

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Gulf War Illness Research Program

Gulf War Illness Epidemiology Research Award

Funding Opportunity Number: W81XWH-16-GWIRP- GWIERA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 15, 2016
- **Invitation to Submit an Application:** August 2016
- **Application Submission Deadline:** 11:59 p.m. ET, October 20, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, October 25, 2016
- **Peer Review:** December 2016
- **Programmatic Review:** February 2017

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

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2016 (FY16) Gulf War Illness Research Program (GWIRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The GWIRP was initiated in 2006 to provide support for research of exceptional scientific merit for studying the effects of deployment in the 1990-1991 Persian Gulf War on U.S. Warfighters. Appropriations for the GWIRP from FY06 through FY15 totaled \$109 million (M). The FY16 appropriation is \$20M.

The GWIRP challenges the scientific community to design high-impact research that will improve the health and lives of Veterans who have Gulf War illness (GWI). GWI is characterized by multiple diverse symptoms that typically include widespread pain, cognitive difficulties, debilitating fatigue, gastrointestinal problems, respiratory symptoms, chronic headache, sleep problems, and other abnormalities that are not explained by established medical diagnoses or standard laboratory tests.

The population of Veterans affected by GWI is a subset of the nearly 700,000 who served during the Gulf War. Specifically, these Gulf War Veterans were deployed to the theatre of operations in Southwest Asia, including Iraq, Kuwait, and Saudi Arabia. Studies indicate that approximately 25% to 33% (or 175,000 to 210,000) of Gulf War Veterans continue to experience symptoms associated with their deployment as described above.

The GWIRP focuses on innovative projects that have the potential to make a significant impact on finding treatments for GWI. While such projects may include identification of objective indicators of pathology that distinguish ill from healthy Gulf War Veterans or studies to understand the underlying pathobiology of GWI, projects should exhibit clear translational potential that leads to treatments for Veterans with GWI.

B. Award Information

The Gulf War Illness Epidemiology Research Award was first offered in FY15. Since then, 11 Gulf War Illness Epidemiology Research Award applications have been received, and 2 have been recommended for funding.

The purpose of this award is to support population-based research to obtain a better understanding of mortality, morbidity, and symptomatology over time in Veterans deployed in the 1990-1991 Persian Gulf War and afflicted by GWI. While individual symptoms experienced by ill Gulf War Veterans can vary from person to person, the types of symptoms reported are comparable and typically include some combination of widespread pain and headaches, fatigue, cognitive impairment, gastrointestinal symptoms, and skin abnormalities. GWI case definitions published to date may be improved through the consideration of additional epidemiological data

describing symptom onset, duration, severity, and laboratory findings. The Gulf War Illness Epidemiology Research Award supports hypothesis-driven or discovery-based research into mortality, morbidity, and symptomatology and/or how these have changed or progressed over time in the Gulf War Veteran population compared to rates and patterns of change with time in appropriate control populations.

Topic areas of interest under the Gulf War Illness Epidemiology Research Award include but are not limited to:

- Mortality (rate and causes)
- Descriptors of symptomatology (e.g., duration, frequency, severity) and changes to those associated with GWI
- Clinical diagnoses and laboratory findings
- Symptom clustering and subgrouping
- Gender and racial differences

The April 2014 report of the Research Advisory Committee on Gulf War Veterans' Illnesses (available online at <http://www.bu.edu/sph/files/2014/04/RAC2014.pdf>) notes that Gulf War Veterans exposed to nerve gas release and oil well fires have elevated rates of death due to brain cancer. However, the report also notes, "very little other research has yet been conducted to determine rates at which Gulf War Veterans have been affected by other medical conditions of possible concern, including neurological diseases such as multiple sclerosis or Parkinson's disease, other cancers, sleep disorders, adverse pregnancy outcomes or rates of birth defects in Veterans' children." Therefore, proposed projects may also address questions related to medical conditions co-occurring with GWI or those related to Gulf War Veteran offspring; however, the primary focus of the study must be epidemiological characterization of the Gulf War Veteran population.

The GWIRP intends to fund studies that address broad populations, or comparative populations that can inform one or more of the topic areas listed above. Studies that address small populations, populations associated with very limited catchment, specific military units or geographic areas of deployment, or studies addressing limited symptoms, markers, or effects must be well justified as to why the scope has been specifically limited. Revisiting previously studied cohorts to generate or extend longitudinal data is one example of a reasonable justification.

The application should include a clearly articulated statistical analysis plan including statistical expertise and a power analysis reflecting sample size projections that will clearly answer the objectives of the study. The application must also include a data management plan and use of an appropriate database to safeguard and maintain the integrity of the data. Applicants proposing to collect human anatomical substances for laboratory study are encouraged to correlate sample analyses to medical/administrative records.

Research involving human subjects is permitted under this Program Announcement/Funding Opportunity but is restricted to studies without clinical trials. A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information about distinguishing clinical trials from clinical research, a Human Subject Resource Document is provided at https://cdmrp.org/Program_Announcements_and_Forms/. Principal Investigator (PIs) interested in applying for funding for a clinical trial should use the FY16 GWIRP Treatment Evaluation Award mechanism; see <http://cdmrp.army.mil/funding/gwirp>.

Studies whose principal focus is on psychiatric disease or psychological stress as the primary cause of GWI will not be funded under this Program Announcement/Funding Opportunity.

While Gulf War Veterans are affected by amyotrophic lateral sclerosis (ALS) at twice the rate of Veterans who did not serve in the Gulf War, the GWIRP will not accept applications focusing on ALS research. However, applications that focus on GWI symptomatology may include Gulf War Veterans with ALS if the latter disorder is included in the study's GWI case definition. For those interested in pursuing ALS-focused studies, the office of the CDMRP offers a separate ALS Research Program; see <http://cdmrp.army.mil/alsrp>.

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

Use of Banked Specimens: Investigators intending to use banked specimens should include in their application a description of steps that will be taken to assess the quality of the materials received and to correct for effects and/or artifacts of sample processing and storage.

Access to Veterans of the 1990-1991 Persian Gulf War: Applicants proposing clinical research involving Gulf War Veterans are encouraged to collaborate with an investigator who has demonstrated access to Gulf War Veterans, particularly investigators within the VA. Access to a Gulf War patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be

included for studies involving active duty military, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.

GWI Case Definitions: In 2014, the Institute of Medicine (IOM) released a report titled “Chronic Multisymptom Illness in Gulf War Veterans: Case Definitions Reexamined” (available online at <http://www.iom.edu/Reports/2014/Chronic-Multisymptom-Illness-in-Gulf-War-Veterans-Case-Definitions-Reexamined.aspx>). In this report, the IOM recommends the use of both, the Centers for Disease Control and Prevention (CDC) definition of GWI and the Kansas definition for GWI. Therefore, applicants proposing clinical research may construct a definition of subgroups or symptom clusters as appropriate to the specific research; however, all cases and controls must additionally be scored and analyzed according to both the CDC and the Kansas definitions of GWI for comparative purposes. Any additional project-specific case definition must recognize the multisymptom nature of GWI.

Another resource includes the 2014 report of the Research Advisory Committee on Gulf War Veterans’ Illnesses, “Gulf War Illness and the Health of Gulf War Veterans: Research Update and Recommendations, 2009-2013,” which provides information on GWI, including case definitions and research on epidemiology, etiology, pathobiology, and treatment. This report can be found online at <http://www.bu.edu/sph/files/2014/04/RAC2014.pdf>.

Collaborative Systems Biology Facility: SysBioCube is the USAMRMC medical research big data/omics suite whose operation is directed by the U.S. Army Center for Environmental Health Research Systems Biology Collaboration Center (SBCC). SysBioCube is hosted by the National Cancer Institute/National Institutes of Health. The SysBioCube comprises military relevant medical research data repositories, data integration and analysis tools, and a networked portal that links databases to computational biology analysis tools. The SBCC facilitates systems biology collaborations among, and information sharing by, USAMRMC investigators and partnering investigators at other Army, DoD, and extramural organizations. Interested researchers should inquire at sysbiocube@mail.nih.gov.

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

C. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to apply.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Submissions from intramural (DoD)

organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. *If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.*

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

D. Funding

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$ 975,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$975,000** direct costs or using an indirect rate exceeding the organization's negotiated rate
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Clinical research costs (*no clinical trials allowed*)
- Veteran subject reimbursement and compensation
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs for up to one investigator to travel to two scientific/technical meeting(s) per year.

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

agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.

The CDMRP expects to allot approximately \$1.6M of the \$20M FY16 GWIRP appropriation to fund approximately one Gulf War Illness Epidemiology Research Award application, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

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

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

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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

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

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. *The Project Narrative and Budget cannot be changed after the application*

submission deadline. Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the [application verification period](#). After the end of the application verification period, the full application cannot be modified.

A. Where to Obtain the Grants.gov Application Package

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

B. Pre-Application Submission Content

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

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any 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.

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):

- **Tab 1 – Application Information**
- **Tab 2 – Application Contacts**
 - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
 - Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on “Add Organizations to this Pre-application.” The organization(s) must either be selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.
 - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

- Enter the name, organization, and role of all collaborators and key personnel associated with the application.
- Applicants with limited experience in research involving Veterans with GWI are strongly encouraged to include at least one collaborator having such experience from the early planning stages onward.
- [FY16 GWIRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to Panel members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

Preproposal Narrative (three-page limit): The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Research Idea:** State the population-based topic area(s) of interest or other research area directly relevant to GWI that will be addressed. State the ideas and reasoning on which the proposed work is based and why the study should be conducted, given the current state of knowledge.

- **Research Strategy:** Concisely state the project’s objectives and specific aims. If the study will use a case definition, in addition to the CDC and Kansas definitions, describe it briefly and summarize the rationale.
- **Impact:** State how the improved understanding of epidemiological patterns of illness and health obtained through the proposed research would advance our understanding of GWI, improve clinical treatment of Gulf War Veterans with GWI in the short-term or long-term, improve the definition and diagnosis of GWI, or otherwise advance the state of GWI treatment or research.
- **Personnel:** Briefly state the qualifications of the PI and expertise of key personnel to perform the described research project. Applicants with limited experience in research involving Veterans with GWI are strongly encouraged to include at least one collaborator having such experience from the early planning stages onward.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to:

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- **Key Personnel Biographical Sketches (five-page limit per individual).** *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

- This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the GWIRP, pre-applications will be screened based on the following criteria:

- **Research Idea:** Whether the proposed research addresses a population-based topic area(s) directly relevant to GWI. Whether the described research focuses specifically on Veterans with GWI and how the rationale supports the proposed research.
- **Research Strategy:** Whether the specific aims and objectives support the research idea. If applicable, the extent to which a case definition(s) in addition to the CDC or Kansas definition is appropriate to the study.

- **Impact:** Whether the proposed research will generate population-based data that will improve our understanding of GWI and make a short-term or long-term improvement in clinical treatment of Veterans with GWI, the definition and diagnosis of GWI, or otherwise advance the state of GWI treatment or research.
- **Personnel:** Whether the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research project. For PIs with little or no GWI research experience, how the PI has integrated a collaborator(s) with GWI expertise onto the research team.
- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

C. Full Application Submission Content

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

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

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

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

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

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

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

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

Grants.gov application package components: For the Gulf War Illness Epidemiology 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. SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section II.C., for detailed information.

2. Attachments Form

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (12-page limit): Upload as “ProjectNarrative.pdf.”** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below. The Project Narrative may include preliminary data relevant to GWI and the proposed project, but these data are not required to have come from GWI research. Applications not supported by preliminary data should be based on sound scientific rationale.

- **Background:** State the population-based topic area(s) of interest or other research area directly relevant to GWI that will be addressed. Present the ideas and reasoning behind the proposed work and why the study should be conducted, given the current state of knowledge. Cite relevant literature.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be achieved. Both hypothesis-driven and discovery-based studies are allowed.
- **Specific Aims:** Concisely explain the project’s specific aims to be funded by this application. If the proposed work is part of a larger study, present only tasks that this award would fund.
- **Research Strategy:** Describe the study design, methods, and analyses, including appropriate controls. If applicable, describe validation strategies

against existing datasets. Address potential problem areas and present alternative methods and approaches.

- All human subjects and controls must be scored at least according to both CDC and Kansas case definitions for GWI for the purpose of comparative analysis. If any additional case definition other than the CDC or Kansas definition is to be used, describe this definition and explain the rationale behind its inception and use. Describe any subgrouping or clustering to be used and explain the significance of each. Any additional case definition must recognize the multi-symptom nature of GWI.
 - If using psychometric measures, describe their reliability and validity.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. **Combine and upload as a single file named “Support.pdf.”** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.***
 - References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
 - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
 - Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
 - Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
 - Letters of Collaboration: 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. Applicants with little or no experience in research involving Veterans with GWI are strongly encouraged to collaborate with researchers that have GWI expertise.

- Access to Gulf War Veterans or Gulf War Veteran Biospecimens/Data (as applicable): Provide a letter showing approved access to Gulf War Veterans if proposing to access the Veteran population or use biospecimens/data from Veterans (e.g., collaborating investigators from the VA, Defense Manpower Data Center Data Request System, etc.). A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving Veterans, VA- or military-controlled study materials, and/or VA or military databases.
- Intellectual Property
 - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
 - Clearly identify all such property;
 - Identify the cost to the Federal government for use or license of such property, if applicable; or
 - Provide a statement that no property meeting this definition will be used on this project.
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, Section K for more information about the CDMRP expectations for making data and research resources publicly available.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The technical abstract is used by all reviewers. The programmatic reviewers may not have access to the full application and may 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.

Technical abstracts should be structured as follows:

- Background: State the topic area to be addressed and present the ideas and reasoning behind the proposed work.
 - Objective/Hypothesis: State the central hypothesis or objective of the project.
 - Specific Aims: State the specific aims of the study.
 - Study Design: Briefly describe the study design including the subject population, controls, subgroups and any case definition(s) in addition to the CDC and Kansas case definition to be used if important to the study purposes.
 - Impact: Briefly describe how the proposed project will have an impact on treatment for Veterans with GWI, our understanding of the natural history of GWI, and future GWI research.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.*** Minimize use of acronyms and abbreviations. The lay abstract is an important component of the application review process because it outlines issues of particular interest to the consumer advocate community.

- Clearly describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without scientific or medical backgrounds. If applicable, indicate the topic area being addressed.
 - Describe the ultimate applicability and impact of the research.
 - Describe the subject and control population being proposed.
 - Explain how this study will improve the diagnosis or care of the population of Gulf War Veterans with GWI.
 - Describe the anticipated contributions of this study to advancing our understanding of GWI.
 - Explain how this study will help inform future GWI research.
- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.”** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Gulf War Illness Epidemiology Research Award mechanism, use the SOW format example titled “SOW for Clinical Research.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

The GWIRP strongly encourages timely dissemination of the results of GWIRP-sponsored research as a product of the research program. Timely dissemination is critical to improvement of the lives of Veterans with GWI, the advancement of the field, and the continued success of the program. Therefore, SOWs submitted to the GWIRP must include at least one task or aim focused on preparation and submission of publications. This task or aim must be scheduled to commence at least 6 months prior to the end of the award's period of performance.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf.”**

Explain how the project addresses one or more of the topic areas of interest or otherwise addresses a critical problem in GWI. Describe how the anticipated outcomes of the project will improve our understanding of mortality, morbidity, and symptomatology in the population of Veterans with GWI, improve the definition and diagnosis of GWI, or otherwise advance the state of GWI treatment or research.

- **Attachment 7: Human Subjects and Statistical Plan (two-page limit): Upload as “SubjectPlan.pdf.”**

- Include a detailed plan for the recruitment of Gulf War Veterans or the acquisition of samples and/or data. Specifically demonstrate plans to access Veterans and or obtain personal data on Veterans. If applicable, describe any existing datasets to be used and how they will be gathered or accessed. Address potential problem areas and present alternative methods and approaches. If applicable, outline past recruitment strategies and successes in recruiting similar populations.
- Describe how the proposed study population is appropriate for the study objectives. Discuss potential issues regarding ethics, information privacy, and assessment of risk versus benefit of participation, and other regulatory considerations.
- Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study. Note: PIs are encouraged to include reimbursement for travel and accommodations and/or other appropriate expenses for participating Gulf War Veterans.
- Describe how the proposed sampling strategy is appropriate for the study hypotheses or objective, design, methods, and analytical/statistical plans, including evidence that the study will be appropriately powered.
- ***Inclusion of Women and Minorities in Study.*** Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the study.

- **Attachment 8: Data Management Plan (no page limit): Upload as “Data_Manage.pdf.”** The Data Management attachment should include the components listed below.
 - a. **Data Management:** Describe all methods used for data collection to include the following:
 - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
 - **Confidentiality:**
 - Explain how the privacy of human subjects and the confidentiality of study data will be protected. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
 - Address who will have access to study records, data, and specimens. Include an acknowledgment that representatives of the DoD are eligible to review study records.
 - Address requirements for reporting sensitive information to state or local authorities.
 - **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data.
 - **Sharing study results:** In cases where the human subject(s) could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.
 - b. **Laboratory Evaluations (if applicable):**
 - **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
 - **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
 - **Storage:** Describe specimen storage including location of storage, length of storage, labeling, specimen disposition, and any special conditions required. Outline the plan to store specimens for future use to include considerations

for informed consent while providing human subjects an opportunity to decline participation in the study.

- **Labs performing evaluations and special precautions:** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.
 - **Linking Samples to Other Data:** Applicants proposing to collect human anatomical substances for laboratory study are encouraged to correlate sample analyses to survey and medical/administrative records gathered or generated in the study.
 - **Attachment 9: Surveys, Questionnaires, and Other Data Collection Instruments, (if applicable, no page limit): Upload as “Surveys.pdf.”** The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments.
 - For each instrument, describe how the information collected is related to the objectives of the study
 - Describe validation of the survey instruments and how they are compatible with instruments used in past published surveys.
 - **Attachment 10: Outcomes Statement (if applicable, one-page limit): Upload as “Outcomes.pdf.”** If applicable, list all prior research projects/awards relating to GWI, including resulting publications, abstracts, patents or other tangible outcomes. Only research and outcomes directly relevant to GWI should be listed. Note: This item will be made available for programmatic review.
 - **Attachment 11: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information.
- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding

Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

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

- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf.”
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

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

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

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

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

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

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. *If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an*

updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline. The Project Narrative and Budget Form cannot be changed after the application submission deadline.

E. Submission Dates and Times

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

F. Other Submission Requirements

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

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

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and GWIRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section III.B., Programmatic Review](#).*** 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 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 hypotheses or objectives, aims, study design, methods, and analyses, are developed and integrated into the project.
 - How well developed and justified are any case definitions if proposed in addition to the required CDC and Kansas case definitions.
 - How well the application demonstrates the feasibility for successful completion of the proposed study within the specified performance period using the available resources.
 - How well the application identifies potential problems and addresses alternative approaches.
 - To what degree the data collection instruments (e.g., surveys, questionnaires), if applicable, are appropriate to the proposed study. Whether proposed data collection instruments are compatible with previous studies.
- **Impact**
 - To what extent the anticipated research outcomes will improve our understanding of mortality, morbidity, and symptomatology in the population of Veterans with GWI, and significantly impact the diagnosis or treatment of GWI or otherwise advance the state of GWI research.
- **Human Subjects and Statistical Plan**
 - How well the proposed study population(s) is described and how well it represents the population of 1990-1991 Gulf War Veterans as a whole.
 - Whether the PI has demonstrated access to the proposed Gulf War Veteran population in numbers that will support a meaningful outcome. Whether the PI has provided a letter from an appropriate authority showing approved access to Gulf War Veterans or use of data from Veterans.
 - Whether an appropriate statistical plan, including sample size projections and power analysis, is present and adequate for the study.
 - How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate contingency plans to resolve them.
 - Whether issues regarding ethics, information privacy, and assessment of risk versus benefit of participation, and other regulatory considerations, have been adequately considered.

- **Data Management Plan**
 - How well-developed and feasible is the proposed data management plan.
- **Personnel**
 - How the levels of effort are appropriate for successful conduct of the proposed work.
 - How well the PI's record of accomplishments demonstrates his/her ability to perform the proposed work.
 - How the research team's background and expertise are appropriate to accomplish the proposed work.
 - For PIs with little or no experience in GWI, whether the PI has integrated a collaborator(s) with GWI expertise into the research team.

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

- **Budget**
 - Whether the direct maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement/Funding Opportunity.
 - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.
- **Environment**
 - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
 - Whether the quality and extent of organizational support are appropriate for the proposed research.
 - If applicable, to what degree the intellectual and material property plan is appropriate.

2. **Programmatic Review:** To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:
 - a. **Ratings and evaluations of the peer reviewers**
 - b. **Relevance to the mission of the DHP and FY16 GWIRP, as evidenced by the following:**
 - Adherence to the intent of the award mechanism
 - Program portfolio composition

- Relative impact
- Outcomes from the PI's previous GWI-related research, if applicable

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.

C. Withdrawal

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

- An FY16 GWIRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY16 GWIRP Programmatic Panel members can be found at <http://cdmrp.army.mil/gwirp/panels/panels16>.*
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The invited application does not propose the same research project described in the pre-application.
- The application describes research focusing on ALS. (Exception: Applications that focus on GWI symptomatology may include Gulf War Veterans with ALS if the latter disorder is included in the study's GWI case definition.)
- The application describes research whose principal focus is on psychiatric disease or psychological stress as the primary cause of GWI.
- The PI does not meet the eligibility requirement.
- The application proposed a clinical trial

D. Withhold

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

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

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

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

B. Administrative Requirements

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

C. National Policy Requirements

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

D. Reporting

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

Quarterly technical progress reports may be required.

E. Award Transfers

Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 4, Section L, for general information on organization or PI changes.

VI. VERSION CODES AND AGENCY CONTACTS

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

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program

Announcement/Funding Opportunity version code [20160210i]. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code [20160210].

B. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

C. Grants.gov Contact Center

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

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

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Human Subject and Statistical Plan: Upload as Attachment 7 with file name "SubjectPlan.pdf."	
	8	Data Management Plan: Upload as Attachment 8 with file name "Data_Manage.pdf."	
	9	Surveys, Questionnaires, and Other Data Collection Instructions: Upload as Attachment 9 with file name "Surveys.pdf," if applicable.	
	10	Outcomes Statement: Upload as Attachment 10 with file name "Outcomes.pdf," if applicable	
	11	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 11 with file name "MFBudget.pdf," if applicable.	
Research & Related Senior/Key Personnel Profile (Expanded)		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach PI Biographical Sketch (Biosketch_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.	