Program Announcement
Department of Defense (DOD)

Defense Health Program

Defense Medical Research and Development Program

U.S. Army Medical Research and Materiel Command (USAMRMC)

Telemedicine and Advanced Technology Research Center (TATRC)

FY13 Militarily Relevant Peer Reviewed Alzheimer's Disease Research Program (MRPRA)

Quality of Life Research Award

Funding Opportunity Number: W81XWH-13-MRPRA-QUAL

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-application Submission Deadline: 23 September 2013**
- **Full Application Submission Deadline: 16 December 2013**
- **Scientific Peer Review: February 2014**
- **Programmatic Review: March 2014**

This Program Announcement 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.

Table of Contents

I. FUNDING OPPORTUNITY DESCRIPTION 3
A. Program Description 3
B. Mechanism Intent and Description 3
C. FY13 MRPRA QUAL Overarching Challenge 4
D. FY13 MRPRA QUAL Focus Areas 4
E. Award Description 4
F. Eligibility Information 5
G. Funding 5
II. SUBMISSION INFORMATION 6
A. Where to Obtain the Application Package 7
B. Pre-application (Pre-proposal) Submission Content, Form, Supporting Documentation and Screening 7
C. Full Application (Full Proposal) Submission Content and Form 8
D. Submission Dates and Times 11
E. Other Submission Requirements 11
F. Helpful Hints 12
III. REVIEW INFORMATION 12
A. Full Application Review and Selection Process 12
B. Application Review Criteria 13
C. Recipient Qualification 15
D. Application Review Dates 16
E. Notification of Application Review Results 16
IV. ADMINISTRATIVE ACTIONS 16
A. Rejection 16
B. Modification 16
C. Withdrawal 17
D. Withhold 17
V. AWARD ADMINISTRATION INFORMATION 17
A. Award Notice 17
B. Administrative and National Policy Requirements 18
C. Reporting, Presentations and Meetings 18
D. Award Transfers 18
VI. AGENCY CONTACTS 18
VII. APPLICATION SUBMISSION CHECKLIST 19

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) Militarily Relevant Peer Reviewed Alzheimer's Disease Research Program (MRPRA) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program Medical Research and Development Office by the United States Army Medical Research Acquisitions Activity (USAMRAA). The Telemedicine and Advanced Technology Research Center (TATRC) located at Fort Detrick, Maryland, is the execution agent for this Program Announcement/Funding Opportunity and USAMRAA will be the awarding agency.

Military personnel who suffer from Traumatic Brain Injuries (TBIs) 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 MRPRA is two-fold. The MRPRA seeks to: 1) build an integrated program devoted to understanding the association between TBI and Alzheimer's disease (AD); and 2) to reduce the burden on those affected by TBI-AD symptoms, especially in the military community. Therefore, the primary objective of the FY13 MRPRA is to facilitate research to characterize the nature of the association between TBI and the subsequent development of AD. A second, but equally important, objective is the development of technologies, or outcomes intended to directly benefit individuals suffering from cognitive and behavioral symptoms that result in functional impairments associated with either TBI or AD. Research falling under this second objective is intended to either increase or maintain the quality of life of those affected by these impairments. Support for these objectives is anticipated to be delivered by the research community through a combination of mechanistic, pre-clinical and pilot studies.

B. Mechanism Intent and Description

Research funded through the FY13 Quality of Life Research Award (QUAL) Program Announcement/Funding Opportunity is intended to develop best practices for in-patient and out-patient care of TBI and/or AD. Applications must include a multi-institutional team of up to 5 partners to: 1) assess the standards of care for their patients across the partners; 2) develop and measure best practices that would reduce the burden on the caregiver and patient; and 3) have a dissemination plan by which the best practices can become the elements of a new standard of care across the partners. Examples of partnering sites can be any combination of educational, non-profit, not-for-profit, and for-profit organizations, including hospitals and departments within an organization. The endpoints of the study should lead to changes in standards of care that positively affect quality of life for the patient and reduce the burden on the caregiver. The research impact is intended to benefit the military community, while meeting a public purpose for the benefit of the civilian community, particularly as it relates to the Overarching Challenge and Focus Areas listed below.

Important: Applications must detail and demonstrate expedited access to a well-defined, already identified study cohort. Preliminary data which supports how the cohort will be used in the study is

also required. The preliminary data must strongly support the proposed research hypotheses. Refer to the Review Criteria in this Program Announcement/Funding Opportunity for details.

C. FY13 QUAL Overarching Challenge

The FY13 MRPRA Research Program outlines 3 Overarching Challenges that applicants are asked to consider when writing their applications. The Overarching Challenges can be found at http://www.tatrc.org/ports_alzheimers.html. Matching with the intent and description of the FY13 QUAL Program Announcement/Funding Opportunity, applicants are required to address Overarching Challenge Number 3 (only):

> The identification and validation of clinical best practices to directly benefit individuals suffering from the symptoms of TBI or AD, while reducing caregiver burden.

Important: As part of the application submission process, an applicant must submit an "Overarching Challenges and Focus Areas" statement which describes how the application addresses this particular Overarching Challenge.

D. FY13 MRPRA QUAL Focus Areas

In addition to addressing the specified Overarching Challenge, applications should also address the following FY13 MRPRA Focus Area in support of the specified Overarching Challenge. An application which contains research outside of this Focus Area is acceptable, as long as the applicant provides a strong rationale.

1. **Quality of Life:** Technologies, tests, interventions, studies or devices that will positively impact the quality of life of those affected by the cognitive and behavioral symptoms that result in functional impairments associated with TBI and AD.

The following research is specifically discouraged under the FY13 MRPRA:

- **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.
- **Phase III Clinical Studies:** Procedures in medical research and drug development that are conducted to allow assessment of efficacy.

E. Award Description

Awards under this Program Announcement/Funding Opportunity will be in the form of assistance agreements (grants and cooperative agreements). *No fee or profit is allowable under an assistance agreement.* The supporting contracting office, USAMRAA, will negotiate and award assistance agreements against applications selected for funding. More information on these funding instruments may be obtained from the USAMRAA Website at https://www.usamraa.army.mil.

Use of Human Subjects and Human Anatomical Substances: All Department of Defense (DoD)-funded research involving new and ongoing research with human subjects and human anatomical substances 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 directives governing all research involving human subjects that is supported by the DoD. These laws and directives will require information in addition to that supplied to the IRB. Allow a minimum of 2-3 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

F. Eligibility Information

- Principal Investigators (PIs)must be independent investigators at any academic level from academia, research institutions, industry, and private foundations that possess the skills, knowledge, and resources necessary to carry out the proposed research.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations
- Cost sharing/matching is not an eligibility requirement.
- Refer to the Application Instructions, Appendix 1, for additional eligibility information.

G. Funding:

An estimated $1.45 million (M) in FY13 funds are available to fund one application submitted in response to the FY13 QUAL, depending on the quality and number of applications received. Funding is contingent upon the availability of funds for this program. The Government reserves the right to increase the estimated $1.45M available to support this program, and to also increase the number of awards made or not make any awards.

1. The maximum period of performance is 3 years.
2. The maximum amount of funding, regardless of whether or not the maximum 3 year period is proposed, is $1.45M, inclusive of all direct and indirect costs.
3. Up to 5 partners can be included. The maximum amount of funding, regardless of the number of partners proposed, is $1.45M, inclusive of all direct and indirect costs. Each partner must be included in the primary award as either a collaborator, consultant, or co-investigator, or through a subaward. Only one award will be made.
4. All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
5. The applicant must submit a comprehensive budget that details the projected funding for the entire period of performance.
6. Justification must be provided to support the requested budget. Reasonableness of the budget, including total direct and indirect costs for the proposed research is a component of the peer review evaluation process.

Refer to the Application Instructions, Section II.D.2, for budget regulations and instructions for the Research & Related Budget form. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply and are so noted in Section II.D.2 of the General Application Instructions.***

Direct costs may include, but are not limited to:

- Salary
- Equipment
- Research supplies
- Clinical research costs
- Research related subject costs
- Travel costs
  - Travel costs to attend scientific/technical meetings. Costs shall not exceed $2,500 total per budget period.
  - Travel costs associated with the execution of the proposed work. Reasonable costs for travel between collaborating organizations may be included and are not subject to the $2,500 total per budget period limitation. Travel Costs must be well justified, to include justification of the number of individuals included in travel requirements. Travel outside the U.S., including between foreign countries, requires prior approval from the Grants Officer, unless identified in the awarded budget. Prior approval of the Grants Officer must be requested 60 days before the proposed foreign travel.
  - Recipient **must** include travel costs to attend one required In Process Review (or equivalent) meeting per budget period. Costs shall not exceed $1,800 per budget period.

No fee or profit will be allowed under this Program Announcement.

II. SUBMISSION INFORMATION

Submission is a multi-step process requiring both (1) Pre-application (Pre-proposal) submission through TATRC via https://tatrc-qual.aibs.org, and (2) Full Application (Full Proposal) submission through Grants.gov (http://www.grants.gov/) **by invitation only**.

This Program Announcement/Funding Opportunity is structured for submissions from single PIs. Applicants will receive notice of the disposition of the Pre-application/Pre-proposal via email from USAMRAA and/or TATRC.

Submission of the same research project to different program announcements/funding opportunities within the same program and fiscal year is prohibited. The Government reserves the right to reject duplicative applications and will make the final determination.

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-13-MRPRA-QUAL.

B. Pre-application (Pre-proposal) Submission Content, Form, Supporting Documentation and Screening

All components must be submitted electronically through https://tatrc-qual.aibs.org by the deadline shown on the title page. The Pre-application consists of the documents and forms found at https://tatrc-qual.aibs.org.

Pre-applications should be submitted at least 72 hours before the Pre-application submission deadline to allow time to resolve any technical issues/difficulties and allow for potential re-submission prior to the Pre-application deadline.

If a change in PI or organization is necessary after submission of the Pre-application, the PI must contact the TATRC Help Desk at ProgramAnnouncements@tatrc.org.

It is *strongly* recommended that applicants use only plain text when completing the Pre-application submission to minimize the potential for technical difficulties with special characters.

Pre-application (Pre-proposal) Screening: All Pre-applications will be screened using the criteria, which are of equal value, listed below. Invitations to submit Full Applications will result from this review.

- **Intent:** How does the Pre-application meet the intent of the FY13 QUAL?
- **Research Hypotheses:** What are the merits of the proposed scientific hypotheses?
- **Scientific Rationale:** What are the merits of the scientific rationale?
- **Preliminary Data:** What are the merits of the preliminary data?
- **Applicant and Key Personnel:** How appropriate the PI and key personnel are to conduct the proposed research. Since the proposed project involves interdisciplinary teams of investigators or consortia, describe the roles of each of the investigators.
- **Estimated Budget:** Whether the estimated budget is consistent with the funding limits for awards and appears consistent with the scope of work to be performed.
- **Access to Cohort:** Is there sufficient evidence to show that the applicant has expedited access to an already identified study cohort?

- **Suitability of the Cohort:** Does the cohort selection appropriately support the proposed research hypotheses?

Notification of Pre-application Screening Results - Following the Pre-application screening, PIs will be notified of whether or not they are invited to submit Full Applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their Pre-applications. Pre-application notification dates are indicated on the title page of this Program Announcement/Funding Opportunity.

C. Full Application (Full Proposal) Submission Content and Form

PIs will be notified whether or not they are invited to submit Full Applications under this Program Announcement/Funding Opportunity. Full Applications will not be accepted unless the PI has received an invitation. PIs and organizations identified in the Full Applications submitted through Grants.gov should be the same as those identified in the Pre-applications. If there is a change in PI or organization after submission of the Pre-application, the PI must contact the submission helpdesk at: https://tatrc.aibs.org or call (703) 674-2500, ext. 207.

Important: When preparing the Full Application, review and consider the helpful hints section of this Program Announcement/Funding Opportunity found in Section II.F.

Applications should be submitted at least 72 hours before the application submission deadline to allow time to resolve any technical issues/difficulties and allow for potential re-submission prior to the application deadline.

Each Full Application submission must include the completed Application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. Note that all sections must be clearly identified with a title or header. The Application package is submitted by the Authorized Organizational Representative (AOR) through the Grants.gov portal (http://www.grants.gov/).

Grants.gov Application Package Components: The Grants.gov Application package includes the following components. (Refer to the Application Instructions, Section II.D., for additional information on Full Application submission.)

1. **SF 424 (R&R) Application for Federal Assistance Form:** Refer to Section II.D.1 of the General Application Instructions for detailed information.

2. **Research & Related Budget Form:** Refer to Section II.D.2 of the General Application Instructions for detailed information.

    - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

3. **Research & Related Project/Performance Site Location(s) Form:** Refer to Section II.D.3 of the General Application Instructions for detailed information.

4. **Research & Related Senior/Key Person Profile (Expanded) Form:** Refer to Section II.D.4 of the General Application Instructions for detailed information. The following information must be included as attachments to this form:

- PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
- PI 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 Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

5. **Research & Related Other Project Information:** Refer to Section II.D.5 of the Application Instructions for detailed information. The following information must be included as attachments to this form.

   Note: For each requested document in blocks 7-12, the applicant must provide a header identifying the PI, Institution, Type of Document (e.g. Abstract or Project Narrative) and Project Title for each page. Failure to do so may be grounds for administrative withdrawal. Each document must also start on a separate page.

   - **Project Summary/Abstract (one-page limit):** Upload as "Abstract.pdf" at Block 7. Describe the proposed research project, including the following elements:
     - Background
     - Objective/Hypothesis
     - Rationale
     - Specific Aims
     - Study Design
     - Relevance/Impact
   - **Project Narrative (25-page limit):** Upload as "ProjectNarrative.pdf" at Block 8. **The Project Narrative includes the statement of work and the body of the application – in that order. Start each section on a separate page.** Required elements of the body of the application include:
     - Background
     - Hypotheses
     - Scientific Rationale
     - Preliminary Data
     - Technical Objectives
     - Methods
     - Project Milestones
     - Military Significance
     - Public Purpose
   - Bibliography& References Cited (no page limit): Upload as "Bibliography.pdf" at Block 9.
   - Facilities & Other Resources (no page limit): Upload as "Facilities.pdf" at Block 10.
   - Equipment (no page limit): Upload as "Equipment.pdf" at Block 11.

- Representations for Assistance Agreements: Upload as “Representations.pdf” at Block 12.
- Certifications and Assurances for Assistance Agreements: Upload as “Certifications.pdf” at Block 12.
- Multimedia Objects, Photographs, Illustrations, Graphs, etc.: Upload as “Multimedia.pdf” at Block 12. **Do not include full-length publications. They will be removed and may be grounds for administrative withdrawal.**
- Acronyms and Symbol Definition: Upload as “Acronyms.pdf” at Block 12.
- Collaboration and Joint Sponsorship: Upload as “Collaboration.pdf” at Block 12.
- Intellectual and Material Property Plan: Upload as “IP.pdf” at Block 12.
- **Overarching Challenges and Focus Areas Statement (one-page limit): Upload as “OCFAS.pdf” at Block 12.** Describe how the proposed study is responsive to the specified QUAL Overarching Challenge (Section I.C). In addition, describe how the Application addresses at least one of the QUAL Focus Areas. **This statement will be scored as part of the peer and programmatic review processes.**
- **Strategy Statement (one-page limit): Upload as “Strat.pdf” at Block 12.** Describe how the proposal will develop best practices for in-patient and out-patient care of TBI and/or AD. Also, describe how the multi-institutional team of up to 5 partners to 1) assess the standards of care for their patients across the partners, 2) develop and measure best practices that would reduce the burden on the caregiver and patient, and 3) have a dissemination plan by which the best practices can become the elements of a new standard of care across the participating institutions. **This statement will be scored as part of the peer and programmatic review processes.**
- **Datasharing Plan (two-page limit): Upload as “Sharing.pdf” at Block 12.**
  <u>A robust datasharing plan is required as part of the application process.</u>
  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 scored as part of the peer and programmatic review processes.**

Important guidelines for developing the datasharing plan:

- Applicants are requested to carefully consider NIH datasharing policies in drafting their plans. Details regarding NIH datasharing policies are available at http://grants.nih.gov/grants/policy/data_sharing/.

- If an applicant's study involves the generation of TBI datasets, the applicant should describe how (s)he will use the National Institute of Neurological Disorders and Stroke TBI Common Data Elements (CDE) (see http://www.commondataelements.ninds.nih.gov). If the proposed research is not compatible with the required CDEs, the applicant should supply a justification why these measures will not be incorporated into the research.

- A plan for reporting to the Federal Interagency Traumatic Brain Injury Research (http://fitbir.nih.gov/tbi-portal/) data repository should also be described in the datasharing plan, if applicable. If the proposed study is not compatible with the database, the applicant should supply a justification for not using the database. Also, see FITBIR guidance for the inclusion of costs in the proposed budget associated with reporting to FITBIR.

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

D. Submission Dates and Times

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

E. Other Submission Requirements

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

All Full Applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have Data Universal Number System (DUNS) numbers . The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (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.

Each applicant is responsible for identifying and gaining approval to use a study population. The MRPRA will not facilitate access to any study populations. If an extramural applicant is proposing research involving access to service members, the applicant is solely responsible for establishing

collaborations with military partners to facilitate such access. If recommended for funding, the applicant will be required to submit confirmation of access to service members prior to award.

F. Helpful Hints:

When preparing the application, carefully consider:

- Ensuring that the application demonstrates technical and personnel expertise in BOTH TBI and AD research.
- Does the age range for human studies match the proposed hypotheses?
- Developing a plan on how to assess, and document the time after injury for the proposed cohort. Will the plan support the proposed hypotheses?
- Describing the post mortem interval for the study samples, if applicable.
- Detailing the definitions of TBI used for the proposed study. Consider resources such as the NINDS Common Data Elements website: (http://www.commondataelements.ninds.nih.gov/TBI.aspx#tab=Data_Standards).
- Describing the statistical plan, and assuring appropriate personnel to support the analysis of the data.
- If the application is centered on repeated trauma, describing how these injuries will be assessed, characterized and documented.

III. REVIEW INFORMATION

A. Full Application Review and Selection Process

All Full Application packages will be reviewed and evaluated using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that reviews applications against established programmatic criteria and compares applications to each other. Applications are then recommended for funding based on scientific merit, relevance to the mission of the DOD and the MRPRA, and the specific intent of the Program Announcement/Funding Opportunity. The programmatic review is performed by the MRPRA Program Steering Committee (PSC). A full list of PSC members is available at http://www.tatrc.org/ports_alzheimers.html.

All 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 Criteria

1. Peer Review: To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance. Refer to the Helpful Hints in Section II.F of this Program Announcement/Funding Opportunity for further guidance regarding how to address these criteria.

- **Study Design:**
    - The quality of the plan that demonstrates how the partners will work together to accomplish the intent of the QUAL.
    - How well the study provides evidence in support of the development of best practice for standards of care and reduction of caregiver burden.
    - How well the scientific rationale and preliminary data, including critical review and analysis of the literature, and clinical evidence support the proposed study and its feasibility and relevance.
    - The quality of the evidence that the PI has already arranged expedited access to relevant populations required for the study.
    - The quality of the plan that outlines how the cohort will be used.
    - The relevance of the cohort to the proposed research hypotheses.
    - The relevance of the cohort to support the intent of this Program Announcement/Funding Opportunity.
    - How well the aims, hypotheses, experimental design, methods, data collection procedures, and analyses are developed.
    - The theoretical or conceptual framework from which the study is premised.
    - How well the logistical aspects of the proposed study (e.g., communication plan, data transfer and management, and standardization of procedures) meet the needs of the proposed study.
    - How well the recruitment, informed consent, and screening processes for volunteers will be conducted to meet the needs of the proposed study.
    - How well the inclusion, exclusion, and randomization criteria meet the needs of the proposed study.
    - How well the PI acknowledges potential problems and addresses alternative approaches.

    - How well the application addresses the availability of volunteers for the study, the prospect of their participation, and the consideration of likelihood of volunteer attrition.
    - How well the plan for addressing unanticipated delays (e.g., slow accrual) is likely to lead to success in completing the proposed study within the performance period.
    - Evidence supporting the potential feasibility of the proposed study.
- **Statistical Plan:**
    - How well the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
    - How well the data analysis plan is consistent with the study objectives.
- **Personnel:**
    - How well the application adequately details the roles and responsibilities of the investigators serving on the interdisciplinary team or consortium.
    - How well the study team's background and expertise are appropriate to accomplish the proposed work (i.e., statistical expertise, expertise in the disease/condition, and clinical studies).
    - How well the levels of effort of the clinical team are appropriate for successful conduct of the proposed study.
- **Environment:**
    - How well the evidence indicates an appropriate scientific environment, clinical setting, and the accessibility of institutional resources to support the study at each participating center (including collaborative arrangements) to support the study.
    - The quality of the evidence for appropriate organizational-level commitment from each participating organization/institution.
- **Overarching Challenges and Focus Area Statement:**
    - How well the proposed study addresses the QUAL's Overarching Challenge and specific Focus Area. Refer to Section I.C of this Program Announcement/Funding Opportunity.
- **Strategy Statement:**
    - How well the proposed research will develop best practices for in-patient and out-patient care of TBI and/or AD. Also, describe how the multi-institutional team of investigators will 1) assess the standards of care for their patients across the partners, 2) develop best practices that would reduce the burden on the caregiver

and patient, and 3) have a plan by which the best practices can become the elements of a new standard of care across the participating institutions.

- To what degree the proposed study could make a significant impact on the FY13 MRPRA's objectives as described in the Program Description.

The following criteria will be scored as either adequate or inadequate.

- **Budget:**
  - How appropriate is the budget for the proposed research including direct and indirect and costs?
- **Datasharing Plan:**
  - The quality of the proposed plan for datasharing to include (but not limited to):
    - 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 data or resource is accessible after the award expires.
    - The appropriateness of the milestones with respect to making the data or resource available.

See Section II.C.5 for suggested datasharing guidelines.

2. Programmatic Review: To determine the application's relevance to the mission of the DOD and the MRPRA, as well as to make funding recommendations, the following criteria which are of equal importance will be used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Responsiveness to the intent of the award mechanism
- Programmatic and military relevance
- Relative impact
- Program portfolio balance

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

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 notification of the funding recommendation. PIs may request scientific peer review summary statements on the strengths and weaknesses of the Full Applications.

IV. ADMINISTRATIVE ACTIONS

After receipt of Pre-applications from the submission portal (https://tatrc-qual.aibs.org) or Full Applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the Pre-application:

- Pre-application Narrative is missing.

The following will result in rejection of the Full Application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of a Full Application for which a letter of invitation was not received.
- Documents provided in non-English language .
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Pre-application Narrative.
- Full length publications will be removed.
- Documents not requested will be removed.
- Following the application deadline, applicants may be contacted by TATRC via email with a request to provide certain missing supporting documents (excluding those listed in Section

IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the Pre-application or Full Application:

- An MRPRA Program Steering Committee (PSC) member is found to be involved in the research proposed or is found to have assisted in the Pre-application or Full Application processes including, but not limited to, concept design, Pre-Application development, Full Application development, budget preparation, and the development of any supporting document. A full list of PSC members is available at http://www.tatrc.org/ports_alzheimers.html.

- Either the Pre-application or Full Application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.

- The application does not address the FY13 MRPRA Overarching Challenge Number 3.

- Not providing headers for any of the documents requested under Section II.C.5 of this Program Announcement.

- Direct costs as shown on the Research and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.

- Inclusion of URLs with the exception of links to published references.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- Inclusion of full-length publications.

D. Withhold

Pre-applications or Full 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 Contracting/Grants Officer for a determination of the final disposition of the Pre-application or Full Application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2014. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

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

C. Reporting, Presentations and Meetings

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

D. Award Transfers

The transfer of an award to another institution is strongly discouraged. A transfer will not be allowed for any institution that includes a study site/clinical trial at its location. Approval of a transfer request from an institution that does not include a study site at its location will be at the discretion of the Grants Officer.

VI. AGENCY CONTACTS

TATRC Help Desk - Questions related to this Program Announcement/Funding Opportunity should be directed to the TATRC Help Desk, Response times may vary depending upon the volume of inquiries. Include the funding opportunity number W81XWH-13-MRPRA-QUAL in the subject line of the email.

Email: programannouncements@tatrc.org

Grants.gov Contact Center - Questions related to application submission through the 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 TATRC Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 1-800-518-4726
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. 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 – The chart below details the forms that should be submitted and their accompanying attachments:

Form	Attachment	Action
SF-424 (R&R) Application for Federal Assistance Form	**N/A**	**Enter the appropriate information in data fields**
Research & Related Budget Form	**Budget Justification for entire performance period. (no page limit; upload as "BudgetJustification.pdf")**	**Complete form as instructed. Attach Budget Justification to Section K in budget year one.**
Research & Related Project/Performance Site Location(s) Form	**N/A**	**Complete form as instructed.**
Research & Related Senior/Key Person Profile Form	**PI Biographical Sketch (4-page limit; upload as "Biosketch_LastName.pdf")**	**Attach to Biographical Sketch field**
	PI Current/Pending Support (no page limit; upload as "Support_LastName.pdf")	**Attach to Current & Pending Support field**
	Key Personnel Biographical Sketches (4-page limit; upload as "Biosketch_LastName.pdf")	**Attach to Biographical Sketch field for each senior/key person**
	Key Personnel Current/Pending Support (no page limit; upload as "Support_LastName.pdf")	**Attach to Current & Pending Support field for each senior/key person**
Research & Related Other Project Information	**Project Summary/Abstract (1-page limit; upload as "Abstract.pdf")**	**Attach to Block 7**
	Project Narrative (25-page limit; upload as "ProjectNarrative.pdf")	**Attach to Block 8**
	Bibliography and References Cited (no page limit; upload as "Bibliography.pdf")	**Attach to Block 9**
	Facilities & Other Resources (no page limit; upload as "Facilities.pdf")	**Attach to Block 10**
	Equipment (no page limit; upload as "Equipment.pdf")	**Attach to Block 11**
	Representations for Assistance Agreements (upload as Representations.pdf")	**Attach to Block 12**
	Certifications and Assurances for Assistance Agreements (upload as "Certifications.pdf")	**Attach to Block 12**
	Multimedia Objects, Photographs, Illustrations, Graphs, etc.	**Attach to Block 12**
	Acronyms and Symbol Definition	**Attach to Block 12**
	Collaboration and Joint Sponsorship	**Attach to Block 12**
	Intellectual Property (upload as "IP.pdf")	**Attach to Block 12**
	Overarching Challenges and Focus Areas Statement (1-page limit; upload as "OCFAS.pdf")	**Attach to Block 12**
	Strategy Statement (1-page limit; upload as "Strat.pdf")	**Attach to Block 12**
	Datasharing Plan (2-page limit; upload as "Sharing.pdf")	**Attach to Block 12**
R&R Subaward Budget Attachment(s) Form (if applicable)		**Complete form(s) as instructed. Attach a separate budget with justification for each subaward.**