Program Announcement

for the

Department of Defense

Defense Health Program

Joint Program Committee 6/Combat Casualty Care Research Program

Congressionally Directed Medical Research Programs

Epilepsy Research Program

Idea Development Award

Funding Opportunity Number: W81XWH-16-ERP-IDA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), August 17, 2016
- **Invitation to Submit an Application:** October 5, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, November 9, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, November 15, 2016
- **Peer Review:** January 2017
- **Programmatic Review:** April 2017

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2016 (FY16) Epilepsy Research Program (ERP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The ERP was initiated in FY15 to develop an understanding of the magnitude of post-traumatic epilepsy (PTE) within the military and to expand research into the basic mechanisms by which traumatic brain injury (TBI) produces PTE. This is reflected in the ERP's vision and mission:

> **Vision:** The ERP envisions a time when the causative links between TBI and epilepsy are understood and PTE is preventable.
>
> **Mission:** The ERP's mission is to fund research to understand the magnitude, and the underlying mechanisms of PTE, especially in Service members and Veterans.

Appropriations for the ERP for FY15 were $7.5 million (M). The FY16 appropriation is $7.5M.

B. Award Information

The ERP Idea Development Award (IDA) mechanism was first offered in FY15. Since then, 24 IDA applications have been received, and 5 have been recommended for funding.

The intent of the ERP IDA is to solicit research to understand the magnitude and underlying mechanisms of PTE, especially in Service members and Veterans while also benefitting the civilian community. To this end, the ERP has identified FY16 Focus Areas by which the intent of the IDA mechanism can be facilitated (see Section I.B., FY16 ERP IDA Focus Areas). These should be carefully considered as part of the application process.

The FY16 ERP IDA offers two levels of funding. Level I is intended to support investigator-initiated research that may be high-risk and/or high-gain. Level II is intended to support advanced studies that may be multidisciplinary in nature and/or have multiple collaborators. For the Level II Collaborator Option, applications must demonstrate how the collaborators bring their unique skills to the project, and how the work cannot be accomplished without their involvement. Collaborators are defined as individuals without whom an application cannot be completed. Level II applications including multiple collaborators should include a Collaboration Statement (Attachment 10). While not required, applications to either Level I or II should provide relevant preliminary data. Preliminary data may come from the Principal Investigator's (PI's) published work, pilot data, or from peer-reviewed literature.

Note: ***When starting the pre-application process (see Section II.B., Pre-Application Submission Content), PIs should ensure that they have selected the appropriate application category (Funding Level) as described in the paragraph above.***

The IDA is open to PIs at or above the level of Assistant Professor (or equivalent) from any field or discipline who seek to bring their expertise to address the ERP's mission (see Section I.A., Program Description). However, as part of the application, the PI should demonstrate that the study team has experience in both TBI and epilepsy research.

FY16 ERP IDA Focus Areas: The FY16 ERP IDA is seeking applications in the Focus Areas described below. Applications should address at least one of the following FY16 ERP IDA Focus Areas. An application that proposes research outside of these FY16 ERP IDA Focus Areas is acceptable, as long as the applicant provides a strong rationale as to the relevance of the research to the ERP's FY16 mission.

- **Epidemiology:** Epidemiological characterization of PTE following TBI, which may include:
    - Risk factors such as demographics, genetic factors, organic head injury factors, or type of insult
    - Differentiation of PTE and Psychogenic Non-Epileptic Seizures (PNES)
    - Outcomes including latency to epilepsy, morbidities and comorbidities, and mortality
    - Pre-existing conditions including psychological and psychiatric risk factors

Note: Applications proposing epidemiological research should be submitted under the Epidemiology Option.

- **Markers and Mechanisms:** Identifying markers or mechanisms (via clinical prospective or preclinical models) that address PTE:
    - Early detection
    - Diagnosis
    - Prognosis
    - Morbidity
    - Comorbidity
    - Mortality
    - Risk stratification
- **Models of PTE:** Development of new models or better characterization of existing etiologically relevant models for PTE, including repetitive TBI.
- **Psychogenic Non-Epileptic Seizures:** Exploration of the epidemiology, mechanisms, risk factors, or markers of PNES subsequent to TBI. Preclinical research on non-pharmacological interventions in this population is also encouraged.

Note: Research focusing on interventional clinical trials (e.g., pharmacological interventions) is strongly discouraged.

C. Information Regarding Human and Animal Research

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is ***not*** required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 6, and the Human Subject Resource Document available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is ***not*** required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 6, for additional information.

D. Information Regarding Common Data Elements and Data Sharing

Use of TBI Common Data Elements: Data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) Common Data Elements (CDEs) or entered into the Federal Interagency TBI Research (FITBIR) data dictionary as new, unique data elements. For the most current version of the NINDS TBI CDEs, go to http://www.commondataelements.ninds.nih.gov. Assistance will be available to help researchers map their study variables to specific CDEs and ensure the formats of the CDEs collected are compatible with the FITBIR Informatics System. If the proposed research data cannot be entered in CDE format, the investigators must supply a proposal for an alternative data submission or data sharing vehicle and justification for its use. Use of the TBI CDEs is required wherever possible 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.

Note: In addition to the TBI CDEs, applicants are also strongly encouraged to consider developing a plan to incorporate the NINDS CDEs for epilepsy found at the link above.

FITBIR Reporting Requirement for Projects Producing TBI Datasets: The DoD requires that awardees make available to the TBI research community all data generated via this award mechanism by depositing de-identified research data into the FITBIR Informatics System on a quarterly basis. The FITBIR Informatics System is a free resource to the TBI community and is designed to accelerate comparative effectiveness research on brain injury diagnosis and treatment. Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and to collaborate with others doing similar research. While there is no direct charge to users of the FITBIR Informatics System, a project estimation tool (https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp) is available to help estimate costs and manpower needs that may be associated with data submission. To contribute to FITBIR, researchers should contact the FITBIR Operations Center ahead of time to arrange for data entry support and to ensure all data has been made compatible with the system. FITBIR guidance and policies, as well as the considerable advantages of FITBIR use to the researcher, are detailed at FITBIR: Federal Interagency Traumatic Brain Injury Research Informatics System (http://fitbir.nih.gov/).

FITBIR allows for de-identification and storage of data (medical imaging, clinical assessment, environmental and behavioral history, etc.) of various types (text, numeric, image, time series, etc.). Use of FITBIR's Global Unique Identifier (GUID) system facilitates repeated and multi-user access to data without the need to personally identify data sources. FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

E. Eligibility Information

- For either Level I or II, the PI must be an independent investigator **at or above** the level of Assistant Professor (or equivalent).
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. ***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.

- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

F. Funding

The requested budget level should be appropriate for the scope of research proposed.

For Funding Level I:

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **$500,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$500,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

For Funding Level II:

- The maximum period of performance is **4** years.
- The anticipated **total (direct and indirect)** costs budgeted for the entire period of performance will not exceed **$3,700,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$3,700,000** total costs or using an indirect rate exceeding the organization's negotiated rate.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

For both Funding Levels:

- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

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

- Travel costs for the PI to disseminate project results at one annual DoD ERP In-Progress Review meeting starting in year 2 and throughout the remaining period of performance. Annual costs associated with travel to this meeting should be included in the budget. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area for a single day. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research-related supplies and subject costs
- Preclinical research costs
- Subject reimbursement and compensation
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Data sharing costs associated with the execution of the data sharing plan.
- Travel costs for up to two investigators to travel to two scientific/technical meetings per year. This is in addition to the aforementioned In-Progress Review meeting.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., 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 Section II.C.4. of the General Application Instructions***.

The CDMRP expects to allot approximately $6.8M of the $7.5M FY16 ERP appropriation to fund approximately four Level I and one Level II Idea Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

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

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (https://eBRAP.org/) and (2) application submission through Grants.gov (http://www.grants.gov/). Refer to the General Application Instructions, Section II.A., for registration and submission requirements for eBRAP and Grants.gov.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM)

registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

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

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-16-ERP-IDA in Grants.gov (http://www.grants.gov/).

B. Pre-Application Submission Content

The pre-application process should be started early to avoid missing deadlines. There are no grace periods. **During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.**

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

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. A change in PI or organization after submission of the

pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507). ***When starting the pre-application process, PIs should ensure that they have selected the appropriate application category:***

- Idea Development Award – **Level I**
- Idea Development Award – **Level I, Epidemiology**
- Idea Development Award – **Level II**
- Idea Development Award – **Level II, Collaborator Option**
- Idea Development Award – **Level II, Epidemiology**
- Idea Development Award – **Level II, Epidemiology and Collaborator 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**
- **Tab 2 – Application Contacts**
  - Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
  - Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on "*Add Organizations to this Pre-application.*" The organization(s) must either be 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. ***When starting the pre-application process, PIs should ensure that they have selected the appropriate application category*** associated with the application.
  - **FY16 ERP Programmatic Panel members should not be involved in any pre-application or application.** For questions related to Programmatic Panel members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- 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 application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

- **Tab 4 – Conflicts of Interest**
  - List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to Appendix 1, Section C of the General Application Instructions for further information regarding COIs.

- **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 (five-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:

  - A description of how the pre-application meets the intent of the IDA mechanism (see Section I.B., Award Information).
  - A description of how the research is aligned with at least one of the FY16 ERP IDA Focus Areas (see Section I.B., FY16 ERP IDA Focus Areas). Research outside of the FY16 ERP IDA Focus Areas is acceptable, but a strong rationale is required and must be included in the Preproposal Narrative.
  - A description of the proposed scientific hypothesis (or hypotheses) and rationale.
  - Relevant preliminary data (if available). Preliminary data may come from the PI's published work, pilot data, or from peer-reviewed literature.
  - A description of how the selected funding level is appropriate for the research proposed.

  Note: Research focusing on interventional clinical trials (e.g., pharmacological interventions) is strongly discouraged.

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:

- 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, 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 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 DHP and the ERP (see Section I.A., Program Description), pre-applications will be screened based on the following criteria:

  - Does the pre-application meet the intent of the FY16 ERP IDA mechanism?
  - Does the pre-application identify and align with one or more of the FY16 ERP IDA Focus Areas? If the proposed research does not align with any of the FY16 ERP IDA Focus Areas, is the rationale clear and reasonable?
  - What are the merits of the scientific hypothesis (or hypotheses) and rationale as they pertain to the mission (see Section I.A., Program Description) of the FY16 ERP?
  - Are the preliminary data, if available, supportive of the proposed hypothesis (or hypotheses) and rationale?
  - Are the qualifications of the PI and key personnel appropriate?
  - Does the study team demonstrate expertise in both TBI and epilepsy?
  - Is the selected funding level appropriate for the research proposed?

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

  Following the pre-application screening, 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 on the title

page of this Program Announcement/Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

C. Full Application Submission Content

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant's organization's Entity registration in the System for Award Management (SAM) well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

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

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.

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 Grants.gov application package for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/).

Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.

If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to the application submission deadline***.

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

Grants.gov application package components: For the Idea Development Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

   Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are

consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (page limit varies by funding level; see below): Upload as "ProjectNarrative.pdf."** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.
    - **Page Limit:** Page limits for the project narrative are correlated with the application's funding level:
        - **Level I:** 15-page limit
        - **Level II:** 20-page limit

      Describe the proposed project in detail using the outline below.
    - **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application.
    - **Preliminary Data:** Provide preliminary data (if available) to support the rationale and feasibility of the study. Preliminary data may come from PI's published work, pilot data, or from peer-reviewed literature.
    - **Hypothesis (or Hypotheses):** State the hypothesis (or hypotheses) to be tested.
    - **Specific Aims:** Concisely explain the project's specific aims.
    - **Project Milestones:** Concisely provide expected project milestones relevant to each of the project's technical objectives and specific aims.
    - **Research Strategy:** Describe the experimental design, methods, and analyses (to include statistical analyses), including appropriate controls, in sufficient detail for analysis. Applications should also identify any potential pitfalls and possible solutions. **Note: Research focusing on interventional clinical trials (e.g., pharmacological interventions) is strongly discouraged.**
    - **Level II Applications:** Describe how the PI is experienced in successfully leading advanced studies that may be multidisciplinary in nature and/or have multiple collaborators.

- **Attachment 2: Supporting Documentation. Start each document on a new page. Combine and upload as a single file named "Support.pdf."** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include***

only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
- **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- **Intellectual Property**
  - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
    - Clearly identify all such property;
    - Identify the cost to the Federal Government for use or license of such property, if applicable; or
    - Provide a statement that no property meeting this definition will be used on this project.

- **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **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.

  Describe the proposed research project including the following elements:

  - **Background:** Present the ideas and reasoning behind the proposed project.
  - **Hypothesis (or Hypotheses):** State the hypothesis (or hypotheses) to be tested.
  - **Specific Aims:** Concisely explain the project's specific aims.
  - **Research Strategy:** Briefly describe the research strategy.

    Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

- **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.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

  Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the lay abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the lay abstract are highly important.

- **Attachment 5: Statement of Work (SOW) (three-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). For the Idea

Development Award mechanism, use the SOW format example titled "SOW (Statement of Work) Generic Format." The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

- **Attachment 6: Focus Areas Statement (one-page limit): Upload as "FAS.pdf."** Describe how the application addresses at least one of the FY16 ERP IDA Focus Areas (see Section I.B., FY16 ERP IDA Focus Areas). An application that proposes research outside of the FY16 ERP IDA Focus Areas is acceptable, as long as the applicant provides a strong rationale. **The application must include a Focus Areas Statement.**

- **Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf."** Detail the anticipated outcome(s) that will be directly attributed to the results of the proposed research (short-term gains). Explain the anticipated long-term gains from the proposed research project. Furthermore, detail how the research efforts will address the ERP's mission, and ultimately affected individuals and their families. **The application must include an Impact Statement.**

- **Attachment 8: Data Sharing Plan (two-page limit): Upload as "Sharing.pdf."** A robust data sharing plan is required as part of the application process. Describe the type of data or resource to be made available as a result of the proposed work. Also, describe the plan for the provision of access to the data or resource generated from the proposed work to the public, and how the data or resource will be made available after the award expires. Provide a milestone plan for data dissemination as part of this statement.
    - **Applications that include studies of TBI must consider the following as part of their Data Sharing Plan:**
        - **Use of Common Data Elements:** If an applicant's study involves the generation of TBI datasets, the applicant must describe how (s)he will use the NINDS TBI CDEs (see http://www.commondataelements.ninds.nih.gov). If the proposed research is not compatible with the required CDEs, the applicant should supply justification why these measures will not be incorporated into the research.

      Note: In addition to the TBI CDEs, applicants are also strongly encouraged to consider developing a plan to incorporate the NINDS CDEs for epilepsy found at the link above.

        - **FITBIR Reporting Requirement:** A plan for reporting to the FITBIR (https://fitbir.nih.gov) data repository must also be described in the data sharing plan, if applicable. If the proposed study is not compatible with the database, the applicant should supply a justification for not using the database. Applicants should review the FITBIR guidance regarding the inclusion of costs in the proposed budget associated with reporting to FITBIR.

For additional guidance regarding Sharing of Data and Research Resources, refer to the General Application Instructions, Appendix 4, Section K.

- **Attachment 9: Epidemiological Research Statement, if applicable (two-page limit): Upload as "Epi.pdf."** Applications submitted under the Epidemiology Option must address how the study will conduct research in accordance with the 2011 International League Against Epilepsy research guidelines found at http://www.ncbi.nlm.nih.gov/pubmed/21899536. For applications not including epidemiological research, note "This attachment left intentionally blank" for this attachment.

- **Attachment 10: Collaboration Statement, if applicable (two-page limit): Upload as "Collab.pdf."** For Funding Level II applications submitted under the Collaborator Option, clearly describe the proposed collaboration. Collaborators are defined as individuals without whom an application cannot be completed. In addition, each collaborator should provide a letter of collaboration describing his/her involvement in the proposed work as part of the application's supporting documentation. The statement should discuss how successful completion of the project depends on the unique skills and contributions of both the PI and the collaborators. Each collaborator should demonstrate how he/she will contribute to the project such that the proposed work could not be accomplished without his/her involvement. This is expected to include both intellectual input and research resources (e.g., supplies, reagents, equipment, personnel, services, tissue samples, or access to patients or populations). For applications not submitted under the Collaborator Option, note "This attachment left intentionally blank" for this attachment.

- **Attachment 11: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as "MFBudget.pdf."** If a Military Facility (military health system facility, research laboratory, 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 the Collaborating DoD Military Facility Budget Form, 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 and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information**.**

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., 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 six-page National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- 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."

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.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.

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.

   Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.Gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 11 Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. 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/Funding Opportunity. ***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 prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

E. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in submission rejection.

F. Other Submission Requirements

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

All extramural applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

A. 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 of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP, Combat Casualty Care Research Program, and ERP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/ Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***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 III.B.2., Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.shtml.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement 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 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 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 Title 18 United States Code 1905.

B. Application Review Process

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

   - **Research Strategy and Feasibility**
     - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, relevant preliminary data (if available), and/or logical reasoning.
     - How well the hypothesis (or hypotheses), aims, experimental design, methods, and analyses, including statistical analyses, are developed.
     - How well the PI acknowledges potential problems and addresses alternative approaches.
   - **Impact Statement:** Assuming the objectives/goals of the proposed research are realized, to what extent:
     - The anticipated outcomes (short-term) will be used as the foundation for future research projects.
     - The anticipated long-term scientific gains will contribute to the goal of achieving the ERP's mission (see Section I.A., Program Description).
     - The efforts will benefit researchers and/or practitioners in the health sciences related to the ERP's mission (see Section I.A., Program Description) and ultimately affected individuals and their families.
   - **Personnel**
     - How well the PI shows potential for addressing the ERP's mission **(**see Section I.A., Program Description**)** based on his/her background and experience.
     - How well the study team's background and related expertise are appropriate with respect to its ability to perform the proposed work.
     - To what extent the composition of the study team, to include the PI, is appropriate and includes expertise in both TBI and epilepsy.
     - To what degree the levels of effort are appropriate for successful conduct of the proposed work.
     - For Level II applications submitted under the Collaborator Option:
       - How well the PI and Collaborator(s) demonstrate the use of their unique skills to successfully complete the project.
       - How well the PI and Collaborator(s) demonstrate that their unique contributions and involvement will lead to the successful completion of the project.

- **Focus Area Statement**
  - How well the proposed study addresses at least one of the FY16 ERP IDA Focus Areas or provides a rationale for research outside the FY16 ERP IDA Focus Areas.
- **Data Sharing Plan**
  - To what degree the proposed plan for data sharing is appropriate, including but not limited to:
    - The description of the type of data or resource to be made available.
    - Ease of access for other researchers to the data or resource.
    - The appropriateness of plans to ensure the data or resource is accessible after the period of performance expires.
    - The appropriateness of the milestones with respect to making the data or resource available.
    - The appropriateness of the FITBIR data sharing plan (if applicable).
- **Epidemiological Research Statement (if applicable)**
  - For applications submitted under the Epidemiology Option, how well the application addresses the 2011 International League Against Epilepsy research guidelines found at http://www.ncbi.nlm.nih.gov/pubmed/21899536.

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

- **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.
- **Budget**

  For Funding Level I:
  - Whether the **direct** maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement/Funding Opportunity.

  For Funding Level II:
  - Whether the **total** maximum costs are equal to or less than the allowable total maximum costs as published in the Program Announcement/Funding Opportunity.

  For both Funding Levels:
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- Whether there may be significant overlap with existing or pending awards of the PI.

- **Intellectual Property**
  - 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.

2. **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:

   a. Ratings and evaluations of the peer reviewers

   b. Relevance to the mission of the DHP and FY16 ERP, as evidenced by the following:

   - Adherence to the intent of the award mechanism
   - Program portfolio composition
   - Programmatic relevance
   - Relative impact

C. Recipient Qualification

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

D. Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

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.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

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 (Attachment 1) exceeds page limit.
- Project Narrative (Attachment 1) is missing.
- Focus Areas Statement (Attachment 6) is missing.
- Impact Statement (Attachment 7) is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities or different funding levels within the same program and fiscal year.

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.

C. Withdrawal

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

- An FY16 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. ***A list of the FY16 ERP Programmatic Panel members can be found at http://cdmrp.army.mil/ERP/panels/panels16.shtml***.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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 FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The invited application does not propose the same research project described in the pre-application.
- An application is submitted by a PI who does not meet the eligibility criteria.

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.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2017. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 4, Section H, for general information on reporting requirements.

Quarterly technical progress reports will be required.

In addition to written progress reports, in-person presentations may be requested.

Copies of all scientific publications and presentations as a result of this funding are required.

Quad Charts will be required.

E. Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and 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 4, Section L, for general information on organization or PI changes.

VI. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code 20160210j. The Program Announcement/ Funding Opportunity numeric version code will match the General Applications Instructions version code 20160210.

B. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

C. Grants.gov Contact Center

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

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

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity 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.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Focus Areas Statement: Upload as Attachment 6 with the filename "FAS.pdf."	
	7	Impact Statement: Upload as Attachment 7 with the filename "Impact.pdf."	
	8	Data Sharing Plan: Upload as Attachment 8 with the filename "Sharing.pdf."	
	9	Epidemiological Research Statement: Upload as Attachment 9 with the filename "Epi.pdf," if applicable.	
	10	Collaboration Statement: Upload as Attachment 10 with file name "Collab.pdf," if applicable.	
	11	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 11 with file name "MFBudget.pdf," if applicable.	
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		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	