

# **Program Announcement**

**for the**

**Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

## **Peer Reviewed Alzheimer's Research Program**

### **Quality of Life Research Award**

**Funding Opportunity Number: W81XWH-15-PRARP-QUAL**

**Catalog of Federal Domestic Assistance Number: 12.420**

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

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), August 19, 2015
- **Invitation to Submit an Application:** October 12, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, November 25, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, December 3, 2015
- **Peer Review:** February 2016
- **Programmatic Review:** April 2016

*The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.*

*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 2015 (FY15) Peer Reviewed Alzheimer's Research Program (PRARP)) 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, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP).

The PRARP (formerly the Militarily Relevant Peer Reviewed Alzheimer's Disease Research Program) was initiated in 2011 to address the long-term consequences of traumatic brain injury (TBI) as they pertain to Alzheimer's disease (AD). Military personnel and other individuals who suffer from TBI face an increased risk for developing several long-term health problems. These conditions include Alzheimer's-like dementia, aggression, memory loss, depression, and symptoms similar to those of other neurological diseases. The PRARP is devoted to (1) understanding the association between TBI and AD; and (2) reducing the burden on affected individuals and caregivers, especially in the military and Veteran communities. Support for these objectives is anticipated to be delivered by the research community through a combination of mechanistic and preclinical studies.

Appropriations for the PRARP from FY11 through FY14 totaled \$51 million (M). The FY15 appropriation is \$12M.

### **B. Award Information**

The PRARP Quality of Life Research Award (QUAL) mechanism was first offered in FY13. Since then, 12 QUAL applications have been received, and 2 have been recommended for funding.

The intent of the research funded through the FY15 QUAL is to reduce the burden on affected individuals and caregivers, especially in the military and Veteran communities. The research impact will benefit the military, Veteran, and civilian communities.

The QUAL is open to Principal Investigators (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 PRARP's mission. However, as part of the application, the PI should demonstrate that the study team has experience in both TBI and AD research. Preliminary data, while not required, is encouraged.

**FY15 QUAL Overarching Challenges:** This QUAL funding opportunity requires applications to address one or more of the following FY15 Overarching Challenges:

- **Quality of Life:** The need for technologies, assessments, interventions, or devices to benefit individuals living with the symptoms of TBI and AD.

- **Caregiver Burden:** The need for technologies, assessments, interventions, or devices with the goal of reducing burden for caregivers of individuals living with the symptoms of TBI and AD.

**FY15 QUAL Focus Areas:** In addition to addressing one or more of the specified FY15 Overarching Challenges, applications should address at least one of the following FY15 Focus Areas in support of the FY15 Overarching Challenges. An application that proposes research outside of these FY15 Focus Areas is acceptable, as long as the applicant provides a strong rationale:

- **Care Interventions and Quality of Life:** Research intended to stabilize or improve the quality of life of those affected by TBI or AD. Examples of research in this Focus Area include: identification and management of co-morbidities and modifiable risk factors (e.g., sleep apnea, obesity); cognitive training interventions; studies of health and wellness and behavioral interventions.
- **Caregiver Support:** Research intended to reduce the burden of care on the caregiver for individuals affected by the symptoms of TBI or AD. Examples of research in this focus area include: Caregiver training, home-based support, behavioral interventions, and relationship interventions.

**The following is specifically discouraged under the FY15 PRARP:**

**Pharmacologic Interventions:** Clinical or Basic research requiring investigational or U.S. Food and Drug Administration (FDA)-approved drugs or medicines.

**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), in addition to the local Institutional Review Board (IRB) of record. Local IRB 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. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 5, 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.

**Use of Common Data Elements:** Data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI 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.

**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 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 3, Section L.*

### **C. Eligibility Information**

- 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 national, international, for-profit, nonprofit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

## D. Funding

- 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.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

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

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

- Travel costs for the PI(s) to disseminate project results at one DoD PRARP In-Progress Review meeting per year. Funds should not be requested for this meeting until year 2 of the application to allow for research to be conducted. 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
- Equipment
- Research-related supplies and subject costs
- Clinical research costs
- Subject reimbursement and compensation
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings in addition to the required meeting described above
- Data sharing costs associated with the execution of the data sharing plan

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a

DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, 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 Section II.A. of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

***The CDMRP expects to allot approximately \$2.8M of the \$12M FY15 appropriation to fund approximately four Quality of Life Research 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 within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

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.

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.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

***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. Any other application component cannot be changed after the end of the application verification period.***

#### **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-15-PRARP-QUAL in Grants.gov (<http://www.grants.gov/>).

#### **B. Pre-Application Submission Content**

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any other changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

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):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
  - 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 SF-424 Form). The Business Official must either be selected from the eBRAP 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.
- **Collaborators and Key Personnel – Tab 3**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
  - **FY15 PRARP Program Steering Committee (PSC) members should not be involved in any pre-application or application.** For questions related to PSC members and pre-applications or applications, see [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.
- **Conflicts of Interest (COIs) – Tab 4**
  - 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).
- **Pre-Application Files – Tab 5**

***Note: Upload document(s) 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, etc.) 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 QUAL mechanism (See [Section I.B., Award Information](#)).
- A description of how the research is aligned against one or more of the FY15 QUAL Overarching Challenges (See [Section I.B., Award Information](#)).
- A description of how the research is aligned against at least one of the FY15 QUAL Focus Areas (See [Section I.B., Award Information](#)). Research outside of these FY15 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 can come from PI's published work, pilot data, or from peer-reviewed literature.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual documents* 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 (five-page limit per individual).
- **Submit Pre-Application – Tab 6**
  - 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 PRARP, pre-applications will be screened based on the following criteria:

- Does the pre-application meet the intent of the QUAL mechanism?
- Does the pre-application identify and align with one or more of the FY15 QUAL Overarching Challenges?
- Does the pre-application identify and align with one or more of the FY15 QUAL Focus Areas? If the proposed research does not align with any of the FY15 QUAL 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 of the PRARP?
- 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 AD?
- **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.

## C. Full Application Submission Content

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

*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 provided in Grants.gov 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*.

**Grants.gov application package components:** For the Quality of Life Research 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. **SF-424 (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 (25-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, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below:

- **Background:** 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 can come from PI's published work, pilot data, or from peer-reviewed literature.
- **Hypothesis (or Hypotheses):** State the hypothesis (or hypotheses) to be tested or the objective to be reached.
- **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 that pharmacologic interventions are specifically discouraged.**
- **Clinical Trial (if applicable):** Provide detailed plans for initiating and conducting the clinical trial during the course of this award. As appropriate, outline a plan for applying for and obtaining Investigational Device Exemption (IDE) status (or other FDA approvals as appropriate). Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
  - Identify the intervention to be tested and describe the projected outcomes.
  - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
  - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random). Provide information on the availability of and access to the appropriate patient population(s), as well as the ability to accrue sufficient subjects for the clinical trial.
  - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
- **Clinical Team (if applicable):** Describe the composition of the clinical team. Provide details on how the team (including investigator[s], study coordinator, statistician) possesses the appropriate expertise in conducting clinical trials.

- **Statistical Plan and Clinical Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
- **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 Patent Abstracts:** 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:**
    - **Background and Proprietary Information:** All software and data first produced under the award are subject to a Federal purpose license. Provide

a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.

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

- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** 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 or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims.
- **Research Strategy:** Briefly describe the research strategy.

The technical abstract is used by all reviewers. 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.”** 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*.

The lay abstract is used by all reviewers. 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.

- **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 QUAL 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.3., for detailed guidance on creating the SOW.

- **Attachment 6: Overarching Challenges and Focus Areas Statement (one-page limit): Upload as “OCFAS.pdf.”** Describe how the proposed study is responsive to one or more of the specified FY15 QUAL Overarching Challenges (see [Section I.B., Award Information](#)). In addition, describe how the application addresses at least one of the FY15 QUAL Focus Areas (see [Section I.B., Award Information](#)). An application that proposes research outside of these FY15 Focus Areas is acceptable, as long as the applicant provides a strong rationale. The application must include the Overarching Challenges and Focus Areas Statement.
- **Attachment 7: Strategy Statement (one-page limit): Upload as “Strat.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 benefit researchers and/or practitioners in the health sciences related to the PRARP’s mission, and ultimately affected individuals and caregivers. The application must include the Strategy 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.
    - **FITBIR Reporting Requirement:** A plan for reporting to the FITBIR (<http://fitbir.nih.gov/tbi-portal/>) 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 L.**

- **Attachment 9: 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), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.
- **PI Biographical Sketch (five-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 five-page National Institutes of Health Biographical Sketch may also be used.
  - **PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”**
  - **Key Personnel Biographical Sketches (five-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.5., 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.6., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** 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, 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 application rejection.

#### **F. Other Submission Requirements**

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

All 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 consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP and PRARP, and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. 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 nondisclosure 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, and/or logical reasoning.
- How well the hypothesis (or hypotheses) or objectives, aims, experimental design, methods, and analyses, including statistical analyses, are developed.
- How well the PI acknowledges potential problems and addresses alternative approaches.
- How well the plan for addressing unanticipated delays is likely to lead to success in completing the proposed study within the performance period.

- **Strategy Statement:**

Assuming the objectives/goals of the proposed research project 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 PRARP's mission.
- The efforts will benefit researchers and/or practitioners in the health sciences related to the PRARP's mission and ultimately affected individuals and caregivers.

- **Clinical Strategy (applicable only to applications that include a clinical trial):**

- How the type of clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives.
- How the clinical trial is designed with appropriate study variables, controls, and endpoints.
- How the application demonstrates the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.

- Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining IDE status (or other FDA approvals), if appropriate.
- Whether potential challenges and alternative strategies are appropriately identified.
- **Study Team:**
  - How the PI shows potential for addressing the PRARP's mission based on his/her background and experience.
  - How the research team's background and related expertise are appropriate with respect to its ability to perform the proposed work.
  - Whether the composition of the study team, to include the PI, is appropriate and includes expertise in both TBI and AD.
  - To what degree the levels of effort are appropriate for successful conduct of the proposed work.
- **Overarching Challenges and Focus Area Statement:**
  - How well the proposed study addresses the FY15 QUAL Overarching Challenge(s) and Focus Area(s), or provides a rationale for research outside the FY15 Focus Areas.
- **Data Sharing Plan:**
  - The quality of the proposed plan for data sharing to include (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 continued access to the data or resource after the period of performance expires.
    - The appropriateness of the milestones with respect to making the data or resource available.
    - (If applicable) The appropriateness of the FITBIR data sharing plan.

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

- **Intellectual Property:**
  - If applicable, to what degree the intellectual and material property plan is appropriate.
  - If applicable, to what degree the commercialization strategy is appropriate.
- **Application Presentation:**
  - To what extent the writing, clarity, and presentation of the application components influence the review and reflect knowledge and respect for the needs of the community of individuals affected.

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

- a. **Ratings and evaluations of the peer reviewers**
- b. **Relevance to the mission of the DHP and FY15 PRARP, as evidenced by the following:**
  - Adherence to the intent of the award mechanism
  - Program portfolio composition]
  - Programmatic relevance

### **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.
- Proposal Narrative exceeds page limit.
- Project Narrative is missing.
- Strategy Statement is missing.
- Overarching Challenges and Focus Area Statement is missing.
- Budget is missing.

### 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 FY15 PRARP Program Steering Committee (PSC) 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 FY15 PRARP PSC members can be found at <http://cdmrp.army.mil/prarp/pscs/psc15.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).

- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., 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.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.
- The PI does not meet eligibility criteria.

#### **D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution 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, 2016. Refer to the General Application Instructions, Appendix 3, 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 3 for general information regarding administrative requirements.

#### **C. National Policy Requirements**

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

## **D. Reporting**

Refer to the General Application Instructions, Appendix 3, Section I, 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.

## **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.

Refer to the General Application Instructions, Appendix 3, Section M, for general information on organization or PI changes.

## **VI. AGENCY CONTACTS**

### **A. 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](mailto:help@eBRAP.org)

### **B. 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

Email: [support@grants.gov](mailto: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
SF-424 (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	Overarching Challenges and Focus Areas Statement: Upload as Attachment 6 with file name "OCFAS.pdf"	
	7	Strategy Statement: Upload as Attachment 7 with file name "Strat.pdf."	
	8	Data Sharing Plan: Upload as Attachment 8 with file name "Sharing.pdf."	
	9	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 9 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.	
Additional Application Components	Upload Order	Action	Completed
Confidential Letters of Recommendation		Confirm upload to eBRAP.	