

# **I. OVERVIEW OF THE FUNDING OPPORTUNITY**

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Epilepsy Research Program**

**Research Partnership Award**

**Announcement Type: Initial**

**Funding Opportunity Number: HT942524ERPRPA**

**Assistance Listing Number: 12.420 Military Medical  
Research and Development**

## **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), June 5, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, June 20, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, June 24, 2024
- **Peer Review:** August 2024
- **Programmatic Review:** October 2024

*This program announcement must be read in conjunction with the General Application Instructions, version 901. 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

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Epilepsy Research Program (ERP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the ERP in 2015 to provide support for longitudinal epidemiological research to better understand the incidence of post-traumatic epilepsy (PTE) following a traumatic brain injury (TBI) and to improve patient care and outcomes. The FY24 ERP challenges the research community to (1) investigate topics related to epileptogenesis for the identification of mechanisms by which brain injury produces epilepsy, (2) study the prevention of PTE and concomitant comorbidities, and (3) develop innovative research tools or biomarkers to better detect, diagnose, or predict the development of PTE. Appropriations for the ERP from FY15 through FY24 totaled \$85.5 million (M). The FY24 appropriation is \$12M.

The ERP encourages collaboration among PTE researchers and urges the scientific community to utilize equitable partnerships with people living with PTE to maximize the translational and impact potential of proposed research. 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. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, their Families and/or care partners.

#### II.A.1. FY24 ERP Focus Areas

To meet the intent of the funding opportunity, applications to the FY24 ERP Research Partnership Award (RPA) should address at least one of the Focus Areas listed below. Applications may address more than one Focus Area. An application that proposes research outside of these FY24 ERP Focus Areas is also acceptable, as long as the applicant provides a strong justification as to why the topic is critical to advance understanding of PTE and how it addresses the ERP mission.

- **Markers and Mechanisms:** Identifying biomarkers or mechanisms of PTE, which may include the following:
  - Predictive biomarkers of epileptogenesis (acute and chronic)
  - Research into the prevention of epilepsy and/or seizures

- **Epidemiology:** Epidemiological characterization of PTE following TBI, which may include the following:
  - Understanding and improving the quality of life of individuals with PTE, their families, and/or their care partners
  - Predictors of the development of epilepsy
  - Outcomes, including latency to and prevention of epilepsy, comorbidities, and mortality
- **Longitudinal Studies:** Studies of the evolution of PTE, which may include the following:
  - Understanding and improving the quality of life of individuals with PTE, their families, and/or their care partners
  - Treatment and health care outcomes research, including quality of care
  - Comorbidities (e.g., psychiatric disorders, cognitive/physical deficits, sleep disorders, fatigue)
- **Innovative Research:** Tools intended to better inform or improve upon PTE research and care, which may include the following:
  - Strategies that will improve seizure detection, characterization, visualization, or diagnosis (e.g., artificial intelligence, bioinformatics, clinical databases, devices, tissue banks)
  - Development of new models or better characterization of existing etiologically relevant models for PTE

## II.A.2. Award History

The ERP RPA mechanism was first offered in FY19. Since then, 41 RPA applications have been received and 12 have been recommended for funding.

## II.B. Award Information

The intent of the FY24 ERP RPA is to create an avenue to support new or existing collaborative research partnerships between/among investigators to address a research problem or question in a manner that would be unachievable through separate efforts. It is expected that investigators will utilize their distinct but complementary perspectives to synergistically address a central problem or question critical to PTE research and those living with PTE, their families, and/or their care partners.

Important aspects of this award mechanism include:

- **Partnership:** The FY24 ERP RPA requires that a minimum of two investigators partner in one overarching study. The investigators may have experience in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application.

The application should demonstrate how the unique skills and contributions of the initiating Principal Investigator (PI) and Partnering PI(s) will support the meaningful and synergistic success of the project. A proposed project in which a partner merely supplies tissue or access to patients will not meet the intent of this award mechanism.

- **Impact:** Applications should articulate the short- and long-term impact of the proposed research on the PTE research field, patient care, and/or those living with PTE. Projects should address one or more of the [FY24 ERP Focus Areas](#) or provide a strong justification as to why the alternative topic is critical to advance understanding of PTE and how it addresses the ERP mission. Applicants are encouraged to consult with individuals living with PTE during the development and execution of the proposed research project, to ensure research outcomes maximize translational and impact potential (see [Community Collaborations](#)).
- **Relevance to Military Health:** Projects must be relevant to military Service Members and/or Veterans with PTE, their Families and/or care partners. Collaboration with military and VA researchers and clinicians is encouraged but not required.
- **Experience in PTE Research:** The Initiating PI and Partnering PI(s) can be from any field or discipline and must demonstrate suitable experience relevant to the proposed research. It is also *critical* that the application demonstrate the study team's experience in PTE research, including expertise in the fields of *both* TBI and epilepsy.
- **Preliminary Data:** Applications must include preliminary and/or published data that support the proposed research project. Preliminary data may be derived from laboratory discovery, clinical observation, population-based studies, or peer-reviewed literature. *In addition, evidence demonstrating the ability of the research team to execute the chosen model of TBI and record subsequent seizure is required, if applicable.*

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of active-duty Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

CDMRP also encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

**Clinical trials are not allowed under this funding opportunity.** Permitted research includes preclinical studies in animal models, observational research with human subjects, or research involving human anatomical substances or data, as well as ancillary studies associated with an existing clinical trial. When appropriate, applicants are encouraged to leverage ongoing cohort studies, such as [Transforming Research and Clinical Knowledge in TBI \(TRACK-TBI\)](#), [TBI-Model Systems](#), and [Long-Term Impact of Military-Relevant Brain Injury Consortium Chronic Effects of Neurotrauma Consortium \(LIMBIC-CENC\)](#).

The RPA requires more than one PI. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as Partnering PI(s). All PIs should contribute significantly to the development and execution of the proposed research project. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PI(s), refer to [Section II.D.2, Content and Form of the Application Submission](#).

**Employing community collaborations to optimize research impact is encouraged but NOT required.** Research funded by the FY24 ERP should be responsive to the needs of people with PTE, their families, and/or their care partners. Research teams are therefore encouraged to establish and utilize effective and equitable collaborations and partnerships with community members with lived PTE experience to maximize the translational and impact potential of the proposed research.

Collaborative research approaches such as community-based participatory research, participatory action research, and integrated knowledge transition, create partnerships between scientific researchers and community members to create knowledge useable by both sets of stakeholders. Recognizing the strengths of each partner, scientific researchers and community members ***collaborate and contribute equitably*** on all aspects of the project, which may include needs assessment, planning, research intervention design, implementation, evaluation, and dissemination. ***Collaborative research approaches feature shared responsibility and ownership for the research project to ensure non-tokenistic involvement of community members within the research team.*** Research results are jointly interpreted, disseminated, and fed back to affected communities and may be translated into interventions or policy. These methods are critically important for community-level interventions and can also have important impacts on translational research and prototype development to identify and augment the potential impact of a research program on people living with PTE, their families, and/or their care partners.

Collaborative relationships with the lived experience community are often established through integrating community members into research teams as co-researchers, advisors, and/or consultants. Some examples for implementing collaborative research approaches include:

- **Lived Experience Consultation:** The research team includes at least one project advisor with lived PTE experience who will provide advice and consultation throughout the planning and implementation of the research project. Lived Experience Consultants may include individuals with PTE, their family members, or their care partners.
- **Partnership with a Community-Based Organization:** The research team establishes partnerships with at least one community-based organization that provides advice and consultation throughout the planning and implementation of the research project. Community-based organizations may include advocacy groups, service providers, policy makers, or other formal organizational stakeholders.
- **Community Advisory Board Utilization:** A community advisory board is composed of multiple community stakeholders and can take many forms, from a board of Lived

Experience Consultants to a coalition of community-based organizations or any combination thereof. As with Lived Experience Consultants and organizational partners, the community advisory board provides advice and consultation throughout planning and implementation of the research project.

Additional information on collaborative research approaches can be found here:

- Correa DJ, Kwon C, Connors S, et al. 2019. [Applying participatory action research in traumatic brain injury studies to prevent post-traumatic epilepsy](#). *Neurobiology of Disease* 123:137–144.
- Wallerstein N and Duran B. 2010. [Community-based participatory research contributions to intervention research: The intersection of science and practice to improve health equity](#). *American Journal of Public Health* 100(S1):S40-S46.
- Jull J, Giles A, and Graham ID. 2017. [Community-based participatory research and integrated knowledge translation: advancing the co-creation of knowledge](#). *Implementation Science* 12(1):150.

**Experimental design should maximize rigor and reproducibility.** All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in Landis SC, et al., A call for transparent reporting to optimize the predictive value of preclinical research. *Nature* 2012, 490:187-191 (<https://www.nature.com/articles/nature11556>). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>.

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

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

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

- (1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does **not** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease,

(b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.

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

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

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

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

The anticipated direct costs budgeted for the entire period of performance for an FY24 ERP RPA should not exceed **\$1,200,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

*The CDMRP expects to allot approximately \$1.92M to fund approximately one Research Partnership Award application. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.*

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

**II.C.1.a. Organization:** Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

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

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



Awards are made to eligible *organizations*, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

### **II.C.1.b. Principal Investigator and Partnering Principal Investigator(s)**

The Initiating PI and Partnering PI(s) may be investigators at any career level.

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

### **II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

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

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

## **II.D. Application and Submission Information**

### **II.D.1. Location of Application Package**

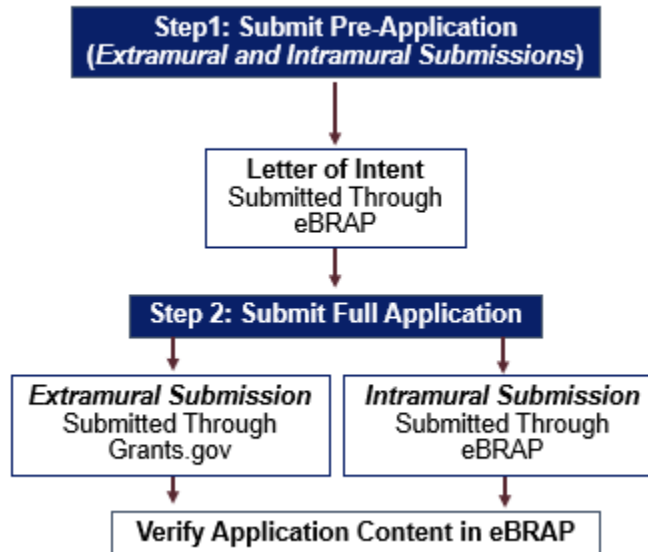
Submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a *full application* (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

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

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

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

## Application Submission Workflow



**Extramural Submission:** An application submitted by an [extramural organization](#) for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524ERPRPA from Grants.gov (<https://grants.gov>). Full applications from extramural organizations **must** be submitted through Grants.gov.

**Intramural Submission:** An application submitted by an [intramural DOD organization](#) for an investigator employed by that organization. Intramural DOD organizations **may** submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524ERPRPA from the anticipated submission portal eBRAP (<https://ebrap.org>) or Grants.gov.

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

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

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

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

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

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

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

Regardless of submission type (i.e., extramural or intramural), all pre-application components must be submitted by the Initiating PI through eBRAP (<https://eBRAP.org/>), including the submission of contact information for each Partnering PI.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for each PI, the Business Official(s), performing organization(s), and contracting organization(s) 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](mailto:help@eBRAP.org) or 301-682-5507 prior to the application submission deadline.

After the Initiating PI confirms submission of the pre-application, the Partnering PI(s) will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI(s) must follow the link in the notification email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI(s) must register in eBRAP.

After associating the pre-application with their eBRAP account, the Partnering PI(s) should email the eBRAP Help Desk ([help@eBRAP.org](mailto:help@eBRAP.org)) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).

***Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI.*** Partnering PIs 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 full application during the verification period in eBRAP.

- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.

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

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for detailed instructions regarding pre-application submission):

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the Focus Area under which the application will be submitted. Research outside of the FY24 ERP Focus Areas is acceptable.

LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. *An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.*

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

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. Each full application package must be submitted using the unique eBRAP log number received by the Initiating and Partnering PIs during pre-application submission. *All associated applications (the Initiating PI's and each Partnering PI's) must be submitted by the full application submission deadline.*

#### II.D.2.b.i. Full Application Submission Type

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

**Intramural Submissions:** Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

## II.D.2.b.ii. Full Application Submission Components for the Initiating PI

Each application submission must include the completed full application package for this program announcement. See [Section II.H.3](#) of this program announcement for a checklist of the required application components.

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

### (b) Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

- **Attachment 1: Project Narrative (18-page limit): Upload as “ProjectNarrative.pdf”**. The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and scientific reasoning behind the proposed research project. Clearly demonstrate that there is sufficient scientific evidence to support the proposed stage of research, including preliminary and/or published data. Cite relevant literature. Describe previous experience most pertinent to this project.
- **Hypothesis or Objectives:** State the hypothesis (or hypotheses) or objectives to be tested in the proposed project.
- **Specific Aims:** Concisely explain the project’s specific aims. Describe only aims that the ERP RPA would fund.
- **Focus Area:** Describe how the work aligns to one of the FY24 ERP Focus Areas, or if the work does not align to an FY24 ERP Focus Area, explain the critical research area the application will address and its relevance to the ERP mission. An application that proposes research outside of the FY24 ERP Focus Areas is acceptable, as long as a strong justification is provided as to why the topic is critical to advance understanding of PTE and how it addresses the ERP mission.
- **Study Design and Feasibility:** Describe the research strategy, methods, and analyses, including appropriate controls, in sufficient detail for evaluation of its appropriateness and feasibility. Describe the statistical plan as appropriate for the

proposed research. Describe how the study is designed to achieve the project aims. Address potential problem areas and present alternative methods and approaches.

Indicate whether ongoing cohort studies, such as TRACK-TBI, TBI-Model Systems, LIMBIC-CENC, will be leveraged in the study. If the research proposed is epidemiologic in nature, describe how the research will be conducted in accordance with the 2011 International League Against Epilepsy (ILAE) research guidelines for epidemiologic studies and surveillance of epilepsy found at <https://www.ncbi.nlm.nih.gov/pubmed/21899536>.

If applicable, briefly describe the development and use of animal model(s) including a rationale for the choice of animal model, injury method, and endpoints/outcome measures to be used. Full details will be required in the Animal Research Plan ([Attachment 10](#)). *If an animal model of TBI will be employed, provide evidence that demonstrates the research team’s ability and capacity to execute the chosen model of TBI and record subsequent seizure.*

If human subjects, human anatomical samples or data will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples or data. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. 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. Include a description of the researcher’s access to the study population at the time of submission and include a plan for maintaining access as needed throughout the proposed research project. Refer to the General Application Instructions, Appendix 4, for additional considerations. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population. **Clinical trials are disallowed in this funding opportunity.**

- **Research Team Composition:** Describe the composition of the research team in enough detail to demonstrate the study team’s experience in PTE research, including expertise in the fields of *both* TBI and epilepsy.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letters of Organizational Support (three-page limit per letter recommended):** 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) (three-page limit per letter recommended):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.
- **Inclusion Enrollment Plan (only required if *clinical research* is proposed):** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instructions 3200.12](#). *Do not duplicate the Data and Research Resource Sharing Plan.* Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.
- **Use of VA Resources (if applicable):** Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. *Abstracts of all funded research projects will be posted publicly.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

- **Background:** Present the scientific rationale behind the proposed research project.
- **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Describe the study design, including appropriate controls.
- **Impact:** Briefly describe the short- or long-term impact of this study on PTE research, patient care, and/or quality of life. Indicate how the proposed research could benefit Service Members, Veterans, their Families and/or care partners.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. *Abstracts of all funded research projects will be posted publicly.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. *Do not duplicate the technical abstract.*



Lay abstracts should address the points outlined below *in a manner that will be readily understood by readers without a background in science or medicine*. Avoid overuse of scientific jargon, acronyms, and abbreviations.

- Summarize the objectives and rationale for the proposed research.
- Describe the ultimate applicability and impact of the research to people living with PTE.
  - What populations will it help, and how will it help them?
  - What are the potential applications, benefits, and risks?
  - What is the projected time it may take to achieve a person-related outcome?
  - If the research is too basic for immediate clinical applicability, describe the interim outcomes.
  - What are the likely contributions of the proposed research project to advancing PTE research, patient care, and/or quality of life?
- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf”.** Refer to the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for the suggested SOW format and recommended strategies for assembling the SOW.

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

- DOD-National Institutes of Health (NIH) [Federal Interagency TBI Research Information System \(FITBIR\)-eligible research](#) should also include the following subtasks in the SOW:
  - FITBIR investigator and study registration within the first 30 days of the award
  - Sharing of draft data collection forms with FITBIR
  - Annual FITBIR data submission

*Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and each Partnering PI should be clearly noted for each task.*

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.** *This attachment should be written with a broad audience in mind, including readers without a background in science or medicine.* Address the impact of the proposed research on one or more of the FY24 ERP Focus Areas or an alternative topic critical to advance

understanding of PTE. Describe the short- and long-term impact of this study on PTE research, patient care, and/or quality of life, including an assessment of the likelihood that a successful outcome of the proposed research project will increase our understanding of PTE and/or lead to a practical application in individuals living with PTE. Indicate how the proposed research project is applicable to the health care needs and quality of life of injured military Service Members, Veterans, and/or their Family members or care partners.

- **Attachment 7: Data and Research Resource Sharing Plan (two-page limit): Upload as “Sharing.pdf”.** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the PTE research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. If applicable, identify and describe the planned National Institute of Neurological Disorders and Stroke [TBI](#) and/or [Epilepsy](#) Common Data Elements (CDEs) to be used/collected.

For additional guidance regarding sharing of data and research resources, refer to the General Application Instructions, Appendix 2, Section K.

**Attachment 8: Transition Plan (one-page limit): Upload as “Transition.pdf”.** Outline the project’s anticipated research outcome(s) (e.g., intervention, product, methodology, finding). Describe the planned immediate next steps to be taken *by the research team* upon successful completion of the project to bring the research outcome(s) to the next stage of development (e.g., next-stage preclinical/clinical research, translational research, clinical trial). Describe/discuss the methods and strategies necessary for the research outcome to impact patient care and outcomes. If applicable, discuss ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award including a plan for resolving intellectual and material property issues among participating organizations. If the intellectual property rights are not owned by the performer(s), describe the planned next steps necessary to make the product available to the PTE community.

- **Attachment 9: Partnership Statement (two-page limit): Upload as “Partnership.pdf”.** Describe the experience and background of the initiating PI and Partnering PI(s). Describe the contribution and the time commitment of each PI toward the proposed research project. Explain how the investigators will utilize their distinct but complementary perspectives to synergistically address the proposed research question, including why the research goals would be unachievable through separate efforts. Outline plans for interactions between/among investigators including communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data. In addition, each Partnering PI should provide a letter of

collaboration confirming their involvement in the proposed work as part of the application's Supporting Documentation ([Attachment 2](#)).

- **Attachment 10: Animal Research Plan (three-page limit): Upload as “AnimalResPlan.pdf”.** (*Attachment 10 is only applicable and required for applications proposing animal studies.*) If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the ARRIVE guidelines 2.0 to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:
  - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology. **Be specific as to why an animal model is necessary to address the study aims, why the specific animal and injury model was chosen over other models, and how it is optimal for modeling post-traumatic epilepsy and addressing the study aims.**
  - Summarize the procedures to be conducted including the method(s) for seizure detection. Describe how the study will be controlled.
  - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
  - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- **Attachment 11: Collaborative Research Plan: Upload as “Collaboration.pdf”.** (*Attachment 11 is only applicable for applications utilizing a [collaborative research approach that engages the PTE lived experience community, and/or PTE community-based organization\[s\]](#).)*
- **Collaborative Research Statement (three-page limit):** For the FY24 ERP, research teams are encouraged to establish and utilize effective and equitable collaborations and partnerships with the PTE lived experience community to maximize the translational and impact potential of proposed research. More detailed description and expectations of these collaborations/partnerships is included in the

**Community Collaboration** section above. If a partnership with the PTE lived experience community will be utilized (e.g., PTE Lived Experience Consultation, partnership with a community-based organization) include the community partner's name and describe the following as applicable.

- The collaborative research approach that will be used (e.g., Lived Experience Consultation, partnership with community-based organization, community advisory board, co-researcher model) including a justification for the approach as well as when the approach will be used within the research project.
  - The input from the community partner that has already and/or will be captured and how this input has and/or will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and/or dissemination of the research.
  - The resource allocation and decision-making processes to be employed.
  - Any training that will be provided to both scientific researchers and community members on collaborative research approaches, decision-making, and equitable participation.
  - Co-learning and capacity-building activities among all partners.
  - The process measures to assess the effectiveness of the chosen collaborative research approach.
- **Letters of Community Collaboration (two-page limit per letter is recommended):** Provide a letter signed by each Lived Experience Consultant or community-based partner confirming their role and commitment to participate on the research team. If a community-based organization will be engaged, the letter of commitment should be signed by **BOTH** the organization point of contact leading the engagement along with the organization's leadership endorsing the collaboration. The letter should include the qualifications and background of the Lived Experience Consultant(s), community-based partner, and/or organization point of contact and describe the relevance of those qualifications to the proposed research project.
- **Attachment 12: 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 8, Section B, Representations.
  - **Attachment 13: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (<https://ebrap.org/eBRAP/public/Program.htm>). The budget should cover the entire period of performance for each

intramural DOD site and include a budget justification as instructed. The **total** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

- (c) **Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.
- (d) **Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (six-page limit):** Upload as “Biosketch\_LastName.pdf”.
- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
- **Key Personnel Biographical Sketches (six-page limit each):** Upload as “Biosketch\_LastName.pdf”.

If applicable, biographical sketches, or an equivalent document should also be included for community partners (e.g., Lived Experience Consultant, representative of community-based organization) to demonstrate background and experience relevant to their role in the proposed research project.

- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
- (e) **Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

***Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization(s) 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.***

- (f) **Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

**(g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only):** Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 13.

#### **II.D.2.b.iii. Full Application Submission Components for Each Partnering PI**

The application submission process for each Partnering PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

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

#### **(b) Attachments:**

- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 12: Representations (Extramural Submissions Only): Upload as “RequiredReps.pdf”.**
- **Attachment 13: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as “IGBudget.pdf”.**

**(c) Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions refer to the General Application Instructions, Section V.A.(c), for detailed information.

**(d) Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed information.

- **PI Biographical Sketch (six-page limit):** Upload as “Biosketch\_LastName.pdf”.
- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.

- **Key Personnel Biographical Sketches (six-page limit each):** Upload as “Biosketch\_LastName.pdf”.
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.

**(e) Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed information.

- **Budget Justification (no page limit):** Upload as “BudgetJustification.pdf”.

*The initiating and Partnering PI(s) 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 any other named PI, even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.*

**(f) Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to General Application Instructions, Section V.A.(f), for detailed information.

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 13.

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

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the “Full Application Files” tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. *The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the full application submission deadline.* Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the

[application verification period](#). The full application cannot be modified once the application verification period ends.

### **II.D.3. Unique Entity Identifier (UEI) and System for Award Management (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. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

### **II.D.4. Submission Dates and Times**

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

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

### **II.D.5. Funding Restrictions**

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

The combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and each Partnering PI should not exceed **\$1,200,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate.

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

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

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

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

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

- **Interim (In-Progress) Review (IPR):** Travel costs for the PI to present information or disseminate project results at a DOD ERP In-Progress Review meeting during the period of performance. For planning purposes, it should be assumed that the meeting will be held during year 2 of the award in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.



May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations associated with the proposed work
- Costs associated with collaborative research approach (e.g., consultant costs, equitable participation training, capacity-building activities)
- Data and research resource sharing costs
- Costs for one investigator to travel to one scientific/technical meeting per year in addition to the IPR meeting described above. The intent of travel to these scientific/technical meetings should be to present project information or disseminate project results from the FY24 ERP RPA.

Must not be requested for:

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

#### **II.D.6. Other Submission Requirements**

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

### **II.E. Application Review Information**

#### **II.E.1. Criteria**

##### **II.E.1.a. Peer Review**

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

- **Research Strategy and Feasibility**
  - How well the ideas and scientific reasoning support the proposed research project and demonstrate sufficient evidence to support moving into the proposed stage of research.
  - How well the hypothesis or objectives, research strategy, methods, and analyses are developed and support successful completion of the project aims.
  - To what extent the proposed research project is feasible as described.
  - How well the application acknowledges potential problems and addresses alternative approaches.

- How well the study is designed to achieve the research objectives, including, if applicable, the development and use of animal model(s) and to what extent the chosen animal, injury method, and endpoints/outcome measures are justified.
  - Whether the statistical plan is appropriate for the proposed research.
  - If applicable, how well the application describes TBI or epilepsy CDEs to be collected and whether those CDEs are appropriate.
  - If applicable, how well the application leverages ongoing cohort studies.
  - If applicable, whether the application includes sufficient evidence to support successful recruitment of and access to human subjects, data, and samples, and whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
  - If applicable, how well the application addresses the [2011 ILAE research guidelines](#) for epidemiologic studies and surveillance of epilepsy.
  - If applicable, to what extent the application demonstrates the research team's ability and capacity to execute the chosen model of TBI and record subsequent seizure.
  - If applicable, how well the study is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
- **Partnership**
    - To what extent the investigators' unique experience and background will be used to synergistically address the proposed research.
    - How well the investigators explain why the research goals would be unachievable through separate efforts.
    - How well the plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data between/among the PI and Partnering PI(s) are described and appropriate for successful completion of the project.
- **Impact**
    - To what extent the proposed study addresses one or more of the FY24 ERP Focus Areas or provides a strong justification as to why the topic is critical to advance understanding of PTE and how it addresses the ERP mission.
    - How likely the short- and long-term impact of this study will make significant contributions on PTE research, patient care, and/or quality of life.

- How likely a successful outcome of the efforts will increase our understanding of PTE and/or lead to a practical application in individuals living with PTE.
  - To what degree the research addresses questions related to the health care needs and quality of life of injured military Service Members, Veterans, and/or their Family members, as well as their care partners.
  - ***If a collaborative research approach that engages the PTE lived experience community and/or PTE community-based organization(s) will be employed***, how well the input of the community partner (e.g., Lived Experience Consultant, representative of community-based organization) has been and/or will be captured and to what extent this input has been and/or will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and/or dissemination of the research.
- **Personnel**
    - To what extent the study team’s background and experience are appropriate to accomplish the proposed research project.
    - How well the composition of the study team demonstrates experience in ***both*** TBI and epilepsy.
    - To what degree the levels of effort are appropriate to ensure successful conduct of the proposed work.
    - How appropriate the levels of effort are for successful conduct of the proposed work.
    - ***If a collaborative research approach that engages the PTE lived experience community and/or PTE community-based organization(s) will be employed***, to what degree the qualifications and background of the Lived Experience Consultant(s), community-based partner(s), and/or organization point of contact are relevant to the proposed research project.

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

- **Data and Research Resource Sharing Plan**
  - Whether project data and research resources will be shared with the PTE research community.
  - To what extent the plan for sharing project data and research resources is appropriate and reasonable. If applicable, whether one or more specific repositories are named where scientific data and resources arising from the project will be archived.
  - Whether data and outcome dissemination activities, with particular focus on feeding back the data to affected communities, is described and appropriate.

- **Transition Plan**
  - To what degree the planned immediate next steps for the research team to take upon successful completion of the project are realistic and appropriate to bring the outcome(s)/ product(s) of the proposed research to the next stage of development (e.g., next-stage preclinical/clinical research, translational research, clinical trial).
  - If applicable, to what degree ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award are considered and planned for.
- **Budget**
  - Whether the budget is appropriate for the proposed research.
- **Environment**
  - To what extent the scientific environment is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - To what extent the quality and level of institutional support are appropriate for the proposed research project.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

#### **II.E.1.b. Programmatic Review**

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the Defense Health Program and FY24 ERP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Relative impact
  - Relevance to military health

## II.E.2. Application Review and Selection Process

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

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

## II.E.3. Integrity and Performance Information

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

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

## **II.F. Federal Award Administration Information**

### **II.F.1. Federal Award Notices**

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

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

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

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

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

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

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

### **II.F.2. PI Changes and Award Transfers**

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

An organizational transfer of an 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 7, Section F, for general information on organization or PI changes.

### **II.F.3. 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 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D General Terms and Conditions](#) and the [USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions](#) for further information.

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

The Epilepsy Research Program requires that all TBI-related clinical research with at least 50 subjects funded by this program be shared through the jointly supported DOD-NIH FITBIR. Recipients will be required to upload study data annually and in accordance with the FITBIR data submission policies. There is no fee to use FITBIR, and detailed guidance and policies, including a cost estimator tool for budgeting considerations, can be found at <https://fitbir.nih.gov>.

### **II.F.4. Reporting**

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

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

PHS Inclusion Enrollment Reporting Requirement (*only required for clinical research studies*): 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 SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

## **II.G. Federal Awarding Agency Contacts**

### **II.G.1. eBRAP Help Desk**

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

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **II.G.2. Grants.gov Contact Center**

*Questions regarding Grants.gov registration and Workspace*

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

Email: [support@grants.gov](mailto:support@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 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

### **II.H.2. Administrative Actions**

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



### **II.H.2.a. Rejection**

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

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Partnership Statement (Attachment 9) is missing.

### **II.H.2.b. Modification**

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

### **II.H.2.c. Withdrawal**

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

- An FY24 ERP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. *A list of the FY24 ERP Programmatic Panel members can be found at <https://cdmrp.health.mil/erp/panels/panels24>.*
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.

- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- A clinical trial is proposed.
- The Initiating and/or Partnering PI does not meet the eligibility criteria.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

#### **II.H.2.d. Withhold**

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

### II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded	
	PI/Initiating PI	Partnering PI
<b>SF424 Research &amp; Related Application for Federal Assistance</b> <i>(Extramural submissions only)</i>	<input type="checkbox"/>	
<b>Summary (Tab 1) and Application Contacts (Tab 2)</b> <i>(Intramural submissions only)</i>	<input type="checkbox"/>	
<b>Attachments</b>		
Project Narrative – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>	
Supporting Documentation – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>	
Technical Abstract – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>	
Lay Abstract – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>	
Statement of Work – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Impact Statement – Attachment 6, upload as “Impact.pdf”	<input type="checkbox"/>	
Data and Research Resource Sharing Plan – Attachment 7, upload as “Sharing.pdf”	<input type="checkbox"/>	
Transition Plan – Attachment 8, upload as “Transition.pdf”	<input type="checkbox"/>	
Partnership Statement – Attachment 9, upload as “Partnership.pdf”	<input type="checkbox"/>	
Animal Research Plan <i>(if applicable)</i> – Attachment 10, upload as “AnimalResPlan.pdf”	<input type="checkbox"/>	
Collaborative Research Plan <i>(if applicable)</i> – Attachment 11, upload as “Collaboration.pdf”	<input type="checkbox"/>	
Representations <i>(Extramural submissions only)</i> – Attachment 12, upload as “RequiredReps.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form <i>(if applicable)</i> – Attachment 13, upload as “IGBudget.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Personal Data</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Senior/Key Person Profile (Expanded)</b>	<input type="checkbox"/>	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>	<input type="checkbox"/>

Full Application Components	Uploaded	
	PI/Initiating PI	Partnering PI
<b>Research &amp; Related Budget</b> ( <i>Extramural submissions only</i> ) Include budget justification	<input type="checkbox"/>	<input type="checkbox"/>
<b>Budget</b> ( <i>Intramural submissions only</i> ) Include budget justification	<input type="checkbox"/>	<input type="checkbox"/>
<b>Project/Performance Site Location(s) Form</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Subaward Budget Attachment(s) Form</b> ( <i>if applicable</i> )	<input type="checkbox"/>	<input type="checkbox"/>

## APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
CDEs	Common Data Elements
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ERP	Epilepsy Research Program
ET	Eastern Time
FAD	Funding Authorization Document
FITBIR	Federal Interagency TBI Research Information System
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
ILAE	International League Against Epilepsy
IPR	In-Progress Review
IRB	Institutional Review Board
LIMBIC-CENC	Long-Term Impact of Military-Relevant Brain Injury Consortium - Chronic Effects of Neurotrauma Consortium
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPA	Research Partnership Award
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TBI	Traumatic Brain Injury
TRACK-TBI	Transforming Research and Clinical Knowledge in TBI
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