

Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Peer Reviewed Alzheimer's Research Program

Quality of Life Research Award

Funding Opportunity Number: W81XWH-14-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), October 16, 2014
- **Invitation to Submit an Application:** December 1, 2014
- **Application Submission Deadline:** 11:59 p.m. ET, January 14, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, January 20, 2015
- **Peer Review:** February 2015
- **Programmatic Review:** April 2015

Important: 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 2014 (FY14) Peer Reviewed Alzheimer's Research Program (PRARP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisition Activity (USAMRAA).

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 mission of the PRARP is twofold. The PRARP is devoted to (1) understanding the association between TBI and AD; and (2) reducing the burden on caregivers and individuals affected by TBI-AD symptoms, especially in the military community. Support for these objectives is anticipated to be delivered by the research community through a combination of mechanistic and pre-clinical studies.

Appropriations for the PRARP from FY11 through FY13 totaled \$39 million (M). The FY14 appropriation is \$12M.

B. Award Information

The intent of the research funded through the FY14 Quality of Life Research Award (QUAL) is to reduce the burden on caregivers and individuals affected by the common symptoms of both TBI and AD, especially in the military community.

Overarching Challenges: This QUAL funding opportunity requires applications to address one or both of the following PRARP Overarching Challenges:

- **Quality of Life:** The need for technologies, tests, interventions, epidemiological studies, or devices with the potential to benefit individuals suffering from common symptoms of TBI and AD.
- **Caregiver Burden:** The need for technologies, tests, interventions, epidemiological studies, or devices with the potential to reduce caregiver burden for individuals affected by the common symptoms of TBI and AD.

Focus Areas: In addition to addressing one or both of the specified Overarching Challenges, applications must also address at least one of the following FY14 PRARP Focus Areas in support of the specified Overarching Challenge(s). An application that proposes research outside of these 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 the common symptoms of TBI and AD. Examples of research in this focus area include:
 - Cognitive Training Interventions
 - Studies of Health and Wellness
 - Behavioral Interventions
 - Neuropsychological Interventions
- **Caregiver support:** Research intended to reduce the burden of care on the caregiver for individuals affected by the common symptoms of TBI and AD. Examples of research in this focus area include:
 - Caregiver Training
 - Home Based Support
 - Behavioral Interventions
 - Relationship Interventions

While the QUAL mechanism can be used to support clinical research, the following is specifically discouraged under the FY14 PRARP:

- **Pharmacologic Interventions:** Clinical or Basic research requiring investigational or FDA-approved drugs or medicines.
- **Drug Discovery and Development:** Clinical or Basic research directly leading to the development of investigational medicines, drugs or agents.

Use of 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 6, for additional information.

The Congressionally Directed Medical Research Programs (CDMRP) intends that 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 L. Please note that there are also additional requirements for data sharing if the proposed research or study involves the generation of TBI-related datasets:

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: The DoD requires that awardees make data generated via this award mechanism available to the TBI research community 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.

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, non-profit, 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 maximum allowable direct costs for the entire period of performance are **\$500,000** plus indirect costs.
- 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.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.4., 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.4. 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 the annual DoD PRARP In Process Review (or equivalent) meeting. Annual costs associated with travel to this meeting, up to \$2,500, should be included in the budget. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Equipment
- Research Supplies
- Research-related subject costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year 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.***

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other federal agencies will be executed through 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.4. Research & Related Budget, for additional information on budget considerations for applications involving federal agencies.

The CDMRP expects to allot approximately \$2.6M of the \$12M FY14 PRARP appropriation to fund approximately 4 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 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/>).

New for FY14: *The CDMRP has replaced its eReceipt System with eBRAP.* Submission remains a two-step process requiring both pre-application and application submission.

PIs must be registered in eBRAP in order to submit a pre-application and receive notification of the status of a pre-application or application. ***A key feature of eBRAP is that an organization's representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated to the organization in eBRAP (see eBRAP User Guide at <https://ebrap.org/eBRAP/public/UserGuide.pdf>).*** Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

Note: Submission of either the pre-application to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. ***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.*** If verification is not completed by the end of the application verification period, the application will be reviewed as submitted

through Grants.gov, provided there is no cause for administrative rejection of the application (see [Section IV.A., Rejection](#)).

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.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-14-PRARP-QUAL.

B. Pre-Application Submission and Content Form

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.

No change in PI will be allowed after the pre-application deadline. If any other changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at 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**
 - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
 - PIs must either invite or name a business official from their Business Office.
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY14 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 or 301-682-5507.

- **Required Files – Tab 4**

Notes: 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 (5-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 (See [Section 1.B., Award Information](#)).
- A description of how the research is aligned against one or both of the QUAL's Overarching Challenges (See [Section 1.B., Award Information](#)).
- A description of how the research is aligned against at least one of the QUAL Focus Areas (See [Section 1.B., Award Information](#)). Research outside of these 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. What are their merits?
- Preliminary data.

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:

- Biographical Sketch (four-page limit) and PI eligibility statement (Upload as "Biosketch.pdf"): For all PIs, include a biographical sketch (four-page limit). Biosketches will be reviewed administratively only; they will not be included in the merit-based preapplication screening.
- 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.

- **Submit Pre-Application – Tab 5**

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?
- Does the pre-application identify and align with one or both of the QUAL's Overarching Challenges?
- Does the pre-application identify and align with either of the QUAL's Focus Areas? If the research does not align with either of the QUAL Focus Areas, is the rationale clear and reasonable?
- What are the merits of the scientific hypothesis (or hypotheses) and rationale?
- Are the preliminary data supportive of the proposed hypothesis (or hypotheses) and rationale?
- Are the qualifications of the PI and key personnel appropriate?

- **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. Application Submission Content and Forms

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

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

New for FY14: Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification. The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing files (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

Note: Changes to either the Project Narrative or Budget are not allowed in eBRAP; if such changes are required, the entire application package must be submitted through Grants.gov as a "Changed/Corrected Application" with the Previous Grants.gov Tracking ID *prior to the*

application submission deadline (which occurs earlier than the end of the application verification period).

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.1, for detailed information.

2. Attachments Form

- **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 will result in administrative withdrawal of the application.

Describe the proposed project in detail using the recommended 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 any preliminary data.
- **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 including appropriate controls, in sufficient detail for analysis. **Note that pharmacologic interventions, drug discovery, and drug development 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 Food and Drug Administration [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).
- **Statistical Plan and Data Analysis (if applicable):** 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.
- **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.
- **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 may result in the removal of those items or 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 (five-document limit):** Include relevant publication URLs and/or patent abstracts. If publications are not

publicly available, then a copy/copies of the published manuscript(s) must 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 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 in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. 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.
 - 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.”

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.”

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 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.” Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Program Announcement and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Quality of Life Research Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.
- **Attachment 6: Strategy Statement (one-page limit):** Upload as “Strat.pdf.”

Address how the research or study will reduce the burden on caregivers and individuals affected by the common symptoms of both TBI and AD, especially in the military community. This statement will be evaluated as part of the peer and programmatic review processes.
- **Attachment 7: Overarching Challenges and Focus Areas Statement (one-page limit):** Upload as “OCFAS.pdf.” Describe how the proposed study is responsive to one or both of the specified QUAL Overarching Challenges (see [Section I.B., Award Information](#)). In addition, describe how the proposed study addresses at least one of the QUAL Focus Areas (see [Section I.B., Award Information](#)). An application that proposes research outside of these Focus Areas is acceptable, as long as the applicant provides a strong rationale. This statement will be evaluated as part of the peer and programmatic review processes.
- **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. This statement will be evaluated as part of the peer and programmatic review processes.

 - **Applications that includes 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.

- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.
 - PI Biographical Sketch (four-page limit): Upload as “Biosketch_LastName.pdf.”
 - PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Key Personnel Biographical Sketches (four-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.”
- 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.

D. Verification of Grants.gov Application in eBRAP

For FY14, a new process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. ***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.***

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 Data Universal Numbering System, or DUNS, number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management, or SAM, with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applicants 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 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>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure 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 of equal 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.
- **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.
- **Personnel:**
 - How the research team's background and related expertise are appropriate with respect to its ability to perform the proposed work.
 - To what degree the levels of effort are appropriate for successful conduct of the proposed work.

- **Strategy Statement:**
 - To what degree the proposed research or study shows potential for reducing the burden on caregivers and individuals affected by the common symptoms of both TBI and AD, especially in the military community.
- **Overarching Challenges and Focus Area Statement:**
 - How well the proposed study addresses the QUAL's Overarching Challenges and Focus Areas, or provides a rationale for not addressing one or more of the 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 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.
 - (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.

2. Programmatic Review: To make funding recommendations, 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 FY14 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 is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities 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 Project Narrative.
- Documents not requested will be removed.
- Following application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

C. Withdrawal

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

- A FY14 PRARP 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 FY14 PRARP PSC members can be found at <http://cdmrp.army.mil/prarp/pscs/psc14>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- 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.
- Not providing a Strategy Statement.
- Not providing an Overarching Challenges and Focus Area Statement.

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, 2015. 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 J, for general information on reporting requirements.

Quarterly technical progress reports will be required.

In addition to written progress reports, oral 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 4, 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

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

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 application package. If the 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	Action	Completed
SF-424 (R&R) Application for Federal Assistance	Complete form as instructed.	
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Strategy Statement: Upload as Attachment 6 with file name "Strat.pdf."	
	Overarching Challenges and Focus Areas Statement: Upload as Attachment 7 with file name "OCFAS.pdf."	
	Data Sharing Plan: Upload as Attachment 8 with file name "Sharing.pdf."	
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.	