

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Gulf War Illness Research Program

Patient–Provider and Health Communications Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-20-GWIRP-PPHCA

**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), May 29, 2020
- **Invitation to Submit an Application:** July 2020
- **Application Submission Deadline:** 11:59 p.m. ET, September 10, 2020
- **End of Application Verification Period:** 5:00 p.m. ET, September 15, 2020
- **Peer Review:** November 2020
- **Programmatic Review:** January 2021

This Program Announcement must be read in conjunction with the General Application Instructions, version 501. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2020 (FY20) Gulf War Illness (GWIRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement 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 effects of deployment to the 1990-1991 Persian Gulf War on U.S. Warfighters. Appropriations for the GWIRP from FY06 through FY19 totaled \$192 million (M). The FY20 appropriation is \$22M.

The proposed research must be relevant to active duty Service members, Veterans, military beneficiaries, and/or the American public.

II.A.1. The Gulf War Illness Landscape

The GWIRP has prepared an overview titled, “The Gulf War Illness Landscape,” which describes what is currently known about topics consistent with the mission of identifying treatments, improving definition and diagnosis, and understanding the pathobiology and symptoms of Gulf War Illness (GWI). *Applicants are strongly encouraged to read and consider The Gulf War Illness Landscape before preparing their applications.* The Landscape may be found at https://cdmrp.army.mil/gwirp/pdfs/GWIRP_Landscape_2020.pdf

II.A.2. FY20 GWIRP Overarching Challenges

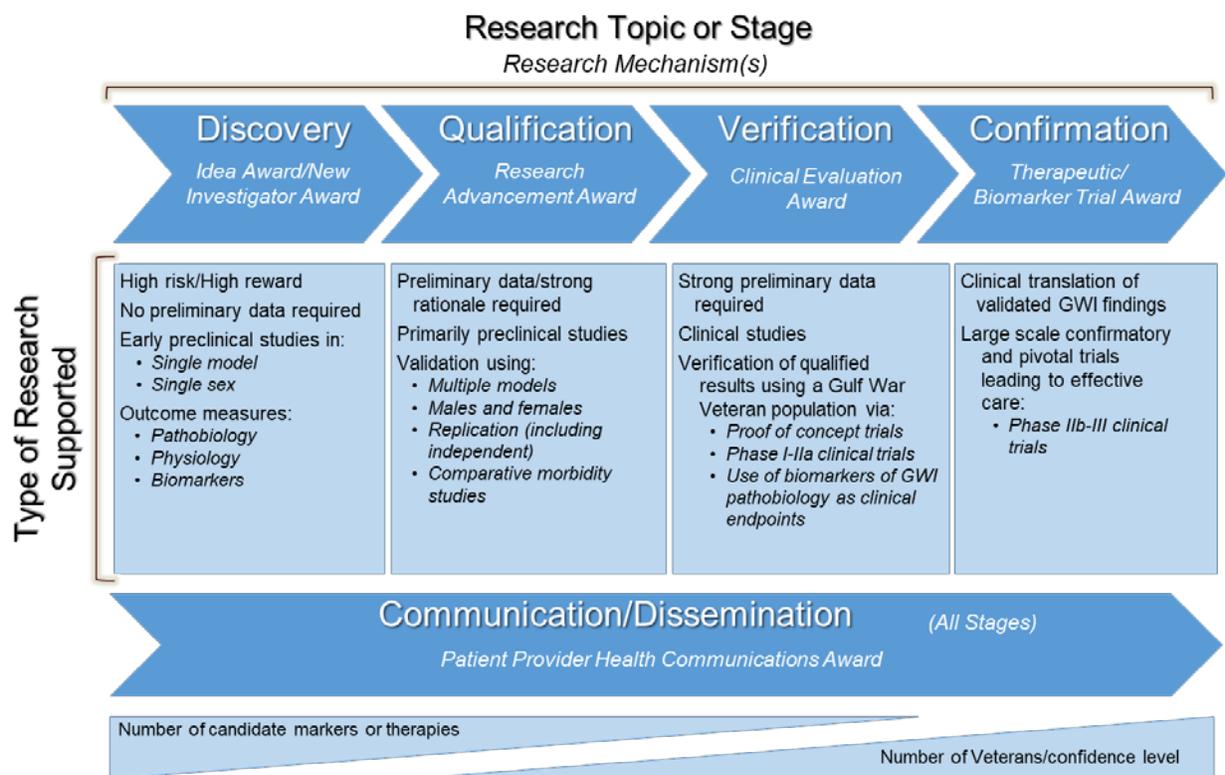
Considering The Gulf War Illness Landscape and the GWIRP’s mission, all FY20 GWIRP applications must address at least one of the following overarching challenges unless adequate justification for exception is provided.*

- **Treatments:** Eliminate the health consequences associated with GWI and revolutionize treatment
- **Diagnosis:** Better define and diagnose GWI
- **Subtyping:** Distinguish symptom clusters to better target treatments, identify underlying causes, and elucidate differences in severity
- **Determinants:** Validate exposures associated with GWI and impacts on organs and systems

- **Consequences:** Determine whether GWI is associated with greater risk for developing other disease states including neurological diseases, cancers, or other life-threatening and severely debilitating conditions
- **Communication:** Help Veterans, their caregivers, researchers and health care providers communicate effectively about GWI, its symptoms, and potential treatments

*With adequate justification, applications may identify and address another overarching challenge related to The Gulf War Illness Landscape. Justification must be provided in the application.

To address the overarching challenges in a step-wise and translational manner, the FY20 GWIRP award mechanisms are aligned to the different phases of the research pipeline illustrated below.



The **Discovery** phase represents innovative biomarker or treatment research that is in the earliest stages of development. Applicants seeking support for research aligning to the Discovery phase should consider the **FY20 GWIRP Idea Award** (Funding Opportunity Number: W81XWH-20-GWIRP-IA).

The **Qualification** phase represents preclinical research already supported by preliminary or published data in the GWI field that is ready for validation through expansion, replication, or comparative studies. Applicants seeking support for the Qualification phase should consider the **FY20 GWIRP Research Advancement Award** (Funding Opportunity Number: W81XWH-20-GWIRP-RAA).

The **Verification** phase represents clinical translation of concepts previously validated through expansion, replication, or comparative studies. Examples of projects in the Verification phase include large-scale biomarker research/biomarker trials or Phase I through IIa intervention trials. Applicants seeking support for the Verification phase should consider the **FY20 GWIRP Clinical Evaluation Award** (Funding Opportunity Number: W81XWH-20-GWIRP-CEA).

The **Confirmation** phase represents large-scale confirmatory and pivotal trials that will transform and revolutionize the clinical management of GWI. Sufficiently powered Phase IIb through Phase III clinical trials of previously piloted interventions will be supported. Objective biomarkers to measure the biological effect of an intervention or predictive/cohort-selective biomarkers that indicate whether a specific therapy will be effective in an individual Gulf War Veteran or Gulf War Veteran subgroup are required. Applicants seeking support for the **Confirmation** phase should consider the **FY20 GWIRP Therapeutic/Biomarker Trial Award** (Funding Opportunity Number: W81XWH-20-GWIRP-TBTA).

The development and maintenance of **strategies to effectively communicate GWI research and clinical recommendations** to Gulf War Veterans, their caregivers, and their healthcare providers, with the goal of informing and raising awareness, shall be considered at each phase of the research pipeline. Applicants seeking support for effective communication strategies should consider the **FY20 GWIRP Patient–Provider and Health Communications Award** (Funding Opportunity Number: W81XWH-20-GWIRP-PPHCA).

NOTE: The scope of research proposed in applications in response to the FY20 GWIRP Program Announcements must align with the research phases outlined above. It is the responsibility of the applicant to select the level that aligns with the scope of the proposed research. The funding mechanism should be selected based on the research scope defined in the Program Announcement, and not on the amount of the budget. Applications submitted under a mechanism that is not deemed appropriate for the scope of research proposed will not be funded.

II.A.3. Award History

The GWIRP Patient–Provider and Health Communications Award mechanism was first offered in FY19. Since then, two Patient–Provider and Health Communications Award applications have been received, and one has been recommended for funding.

II.B. Award Information

The FY20 GWIRP Patient–Provider and Health Communications Award supports projects aimed at tools and processes to raise awareness of GWI research and clinical findings within communities, including Veterans with GWI and/or their caregivers or advocates, healthcare providers who serve Veterans with GWI, and/or public health professionals relevant to Veterans with GWI. Strategies developed under this funding opportunity should consider GWI findings at any phase of the research pipeline.

Impact: Activities supported by the Patient–Provider and Health Communications Award will have potential for major impact on quality of life for Veterans with GWI by increasing

awareness, understanding, and education of current evidence-based GWI research in diverse audiences. The impact should be near-term and demonstrate strong potential to help Veterans, caregivers, or clinicians communicate effectively about GWI, potential treatments, and disease management.

Gulf War Veteran Involvement: Applications are required to include involvement of at least one Gulf War Veteran with GWI. This individual(s) will be integral throughout the planning and implementation of the research project. The Gulf War Veteran(s) should be involved in the development of the research idea, project design, oversight, and evaluation to help ensure a substantial positive impact on Gulf War Veterans with GWI. Interactions between the Veteran(s) and other team members should be thoroughly integrated into the project and ongoing, not limited to attending seminars or semi-annual meetings. A Gulf War Veteran's role in the project should be independent of their employment, i.e., they cannot be employees of any of the organizations participating in the application. They may, however, receive compensation as consultants or collaborators. A Gulf War Veteran's role should be focused on providing objective input on the communication strategy or other project deliverables and the potential for substantive impact on individuals with GWI. The Gulf War Veteran(s) should have a high level of knowledge and understanding of GWI symptoms and the scope of GWI's impact on Veterans with GWI, (2) current GWI issues including clinical care challenges, and (3) existing GWI research to be able to successfully contribute to the project.

Communication and Dissemination Strategies: This award will support development of health communication strategies including media, technical and organizational platforms, and/or other venues that will disseminate current research findings contributing to a state-of-the-science understanding of GWI. The strategies should encourage adoption of new evidence-based approaches to understanding, managing, and treating GWI; refute professional, personal, or institutional stigmas or barriers associated with GWI; or otherwise generate interest in becoming and staying well-informed regarding GWI. Applications should address the following components:

- Identification of one or more of the following GWI community groups as the target audience and identification of the information gaps and needs of that target audience: (1) Veterans with GWI, (2) healthcare providers who serve Veterans with GWI, (3) public health professionals relevant to Veterans with GWI, and/or (4) caregivers of Veterans with GWI.
- An effective and viable communication strategy aimed at informing and engaging the target audience(s). The strategy should demonstrate consideration of optimal media, technical and organizational platforms, and venues to achieve maximal effectiveness in the target audience(s). When the target audience includes health professionals, the plan must include well-rationalized approaches for engagement and participation.
- A process for evaluating and ranking GWI research or clinical information prior to its inclusion in the dissemination process. Approaches for the continuous accrual of evidence-based research findings or healthcare information should be considered.
- A system of ongoing assessments employing metrics to gauge the effectiveness of the communication tool within the GWI community. For example, scoring of pre- and post-

intervention knowledge; measurements of changes in practice of clinicians, patients, or caregivers. Mechanisms that enable improvement through community feedback are encouraged.

- Evidence of processes, partnerships, organizations, or agreements as necessary for the maintenance and sustainment of the established process, tool, or material beyond the end of the award period.

Examples of Information Resources: Advocacy groups and researchers have created tools for the dissemination of information for specific medical disorders. Examples are cited below. *This list does not address the full scope of needs of the GWI Veteran community nor does it constitute an endorsement of a particular strategy.* The proposed strategy should be driven by the considerations described in the outline above.

- **ALS Untangled** (<http://www.alsuntangled.com/>): Amyotrophic lateral sclerosis (ALS) patients recommend, through social media and other online mechanisms, off-the-shelf or media-hyped treatments in need of scientific/clinical review. Reviews are performed by a body of ALS experts/clinicians, and treatments are scored and posted for patient consideration.
- **BrainMetsBC.org** (<https://www.brainmetsbc.org/>): Online resource that provides information about brain metastases. The website includes updates on current research, treatments, and clinical trials, as well as personal experiences written by patients.
- **BreastCancerTrials.org** (www.breastcancertrials.org/BCTIncludes/index.html): Online resource that educates patients about breast cancer clinical trials and matches them with appropriate trials.
- **ImPACT Online** (<https://psychology.psy.msu.edu/autismlab/impactonline>): A web-based, distance-learning program that teaches parents to support their child's social communication development using a novel blend of evidence-based intervention techniques.

Activities not supported under this Program Announcement include:

- Studies focusing on psychiatric disease or psychological stress as the primary cause of GWI or implementation of care guidelines placing significant emphasis on psychiatric pathologies or psychiatric remedies.
- Applications focusing on amyotrophic lateral sclerosis (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 CDMRP offers funding opportunities through the ALS Research Program (see <https://cdmrp.army.mil/alsrp>).
- Clinical trials. *A clinical trial is defined* as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Investigators interested in clinical trials should consider applying

under the FY20 GWIRP Clinical Evaluation Award or Therapeutic/Biomarker Trial Award (Funding Opportunity Numbers: W81XWH-20-GWIRP-CEA and W81XWH-20-GWIRP-TBTA, respectively). For information about these award mechanisms, see <https://cdmrp.army.mil/funding/gwirp>.

The anticipated direct costs budgeted for the entire period of performance for an FY20 GWIRP Patient–Provider and Health Communications Award will not exceed **\$600,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2021. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The CDMRP expects to allot approximately \$960,000 to fund approximately one Patient–Provider and Health Communications Award application. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY20 funding opportunity will be funded with FY20 funds, which will expire for use on September 30, 2026.

The types of awards made under the Program Announcement will be assistance agreements. An assistance agreement is appropriate when the Federal Government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the Department of Defense (DoD) during project performance is the key factor in determining whether to award a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All 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 Development Command (USAMRDC) 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. *Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.* Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research

Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information. If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

GWV Case Definitions: In 2014 the Institute of Medicine (IOM) (now called National Academy of Medicine) released a report, “Chronic Multisymptom Illness in Gulf War Veterans: Case Definitions Reexamined” (available online at <https://www.nap.edu/catalog/18623/chronic-multisymptom-illness-in-gulf-war-veterans-case-definitions-reexamined>). In this report, the IOM recommended the use of both the U.S. Centers for Disease Control and Prevention’s (CDC) definition of GWV and the “Kansas” definition of GWV. 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 GWV, including case definitions and research on epidemiology, etiology, pathobiology, and treatment. This report can be found online at <https://www.va.gov/RAC-GWVI/RACReport2014Final.pdf>.

Common Data Elements for Clinical Research: Through a collaboration of the National Institutes of Health (NIH), CDC, VA, DoD GWVIRP, and the GWV community, Common Data Element (CDE) recommendations are being developed for GWV. The goals of this effort are to increase the efficiency and effectiveness of clinical research studies and treatment, increase data quality, facilitate data sharing and aggregation of information across studies, and help educate new clinical investigators. In early 2018, members from the GWV community participated in a CDE development working group to prepare standard template case report forms and instrument recommendations for clinical research studies. The version 1.0 recommendations were posted on the GWVIRP website (<https://cdmvp.army.mil/gwvvp/default>) in January 2019. **The GWVIRP strongly encourages all applicants, particularly the clinical research community, to read and consider the CDEs when preparing applications.** Use of CDEs is expected to expedite study start-up, standardize data collection, and allow for future data sharing. It should be noted that the development of CDEs is an iterative process. Updates will be made to the GWV CDEs as research progresses and feedback is received from the community.

Use of DoD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

Recruitment of Veterans: Applicants intending to recruit Veterans for clinical studies are encouraged to leverage existing cohorts recruited in other GWVIRP-supported studies and should refer to the GWVIRP Supported Initiatives on the GWVIRP website. Applicants recruiting Veterans are also highly encouraged to consider the outreach and recruitment best practices described

online at [https://cdmrp.army.mil/gwirp/pdfs/General%20 Guidance for Gulf War Veteran Outreach and Recruitment.pdf](https://cdmrp.army.mil/gwirp/pdfs/General%20Guidance%20for%20Gulf%20War%20Veteran%20Outreach%20and%20Recruitment.pdf).

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.

Government Agencies Within the United States: Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this Program Announcement may be submitted by extramural and intramural organizations, these terms are defined below.

Extramural Organization: An eligible non-DoD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, Federal Government organization other than the DoD, and research institutes.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center. ***Intramural Submission: Application submitted by a DoD organization for an intramural investigator working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.***

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Independent investigators at or above the level of Assistant Professor may be named by the organization as the PI on the application.

There are no limitations on the number of applications for which an investigator may be named as a PI.

An eligible Principal Investigator (PI), regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <https://orcid.org/>.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

II.D. Application and 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).

Extramural Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

Intramural DoD Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org

Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov through a research foundation.

II.D.1. Address to Request Application Package

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.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

II.D.2. Content and Form of the Application Submission

Submission is a two-step process requiring both *pre-application* (eBRAP.org) and *full application* (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application

submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to [Table 1. Full Application Guidelines](#)).

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate 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 submission deadline.

II.D.2.a. Step 1: Pre-Application Submission Content

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

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

The applicant organization and associated PI 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 applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

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**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://ebrap.org/eBRAP/public/Program.htm>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **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 Research & Related Form). The Business Official must be either 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 Research & Related Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either 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.

[FY20 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 II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **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:

- Briefly state how the proposed research addresses the FY20 GWIRP Overarching Challenge of communication and how the study will effectively disseminate information about GWI, its symptoms, and potential treatments.
- Briefly describe the proposed evidence-based communication strategy to be developed and the intended target audience. Also, include considerations for how GWI information will be accrued and assessed for validity prior to distribution and an evaluation process to measure the impact on the GWI community.
 - Briefly state how Gulf War Veteran(s) will be integrated into the planning, design, implementation, and evaluation of the communication/dissemination strategy.
 - Describe the feasibility of sustaining the communication/dissemination plan beyond the end of the award.
- **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 the following:
 - 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, reference title, and reference source, including 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:

- To what degree the pre-application addresses the FY20 GWIRP Overarching Challenge of communication and how well how the study will effectively disseminate information about GWI, its symptoms, and potential treatments.

- How well development of the proposed evidence-based communication strategy is summarized and its suitability for the intended target audience. To what degree the proposed strategy includes considerations for how GWI information will be accrued, assessed for validity, and evaluated to measure the impact on the GWI community.
 - To what degree Gulf War Veterans are integrated into the planning, design, implementation, and evaluation of the communication/dissemination strategy.
 - To what degree the sustainment plan for the communication/dissemination tool demonstrates feasibility.
- **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 in [Section I, Overview of the Funding Opportunity](#). Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

II.D.2.b. Step 2: Full Application Submission Content

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

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 full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://www.grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the *same version* of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further

information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Do not password protect any files of the application package, including the Project Narrative.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
<p>Download application package components for W81XWH-20-GWIRP-PPHCA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.</p>	<p>Download application package components for W81XWH-20-GWIRP-PPHCA from eBRAP (https://ebrap.org).</p>
Full Application Package Components	
<p>SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.</p>	<p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form (if applicable) 	<p>Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>

Extramural Submissions	Intramural DoD Submissions
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package at least 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p>Note: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget 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 <i>prior to</i> the application submission deadline. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>
<u>Application Verification Period</u>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i> Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>

Extramural Submissions	Intramural DoD Submissions
Further Information	
<p>Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

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

II.D.2.b.ii. Full Application Submission Components

- **Extramural Applications Only**

SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full application package may not exceed 200 MB. *It is important to include the attachment name as a header on each page of the attachment files.*

- **Attachment 1: Project Narrative (15-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) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Describe the ideas and reasoning on which the proposed work is based. Clearly demonstrate a comprehensive understanding of critical barriers and gaps in GWI health information knowledge and communication to be addressed in the project. Explain why these particular obstacles comprise significant impediments to effective health care for Veterans with GWI.
- **Specific Aims:** Concisely explain the project's specific aims to be funded by this award. If the proposed research project is part of a larger study, present only tasks that this GWIRP award would fund.
- **Project Design:**
 - Clearly describe one or more of the following groups as the target audience(s): Veterans with GWI and/or their caregivers or advocates, healthcare providers who serve Veterans with GWI, and/or public health professionals relevant to Veterans with GWI.
 - Explain the types of information that will be communicated and how the information addresses critical gaps or barriers in knowledge, beliefs, and attitudes in the target audience(s).
 - Describe the communication strategy. Explain the proposed media, technical and organizational platforms, and venues and present evidence and/or rationale explaining why these approaches are expected to be effective for the intended audience. If the dissemination effort involves healthcare professionals, describe the plan for engaging and motivating participation.
 - Detail integration into the project of one or more Veterans with GWI who has a high level of knowledge and understanding of (1) GWI symptoms and the scope of GWI's impact on Veterans with GWI, (2) current GWI issues including clinical care challenges, and (3) existing GWI research to be able to successfully contribute to the project.
 - Describe the accrual of new information or review and selection of existing GWI information, products, or published results that will be used to create content.
 - Describe evaluation metrics and tracking to assist in measuring the success of the communication tool. Evaluation metrics should assess the effect of the tool within the GWI community, e.g., how effective the dissemination strategies/platforms are at increasing awareness of GWI, changing existing misconceptions of GWI, or increasing understanding and education of current evidence-based research of GWI. If applicable, describe how the evaluation mechanism enables improvement through community feedback.

- Briefly describe sustainability of the process beyond the end of the award period. A full description of sustainability should be provided in [Attachment 7, Sustainment Plan](#).
- Address potential problem areas and present alternative methods and approaches.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative 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 articles 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, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work including, but not limited to:

- Availability of, and access to, the appropriate subject population(s).
 - Gulf War Veteran Letter(s) of Commitment: Provide a letter signed by each Gulf War Veteran confirming his/her commitment to participate on the research team.
 - 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.
- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
 - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
 - 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 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
 - Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.
 - Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **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 reviewer. 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: Describe the types of information intended for dissemination and the intended audiences for the various types of information.
 - Objective/Hypothesis: State the objective to be reached/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
 - Specific Aims: State the specific aims of the study.
 - Project Design: Describe the communications strategies, media, technology and organizational platforms, and the approaches to be used. Identify why the approach proposed is the most effective strategy or technology for engaging and informing the target audience segments.
 - Implementation and Sustainment: Outline general plans for implementation of the chosen strategies. Outline potential organizational plans for accruing, curating, and disseminating new information. Identify and describe partner organizations that will sustain the platform after the end of the award period of performance.
 - Impact: Describe the potential impact of the proposed dissemination tool or strategy on patient care and/or quality of life of Veterans of the 1990-1991 Gulf War with GWI.
- **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 addresses issues of particular interest to the consumer advocate community.

- Rationale: Describe the rationale for the proposed project in a manner that will be readily understood by readers without scientific or medical backgrounds.
- Timeline: Describe the projected timeline for achieving the desired outcome.
- Contributions: Describe the likely contributions of the proposed research project to quality of GWI patient care and/or quality of life of Veterans with GWI

- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested Statement of Work (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 Patient–Provider Health Communication Award mechanism, use the SOW format example titled, “SOW Generic Format.” The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.** Describe the short-term impact of this project on Gulf War Veteran care and/or quality of life. Include a description of how this strategy will serve as an educational tool for Veterans with GWI and/or their caregivers or advocates, healthcare providers who serve Veterans with GWI, and/or public health professionals relevant to Veterans with GWI.
- **Attachment 7: Sustainment Plan (three-page limit): Upload as “Sustainment.pdf.”** Outline potential resources and plans for long-term sustained operations and improvements:
 - Describe processes, partnerships, or agreements for obtaining support for maintenance and sustainment of the dissemination effort beyond the award period of performance. Provide a signed letter demonstrating sustained commitment by the organization or foundation.
 - Provide plans for sustainable operations including continual accrual and curation of evidence-based healthcare information for Veterans with GWI and research findings contributing to a state-of-the-science understanding of GWI. Demonstrate continued metrics for gauging community impact.
- **Attachment 8: Outcomes Statement (if applicable, one-page limit): Upload as “Outcomes.pdf.”** If applicable, list all of the PI’s 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. Attachment 8 will be available for programmatic review only.

- **Attachment 9: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 10: Suggested Collaborating DoD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical 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 a separate budget, using “Suggested Collaborating DoD Military Facility Budget Format,” 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 & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, 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 National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- **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”.

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.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.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DoD Collaborator(s):** Complete the “Suggested Collaborating DoD Military Facility Budget Format” and upload to Grants.gov attachment form as [Attachment 10](#). (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all sub-recipient 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. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that

determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through December 2020, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

For Both Extramural and Intramural Applicants: eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific Program Announcement requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

Intramural DoD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business

Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

The maximum period of performance is **3** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$600,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$600,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

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

- Communication platform and infrastructure costs
- Research and healthcare data evaluation and tracking costs
- Travel in support of multidisciplinary collaborations
- Costs for two investigators to travel to two scientific/technical meetings per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY20 GWIRP Patient–Provider and Health Communications Award.

Must not be requested for:

- Clinical trial costs

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, 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 the General Application Instructions, Section III.A.5.***

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following **scored criteria**, which are of equal importance:

- **Impact**
 - To what extent the proposed project describes the short-term impact on Gulf War Veteran care and/or quality of life.
 - How well the proposed strategy will serve as an educational tool for Veterans with GWI and/or their caregivers or advocates, healthcare providers, and/or public health professionals relevant to Veterans with GWI.
- **Project Design**
 - To what extent the application demonstrates a comprehensive understanding of critical barriers and gaps in GWI health information knowledge and communication and how they impact health care for Veterans with GWI.
 - Whether the target audience(s) is described and to what extent the proposed communication strategy is appropriate for the target audience(s).
 - How well the types of information to be communicated are described and how well the information addresses critical gaps or barriers in knowledge, beliefs, and attitudes in the target audience(s).
 - How well the communication strategy including the proposed media, technical and organizational platforms, and venues is described. How well the evidence and/or rationale explaining why these approaches are expected to be effective for the intended audience are presented. If the dissemination effort involves healthcare professionals, how well the plan for engaging and motivating participation is described.
 - How well accrual of new information or review and selection of existing GWI information, products, or published results are described.
 - How well the application describes evaluation metrics and tracking to assist in measuring the success of the communication tool. If applicable, how well the evaluation mechanism enables improvement through community feedback.

- Whether potential problem areas and alternative methods and approaches are present and addressed.
- **Sustainment Plan**
 - To what extent the application describes processes, partnerships, or agreements for obtaining support for maintenance and sustainment of the dissemination effort beyond the award period. Whether a signed letter demonstrating sustained commitment by the organization or foundation is provided.
 - Whether plans for sustainable operations including continual accrual and curation of evidence-based healthcare information for Veterans with GWI and research findings contributing to a state-of-the-science understanding of GWI are provided. How well continued metrics for gauging community impact are incorporated into the sustainment plan.
- **Personnel**
 - How well one or more Veteran with GWI who has a high level of knowledge and understanding of (1) GWI symptoms and the scope of GWI's impact on Veterans with GWI, (2) current GWI issues including clinical care challenges, and (3) existing GWI research is integrated into the project.
 - Whether the levels of effort by the PI and other key personnel are appropriate to ensure success of the project.
 - How well the PI's record of accomplishment demonstrates his/her ability to perform the proposed work.
 - How appropriate the PI and research team's background and expertise are with regard to their ability to accomplish the proposed work.

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

- **Environment**
 - To what extent the scientific environment is appropriate for the proposed research project.
 - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
 - To what extent the quality and level of institutional support are appropriate for the proposed research project.
 - If applicable, to what degree the intellectual and material property plan is appropriate.

- **Budget**
 - Whether the **direct** costs exceed the allowable direct costs as published in the Program Announcement.
 - 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.

II.E.1.b. 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:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY20 GWIRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relative impact
 - Relative outcomes from the PI's previous GWI-related research (if applicable)

II.E.2. 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**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC, on behalf of the DHA and the OASD(HA). ***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 II.E.1.b, Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the GWIRP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring 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 and approval 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 and approval 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 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

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.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY20 funds are anticipated to be made no later than September 30, 2026. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

Pre-Award Costs: An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the Government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.B.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. **The award document signed by the Grants Officer is the official authorizing document.**

Federal Government Organizations: Funding made to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

II.F.1.a. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

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 2, Section B, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

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

Refer to full text of the latest [DoD R&D General Terms and Conditions](#); the [General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. *If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.*

Annual progress reports as well as a final progress report will be required. The Award Terms and Conditions will specify if more frequent reporting is required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template “Award Expiration Transition Plan,” available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) under the “Progress Report Formats” section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission 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

II.G.2. Grants.gov Contact Center

Questions related to extramural 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 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.

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 501d. The Program Announcement numeric version code will match the General Application Instructions version code 501.

II.H.2. Administrative Actions

After receipt of pre-applications or applications, the following administrative actions may occur:

II.H.2.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.

II.H.2.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.

II.H.2.c. Withdrawal

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

- An FY20 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 FY20 GWIRP Programmatic Panel members can be found at <https://cdmrp.army.mil/gwirp/panels/panels20>.*
- The application fails to conform to this Program Announcement description.
- 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 FY20, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The invited application proposes a different research project than that described in the pre-application.
- The application describes research focusing on ALS.
- The application describes research whose principal focus is on psychiatric disease or psychological stress as the primary cause of GWI.
- A clinical trial is proposed.

- The PI does not meet the eligibility criteria.
- One or more Gulf War Veterans with GWI are not included on the research team as required by this Program Announcement.

II.H.2.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.

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance (extramural submissions only)	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) (intramural submissions only)	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Sustainment Plan: Upload as Attachment 7 with file name "Sustainment.pdf"	
	Outcomes Statement: Upload as Attachment 8 with file name "Outcomes.pdf" if applicable	
	Representations (extramural submissions only): Upload as Attachment 9 with file name "RequiredReps.pdf" if applicable	
	Suggested Collaborating DoD Military Facility Budget Format: Upload as Attachment 10 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

Application Components	Action	Completed
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget (extramural submissions only)	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget (intramural submissions only)	Suggested DoD Military Budget Format, including justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ALS	Amyotrophic Lateral Sclerosis
CDC	Centers for Disease Control and Prevention
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FY	Fiscal Year
GWI	Gulf War Illness
GWIRP	Gulf War Illness Research Program
HRPO	Human Research Protection Office
IOM	Institute of Medicine (now known as the National Academy of Medicine)
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs