research. Describe relevant background and qualifications that demonstrate appropriate expertise to accomplish the proposed work, including previous interactions with the FDA, if applicable.
- **Partnership (for applications submitted under the Multiple 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. Describe how the complementary efforts of each PI can better address the research question and why the work should be done together rather than through separate individual efforts. Explain how each PI has 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 each PI or otherwise provide appropriate justification.
- **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial is cooperative (i.e., involving more than one institution), clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. Provide a regulatory submission plan for the master protocol and master consent form by the lead institution. A single IRB is required for all institutions located in the United States that are engaged in cooperative research. If applicable, describe how communication and data transfer between the collaborating institutions will occur, as well as how data, specimens, and/or imaging products obtained during the study will be handled and shared.
- **Collaboratory Participation:** Identify members of the research team that will participate in the working groups of the PMC3, including but not limited to Electronic Health Records, Stakeholder Engagement, Phenotypes & Outcomes, Ethics & Regulatory, Study Design & Biostatistics, Data Sharing and Implementation Science. Describe the team members experience and expertise and how they will support the efforts and goals of the associated working group. For additional details on the coordinating center and anticipated working groups please reference the [PMC3 working groups website](#).
- **Attachment 14: 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.

- **Attachment 15: 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 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”.
 - 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.

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 Partnering PI(s) 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 15](#). (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 15](#)) 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 each Partnering PI, if applying under the Multiple PI Option

Each Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, must 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 each Partnering PI, the Initiating PI must identify if each 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). Each 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 each Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

Attachments:

- **Attachment 5: Statement of Work (eight-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 each Partnering PI should be noted for each task.
- **Attachment 14: 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 15: 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”.
 - 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.

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 each 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 15](#). (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

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

The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/SAM/>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. *As of April 2022, all federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI generated through SAM.gov.* Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

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 **15 months** for the planning phase.

The application's direct costs budgeted for the entire period of performance (i.e. the planning phase) should not exceed **\$500,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with 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.

Clinical trial work is considered an ***optional research effort***. ***The application must include two severable, but related, budgets and SOWs corresponding to the planning phase and the clinical trial.*** The budget for the clinical trial should be submitted using the Research & Related Subaward Budget Attachment(s) Form.

The clinical trial has a maximum period of performance of **4** years. The anticipated direct costs budgeted for the entire period of performance of this optional research effort (i.e., the clinical

trial) should not exceed **\$3.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate.

Multiple PI Option

The maximum period of performance is **15 months** for the planning phase.

The anticipated combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and each Partnering PI of this planning phase award (i.e., the planning phase) should not exceed **\$500,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organization should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

Clinical trial work is considered an optional research effort. ***The application must include two severable, but related, budgets and SOWs corresponding to the planning phase and the clinical trial.*** The budget for the clinical trial should be submitted using the Research & Related Subaward Budget Attachment(s) Form.

The clinical trial has a maximum period of performance of **4** years. The anticipated combined direct costs budgeted for the entire period of performance in the application of the Initiating PI and each Partnering PI of this optional research effort (i.e., the clinical trial) should not exceed **\$3.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate.

Exercise of the clinical trial option phase is contingent upon the completion of the planning phase to include all necessary regulatory approvals and SOW milestones under the planning phase award, CPMRP Programmatic Panel review and recommendations for acceptable performance, and availability and alignment of sufficient future congressional appropriations to the CPMRP.

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The applicant may request the entire maximum funding amount for the option research effort 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 each Partnering PI should be the same.

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

- Travel costs for the PI(s) to attend the 2-day annual steering committee meetings organized by the PMC3 in the National Capital Region.

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 clinical trial optional research effort. 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 meetings is to present project information or disseminate project results from the FY23 CPMRP PMCCRA.
- Costs for stakeholder engagement activities or consultations.

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 of equal importance:

- **Planning Phase**
 - How well the plan is described for obtaining IND/IDE status (or other FDA approvals) during the 15-month or less period of performance if an IND or IDE is required.
 - Whether there is a regulatory sponsor specified and a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.

- If applicable, how well the planning phase will enable finalization or completion of:
 - Study procedures and/or clinical monitoring plan
 - Study population, inclusion/exclusion criteria, recruitment process, informed consent process, and/or screening procedures
 - CDEs and research data collection instruments
 - Organizational chart, study personnel description, and/or study management plan
 - Data management
 - Stakeholder engagement plan
- To what degree the overall regulatory strategy and transition plan will support the planned product indication.
- How well the plans for other administrative approvals (e.g., IRB, DOD OHRO) are outlined.
- **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 [FY23 CPMRP PMCCRA Focus Areas](#).
 - How well the preliminary data and scientific rationale support the research project.
 - If applicable, whether the proposed interventions have established efficacy in relevant clinical settings and are significantly mature to meet the requirements of the FY23 CPMRP PMCCRA.
 - To what extent stakeholder engagement activities were performed and to what degree it helped formulate the 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.
 - The degree to which appropriate outcome measures and clinical endpoints were selected to meet the objectives of the study.
 - 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.
 - How well the application describes the target population(s). The degree to which the study population and inclusion exclusion criteria are appropriate for the clinical study.

- If applicable, the degree to which the study addresses health disparities, increased medical burden and or challenges for Service Member and/or Veteran populations, to include whether existing barriers to equitable levels of pain management access and care have been identified and how well the work will overcome such barriers.
- ***For studies utilizing a biopsychosocial model of pain assessment:***
 - Whether the proposed biopsychosocial model of assessment is appropriate to the research study.
 - How relevant the research data collection vehicles, as well as 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.
- How well the application outlines a plan for management and sharing of research data, as appropriate, for the type of study.
- **Impact and Relevance to Military Health**
 - 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.
 - Whether the proposed research addresses health care needs and quality of life for Service Members, Veterans, and/or their family members or beneficiaries living with chronic pain.
 - To what degree the research is expected to fill an unmet need in patient care within the DHA and/or VHA.
- **Statistical Plan and Data Analysis**
 - To what degree the statistical model and data analysis plan are suitable for the planned study.
 - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.

- Whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.
- **Clinical Strategy**
 - How thoroughly the human subject interaction, including any study interventions they will experience, are articulated and are appropriate for the proposed clinical study.
 - How thoroughly the potential challenges and alternative strategies for the proposed clinical study are described.
 - If applicable, whether a strategy for single IRB regulatory submission is described.
 - How well the applicant describes access to the study population and presents feasible recruitment plans.
 - How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate mitigation plans to resolve them.
 - 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 is provided and to what degree it is appropriate to meet the study objectives.
 - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical study, if applicable.
 - To what extent the proposed clinical study might affect the daily lives of the individual human subjects participating in the study, as applicable.
 - Whether the population selected to participate in the trial stands to benefit from the knowledge gained.
 - How the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.
 - To what degree privacy and confidentiality issues are appropriately considered.
 - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
- **Regulatory Strategy and Transition Plan**
 - Whether the current regulatory status (e.g., FDA-approved, -unapproved, -licensed, -cleared, -exempt) of the study intervention is clearly defined.

- How well the plan for initiation of the clinical trial within 15 months is described, including FDA IND/IDE application submission plans within 60 calendar days of the award, if applicable.
 - 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, Communication, and Collaboration**
 - Whether the composition of the study team is appropriate.
 - To what degree the study team's background and expertise are appropriate to accomplish the proposed work.
 - How the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
 - How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical trial.
 - For clinical trials that are cooperative (i.e., involving more than one institution), to what degree the multi-institutional structure governing the research protocol(s) across all participating institutions and regulatory submission plan are described and appropriate.
 - The degree to which research team members with appropriate experience and expertise were identified for participation in collaborative working group efforts.
 - **Multiple PI Option Only – Partnership**
 - How well the partnership and combined expertise of the Initiating and Partnering PI(s) contribute to the research strategy and completion of the SOW.
 - To what degree the complementary efforts of each PI will better address the research question together rather than through separate individual efforts.

- How well the application reflects both PIs' equal intellectual input into the design of the project and their commitment to devoting similar and appropriate levels of effort to the conduct of the project.
- Whether funding will be balanced between both PIs or is otherwise appropriately justified.

- **Stakeholder Engagement**

- The degree to which the stakeholders' personal experience is relevant to the study's target patient profile and can provide meaningful insight into that group's opinions and priorities.
- How well the anticipated benefits of engagement are articulated for the study team and the stakeholder participants.
- The degree to which the stakeholder role is described and appropriate in the planning, design, implementation, and evaluation phases of the research project.
- The degree to which the stakeholders have been integrated into the research team.
- Whether a reasonable engagement structure is present that facilitates information sharing and integration of the stakeholders input and perspectives into the research project.
- If applicable, the degree to which broader stakeholder engagement is planned, including outreach to clinicians, hospital/health system administrators, and health care policymaking stakeholders.

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 is appropriate for the proposed research.
- To what degree the quality and extent of organizational support are appropriate.
- If applicable, to what degree the intellectual and material property plan is appropriate.

- **Application Presentation**

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

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY23 CPMRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relative clinical 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.health.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 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the 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 FY23 funds are anticipated to be made no later than September 30, 2024. 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 the 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, other non-profit, or for-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.

An organizational transfer of an award supporting an 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](#) and the [USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions](#) for further information.

Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI, Partnering PIs (if applicable), and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

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 with quad charts as well as a final progress report will be required.

Quarterly progress reports will be required for the clinical trial.

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 whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to 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. These recipients are required to

disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP 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 eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET (closed on most U.S. federal holidays). 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 eBRAP 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 803a. The program announcement numeric version code will match the General Application Instructions version code 803.

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 FY23 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 FY23 CPMRP Programmatic Panel members can be found at <https://cdmrp.health.mil/cpmrp/panels/panels23>.*
- 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 FY23, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>). 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 proposed research is not a clinical trial.
- The invited application proposes a different research project than that described in the pre-application.
- The application does not address at least one of the [FY23 CPMRP PMCCRA Focus Areas](#).
- 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 Clinical Strategy Statement ([Attachment 8](#)) is missing
- The Regulatory Strategy attachment ([Attachment 10](#)) is missing.
- The Stakeholder Engagement Plan ([Attachment 12](#)) is missing.
- The Study Personnel and Organization attachment ([Attachment 13](#)) is missing.
- The PI(s) do not meet the eligibility criteria.
- At least two [key stakeholders](#) (e.g., patients, immediate caregivers [not medical providers], patient advocates, community leaders) are not included as members of the research team.
- Application includes classified research data and/or proposes research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns.
- **Multiple PI Option:** Failure to submit all associated (Initiating and each 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	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"		
	Transition Plan: Upload as Attachment 11 with file name "Transition.pdf"		
Stakeholder Engagement Plan: Upload as Attachment 12 with file name "Stakeholder.pdf"			

Application Components	Action	Initiating PI Completed	Partnering PI Completed
	Study Personnel and Organization: Upload as Attachment 13 with file name "Personnel.pdf" if applicable		
	Representations (extramural submissions only): Upload as Attachment 14 with file name "RequiredReps.pdf"		
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 15 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
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
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
LAR	Legally Authorized Representative
M	Million
MB	Megabytes
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
MTF	Military Treatment Facilities
NIH	National Institutes of Health
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORCID	Open Researcher and Contributor ID, Inc.
PCORI	Patient-Centered Outcomes Research Institute
PDF	Portable Document Format

PHS	Public Health Service
PI	Principal Investigator
PMC	Pain Management Collaboratory
PMCCRA	Pain Management Collaborative Clinical Research Award
PMC3	Pain Management Collaboratory Coordinating Center
PTSD	Post-Traumatic Stress Disorder
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	U.S. 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.afrl.af.mil/AFOSR/>

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

Armed Forces Radiobiology Research Institute
<https://afrii.usuhs.edu/home>

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

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

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

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

Defense Suicide Prevention Office
<https://www.dspo.mil/>

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

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

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

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

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

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

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

Navy and Marine Corps Public Health Center
<https://www.med.navy.mil/sites/nmcphc/>

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

Office of Naval Research
<https://www.onr.navy.mil/>

Office of the Under Secretary of Defense for Acquisition & Sustainment
<https://www.acq.osd.mil/>

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

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

U.S. Air Force 59th Medical Wing
<https://www.59mdw.af.mil/>

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

U.S. Army Combat Capabilities
Development Command
<https://www.army.mil/devcom>

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

U.S. Army Medical Materiel Development
Activity
<https://usammda.health.mil/>

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

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

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

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

U.S. Army Sharp, Ready, and Resilient
Directorate
<https://www.armyresilience.army.mil/sharp/index.html>

U.S. Department of Defense Blast Injury
Research Program
<https://blastinjuryresearch.health.mil/>

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

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

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

APPENDIX 3: FITBIR REQUIREMENTS

In order to share data with FITBIR, three elements *must be included* in the proposed research:

1. Updated informed consent language that includes FITBIR data sharing. Sample consent language is included below.
2. FITBIR Global Unique Identifier (GUID): The FITBIR GUID is a subject ID that allows researchers to share data specific to a study participant without exposing Personally Identifiable Information (PII) and makes it possible to match participants across laboratories and research data repositories. In order to generate a GUID for a subject, the following PII must be collected in the proposed research (this PII is never sent to the FITBIR system):
 - Complete legal given (first) name of subject at birth
 - Complete legal additional name of subject at birth (if subject has a middle name)
 - Complete legal family (last) name of subject at birth
 - Day of birth
 - Month of birth
 - Year of birth
 - Name of city/municipality in which subject was born
 - Country of birth

Note that this PII is never sent to the FITBIR system. PII cannot be extracted from the GUID. Information on GUID compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations can be found at <https://fitbir.nih.gov/content/global-unique-identifier>.

3. National Institute of Neurological Disorders and Stroke (NINDS) TBI CDEs: Research data elements *must be reported* using the NINDS TBI CDEs or entered into the FITBIR data dictionary as new, unique data elements (UDEs). For the most current version of the NINDS TBI CDEs, go to <https://www.commondataelements.ninds.nih.gov>. Assistance will be available to help the researchers map their study variables to specific CDEs and ensure that the formats of the CDEs collected are compatible with the FITBIR Informatics System. Use of the TBI CDEs is required as applicable in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI. Applicants are strongly required to review TBI CDEs and associated form structures during the development of the study collection methods. *If approved CDEs are not incorporated, justification is required and subject to program approval.*

While there is no direct charge to users of the FITBIR Informatics System, a project estimation tool is available to help estimate costs and manpower needs that may be associated with data submission.

Sample Consent Language

Data from this study may be submitted to the Federal Interagency Traumatic Brain Injury (FITBIR) informatics system. FITBIR is a computer system run by the National Institutes of Health that allows researchers studying traumatic brain injury to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about traumatic brain injury more quickly than before.

During and after the study, the researchers will send information about you or your child's health and behavior and in some cases, you or your child's genetic information, to FITBIR. However, before they send it to FITBIR, they will remove information such as name, date of birth, and city of birth, and replace that information with a code number. Other researchers nationwide can then file an application to obtain access to your study data for research purposes. Experts who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You or your child may not benefit directly from allowing your information to be shared with FITBIR. The information provided to FITBIR might help researchers around the world treat future children and adults with traumatic brain injury so that they have better outcomes. FITBIR will report on its website about the different studies that researchers are conducting using FITBIR data; however, FITBIR will not be able to contact you or your child individually about specific studies.

You may decide now or later that you do not want to share you or your child's information using FITBIR. If so, contact the researchers who conducted this study, and they will tell FITBIR, which can stop sharing the research information. However, FITBIR cannot take back information that was shared before you changed your mind. If you would like more information about FITBIR, this is available on-line at <https://fitbir.nih.gov>.

Language to be used to describe certificates of confidentiality (three versions):

1. Language for new studies that will be consenting subjects for the first time or for ongoing studies that will be re-consenting subjects because they are applying for a Certificate of Confidentiality (COC) for the study

To help protect you and/or your child's privacy the investigators of this study [have applied for]/[have obtained] a Certificate of Confidentiality from the National Institutes of Health, part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government.

With this Certificate, we, the investigators, cannot be forced (e.g., by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Be aware that disclosure of you and/or your child's identity may be found necessary, however, upon request of DHHS for the purpose of audit or evaluation.

You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from **voluntarily** releasing information about your child, yourself, or your involvement in this research. Note however, that if an insurer or employer learns about you and/or your child's participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

We are also asking your consent to provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system. FITBIR is a biomedical informatics system and data repository, created by the Department of Defense and the National Institutes of Health to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injuries.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by qualified researchers only. Data provided to FITBIR as part of you and/or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will retain individually identifying information related to the data they provide, NIH has issued a legislatively authorized "Certificate of Confidentiality" that will help FITBIR and participating institutions avoid being forced to disclose information that may identify you as a FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Finally, you should understand that we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you, your child, or others. With respect to you and/or your child's participation in FITBIR, we do not plan to make voluntary disclosures except if there were severe threats to the public health or safety.

2. Language for studies that already have a Certificate and will be re-consenting subjects about FITBIR

With your consent, this study will collect and provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system. FITBIR is a biomedical informatics system and data repository created by the Department of Defense and National Institutes of Health—part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government—to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injury.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by researchers only. Data provided to FITBIR as part of you and/or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will retain individually identifying information related to the data they provide, NIH has issued a legislatively authorized "Certificate of Confidentiality" to help FITBIR and participating institutions avoid being forced (e.g., by court subpoena) to disclose information that may identify you as an FITBIR participant in any federal, state, or local civil, criminal, administrative,

legislative, or other proceedings. Be aware that disclosure of you and/or your child's identity may be found necessary, however, upon request of DHHS for the purpose of audit or evaluation.

As you know, we have obtained a Certificate of Confidentiality from NIH that enables us to keep the individually identifiable information that you provide as a research subject private. With this Certificate, we, the investigators cannot be forced to disclose research information collected in this study that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. This protection will continue to protect you and/or your child's privacy even though we are providing de-identified data to FITBIR.

You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from **voluntarily** releasing information about your child, yourself, or your involvement in this research. Note however, that if an insurer or employer learns about you and/or your child's participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Finally, as we explained when we told you about this privacy protection before, we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you and/or your child or others based on information they learn during this study. With respect to you and/or your child's participation in FITBIR, we do not plan to make voluntary disclosures except if there were severe threats to the public health or safety.

3. Language for studies without a Certificate of their own

With your consent, this study will collect and provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system. FITBIR is a biomedical informatics system and data repository created by the Department of Defense and the National Institutes of Health—part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government—to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injury.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by researchers only. Data provided to FITBIR as part of you or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will still retain individually identifying information related to the data provided, the NIH has issued a legislatively authorized "Certificate of Confidentiality" to help FITBIR and participating institutions avoid being forced (e.g., by court subpoena) to disclose information that may identify you as an FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Finally, you should understand that we, the investigators, are also permitted to make voluntary disclosures with respect to information that is submitted to FITBIR, but do not plan to do so except in the event of severe threats to public health or safety. If, as part of your participation in this research study itself, we learn about serious harm to you, your child or someone else, we

would take steps to prevent that harm including notifying appropriate authorities like the police or child welfare.