

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

Research Advancement Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-21-GWIRP-RAA

**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 7, 2021
- **Invitation to Submit an Application:** June 2021
- **Application Submission Deadline:** 11:59 p.m. ET, August 19, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, August 24, 2021
- **Peer Review:** October 2021
- **Programmatic Review:** December 2021

This program announcement must be read in conjunction with the General Application Instructions, version 601. 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 2021 (FY21) Gulf War Illness Research Program (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 FY20 totaled \$214 million (M). The FY21 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 can be found at https://cdmrp.army.mil/gwirp/pdfs/GWIRP_Landscape_2020.pdf.

II.A.2. FY21 GWIRP Overarching Challenges

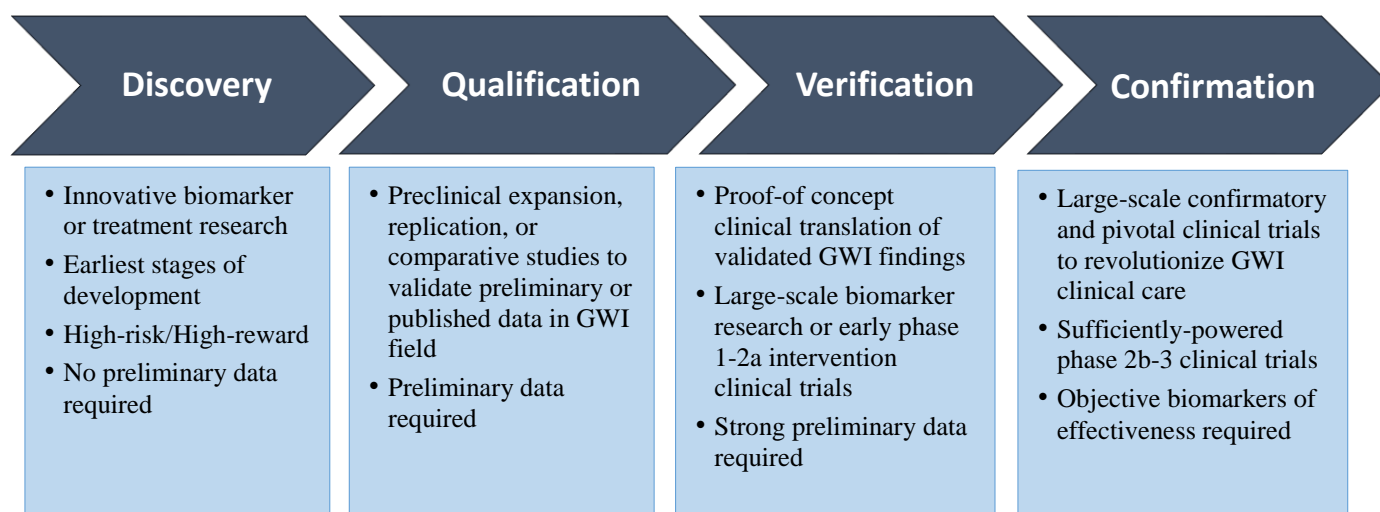
Considering The Gulf War Illness Landscape and the GWIRP’s mission, all FY21 GWIRP applications must address at least one of the following overarching challenges unless adequate justification for exception is provided.*

- **Treatments:** Eliminate the health consequences associated with GWI and/or revolutionize treatment
- **Diagnosis:** Better define and diagnose GWI
- **Subtyping:** Distinguish subtypes to better target treatments, monitor therapy, identify severity of GWI, or to identify why GWI is worse for some Veterans than for others
- **Determinants:** Identify and validate determinants of GWI, including latency and impacts on organs and systems

- **Consequences:** Determine whether GWI alters risk for developing neurological conditions, cancers, or other serious conditions; or whether GWI alters outcomes of other infections/diseases
- **Communicate & Educate:** Help Veterans, their caregivers, and clinicians 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 FY21 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 **FY21 GWIRP Idea Award** (funding opportunity number W81XWH-21-GWIRP-IA) or the **FY21 New Investigator Award** (funding opportunity number W81XWH-21-GWIRP-NIA).

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 **FY21 GWIRP Research Advancement Award** (funding opportunity number W81XWH-21-GWIRP-RAA) or the **FY21 New Investigator Award** (funding opportunity number W81XWH-21-GWIRP-NIA).

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 trials or phase 1 through 2a intervention trials. Applicants seeking support for the Verification phase should consider the **FY21 GWIRP Clinical Evaluation Award** (funding opportunity number W81XWH-21-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 2b through phase 3 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 **FY21 GWIRP Therapeutic/Biomarker Trial Award** (funding opportunity number W81XWH-21-GWIRP-TBTA).

NOTE: The scope of research proposed in applications in response to the FY21 GWIRP program announcements must align with the research phases outlined above. It is the responsibility of the applicant to select the award mechanism 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 Research Advancement Award mechanism was first offered in FY19. Since then, 28 Research Advancement Award applications have been received, and 14 have been recommended for funding.

II.B. Award Information

The FY21 GWIRP Research Advancement Award supports applied research in GWI that is aimed at continued expansion and validation of markers and treatments that are supported by evidence in the GWI field. **The Research Advancement Award targets the Qualification phase of the research pipeline as outlined in [Section II.A.2.](#)**

Preliminary Data: Inclusion of preliminary data in the field of GWI and other supporting information is required. The project should include a well-formulated, testable hypothesis based on existing evidence in the GWI field that holds translational potential.

Impact: Applications must articulate how results will lead to a clinical impact for Veterans with GWI even if a clinical impact is not an immediate outcome. All applications must focus on features of GWI and Veterans of the 1990-1991 Gulf War affected by GWI. The application should clearly and explicitly articulate the project's potential impact on GWI.

The types of activities supported include 1) expansion of limited data on candidate markers, mechanistic targets, therapeutics, or other interventions; 2) replication of druggable mechanistic targets, further development of leading compounds, or the collection of preclinical data for repurposing an existing approved drug or for new Investigational New Drug (IND) application submissions to the U.S. Food and Drug Administration (FDA). Applicants proposing to test FDA-approved drugs in animal models for efficacy must explain why preclinical testing is required prior to clinical pilot trials in humans.

FY21 GWIRP Research Advancement Award Areas of Emphasis: The FY21 GWIRP Research Advancement Award has a special interest in the exploration of the topics listed below. Applicants are not restricted to this list and may propose studies in any other GWI research area relevant to the mission of the GWIRP and in the context of the [FY21 GWIRP Overarching Challenges](#).

- Replication and/or validation of treatments for GWI, particularly areas that already show positive impact on the disease
- Expeditiously advancing and translating new and promising areas of GWI understanding
- Replication and/or validation of the causes of and treatment targets for dysregulated biological system function. Emphasis should be placed on:
 - Cognitive difficulties to include memory deficits, mood and behavior disturbances
 - Non-restorative sleep or sleep disturbances
 - Chronic widespread pain
 - Chronic debilitating fatigue
 - Gastrointestinal (GI) effects including dietary intolerances, gastroesophageal reflux disease (GERD), and functional GI disorders (FGIDs)
 - Sinus and respiratory effects
 - Headaches
 - Dermatological issues
 - Neurological dysfunction (central, peripheral, autonomic, and/or neuromuscular)
 - Immune system dysfunction
 - Endocrine, exocrine, and/or excretory system dysfunction, with special attention to kidney and liver (e.g., cytochrome P450 abnormalities)
 - Microbiome variants
 - The impact of stressors (e.g., exertion, immune challenge) on the severity and duration of the symptoms
 - Disordered system crosstalk (e.g., immunological dysfunction that alters the nervous system, autonomic dysfunction that impacts functioning of the GI tract) that contributes to malfunction in several physiological systems

- Identification of molecular signatures (e.g., genomic, proteomic, metabolic, and epigenetic) underlying symptoms and the grouping of symptom sets based on common underlying pathobiology
- Investigation of comorbidities, mortality, sex, or ethnic differences
- Investigation of whether GWI alters outcomes of other infections/diseases
- Treatments and biomarkers for specific GWI subtypes

Biorepository Contribution Option: In FY17, the GWIRP awarded infrastructure support for a GWI Biorepository. The Boston Biorepository, Recruitment, and Integrative Network (BBRAIN) for GWI has now been established for the retention and distribution of Gulf War Veteran biospecimens and/or data related to GWI research. Applicants to the FY21 GWIRP are encouraged to contribute Gulf War Veteran biospecimens and data to this repository network. The FY21 GWIRP Research Advancement Award offers a nested Biorepository Contribution Option with higher levels of funding for qualified applications as described in [Section II.D.5, Funding Restrictions](#). See [Attachment 10, Biorepository Contribution Statement](#) for additional submission requirements. For additional details about BBRAIN, refer to the section below titled, [Access to Data and/or Previously Collected Biospecimens from Veterans of the 1990-1991 Gulf War](#).

Activities not supported under this program announcement include:

- Investigations involving derivation of GWI diagnostic biomarkers from animal models.
- Trials of FDA-approved drugs in animals if there exists sufficient evidence or rationale to support clinical trials in humans instead.
- Studies focusing on psychiatric disease or psychological stress as the primary cause of GWI.
- 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 Amyotrophic Lateral Sclerosis 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 FY21 GWIRP Clinical Evaluation Award or Therapeutic/Biomarker Trial Award (funding opportunity number W81XWH-21-GWIRP-CEA and W81XWH-21-GWIRP-TBTA, respectively). For information about these award mechanisms, see <https://cdmrp.army.mil/funding/gwirp>.

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.

The anticipated direct costs budgeted for the entire period of performance for an FY21 GWIRP Research Advancement Award will not exceed **\$600,000**. If applying under the Biorepository Contribution Option, direct costs will not exceed **\$620,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The CDMRP expects to allot approximately \$1.92M to fund approximately two Research Advancement Award applications. 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 FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.

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.

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 or VA 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 GWIRP-supported studies and should refer to the GWIRP Supported Initiatives on the GWIRP 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).

Access to Data and/or Previously Collected Biospecimens from Veterans of the 1990-1991 Gulf War: The following repositories may contain 1990-1991 Gulf War Veteran data and/or specimens for various research topics related to GWI. *If the research project proposed in the application includes the use of banked specimens, the application should include a description of steps that will be taken to assess the quality of the materials received and to identify and correct for effects and/or artifacts of sample processing and storage.* Researchers are not required to use any of the following limited examples or any one particular dataset.

- BBRAIN for GWI. Funded by the FY17 GWIRP, the BBRAIN has been established at the Boston University School of Public Health. The BBRAIN provides a centralized cataloging and coordination of retrospective and prospective Gulf War Veteran biospecimens and data from institutions conducting GWI research. Applicants interested in collaborating with this network should refer to the GWIRP Supported Initiatives on the GWIRP website (<https://cdmrp.army.mil/gwirp/default>).
- Defense Manpower Data Center (DMDC; <https://www.dmdc.osd.mil>) maintains the largest archive of personnel data in the DOD. DMDC does not participate in distribution of data with non-U.S. government entities. Investigators must partner with a DOD or VA entity to request DMDC data. Once a relationship is established, the institution's network must be DOD-accredited or have other federal equivalent accreditation (DOD Information Assurance Certification [DIACAP] or Federal Information Security Management Act [FISMA]) to release the requested sensitive information from the federal entity to the institution.
- DOD Serum Repository (formerly, Armed Forces Serum Repository; <https://www.health.mil/Military-Health-Topics/Combat-Support/Armed-Forces-Health-Surveillance-Branch/Data-Management-and-Technical-Support/Department-of-Defense-Serum-Repository>). This repository contains Gulf War-era and other specimens and releases de-identified data and specimens to approved DOD investigators. Access requires an appropriate collaboration; requesters of data or analyses must be military Service Members

or government employees working for U.S. military organizations. A fee is charged for specimens.

- MAVERIC Core Laboratory (Massachusetts Veterans Epidemiology Research and Information Center; <http://maveric.org>). One of four MAVERIC components, the Core Laboratory is a fully equipped, state-of-the-art biological specimen collection and processing center holding over 50,000 specimens, including samples from an estimated 1,500 Gulf War Veterans and an equivalent number of specimens from their spouses. Access to samples requires consent and approval from the VA Central Office.
- Millennium Cohort Study (<https://millenniumcohort.org/>). Initiated in 2001, the Millennium Cohort Study is ongoing and comprises a collection of epidemiological data on Service Members. Access requires collaboration with one of the Millennium Cohort Study investigators and approval of the Millennium Cohort Study oversight committee by way of a preproposal/proposal process.
- VA Gulf War Veterans' Illnesses Biorepository (GWVIB) and the VA Biorepository Brain Bank (VABBB) (https://www.research.va.gov/programs/tissue_banking/gwvib/ and https://www.research.va.gov/programs/tissue_banking/als/, respectively) contain biomaterial and clinical data from Gulf War Veterans. The GWVIB was initiated in 2012, but to date contains little material; however, the VABBB contains a more substantial collection of material from Gulf War Veterans, with and without GWI, particularly from Veterans with ALS (also known as Lou Gehrig's disease). Researchers must submit a request to obtain access to specimens and data from this collection.
- The Million Veteran Program (MVP; <https://www.research.va.gov/MVP/default.cfm>). The MVP is a national, voluntary research program funded by the VA Office of Research & Development. MVP is building one of the world's largest medical databases to study how genes affect health by safely collecting blood samples and health information from one million Veteran volunteers receiving their care in the VA Healthcare System. The MVP has enrolled over 550,000 Veterans, including Veterans from the Gulf War era. Researchers must submit a request to obtain access to specimens and data from this collection.
- VA Gulf War Era Cohort and Biorepository (GWECEB), CSP#585. <https://www.research.va.gov/programs/csp/585/repository.cfm>. This dataset and biorepository was developed by the VA to learn about the health conditions and related factors among 1990-1991 Gulf War Veterans through research studies. Over 1,200 Veterans have been enrolled in the cohort and biorepository. Resources are available to VA and non-VA investigators through the Cooperative Studies Program Epidemiology Center (CSPEC)-Durham Data and Specimen Repository. Investigators may submit data requests to the CSPEC-Durham Data and Specimen Repository for research under an IRB-approved protocol. Interested investigators are encouraged to contact the repository coordinators to arrange a consultation prior to IRB review. Data use agreements and/or materials transfer agreements may be required.

GWI Case Definitions for Clinical Research: 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 <http://www.nationalacademies.org/hmd/Reports/2014/Chronic-Multisymptom-Illness-in-Gulf-War-Veterans-Case-Definitions-Reexamined.aspx>). In this report, the IOM recommended the use of both the U.S. Centers for Disease Control and Prevention’s (CDC) definition of GWI and the “Kansas” definition of GWI. 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 for clinical investigations 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 <https://www.va.gov/RAC-GWVI/RACReport2014Final.pdf>.

Common Data Elements (CDEs) for Clinical Research: Through a collaboration between the National Institutes of Health (NIH), CDC, VA, DOD GWIRP, and the GWI community, CDE recommendations are being developed for GWI. 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 GWI 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 GWIRP website at <https://cdmrp.army.mil/gwirp/default> in January 2019. **The GWIRP strongly encourages applicants in the clinical research community, whether or not collaborating with the Gulf War Illness Clinical Trials and Interventions Consortium (GWICTIC), to read and consider the CDEs, which are used by GWICTIC, when preparing applications.** Use of CDEs is expected to expedite study start-up, standardize data collection, and allow for future data sharing. CDEs will be required in clinical research going forward and must be considered by investigators submitting samples to the BBRAIN under the Biorepository Contribution Option. It should be noted that the development of CDEs is an iterative process. Updates will be made to the GWI CDEs as research progresses and feedback is received from the community.

Research Involving Animals: All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

Animal Models: Studies that characterize chronic effects of neurotoxic exposures at dosages comparable to those encountered in-theater during the Gulf War and/or shed light on treatment targets are of interest. Such studies using animal models should focus on long-term and latent effects of toxic exposures to closely represent the current status of GWI patients. All studies using animal models should use an established model unless there is a compelling scientific justification for the development or use of a new model. Development of new animal models is

discouraged. A list of GWIRP funded animal models are available on the GWIRP website at <https://cdmrp.army.mil/gwirp/resources/amodels>.

Rigor of Experimental Design: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit [Attachment 7, Animal Research Plan](#), as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at <https://journals.plos.org/plosone/article/file?type=supplementary&id=info:doi/10.1371/journal.pone.0146533.s001>.

Other policies and resources that should be consulted to enhance reproducibility include:

- “**Enhancing Reproducibility through Rigor and Transparency**” policy, developed by NIH, to clarify expectations for grantees and reviewers in describing or assessing proposed studies in applications and progress reports, announced in 2015 and implemented in 2016. For more information, see <https://grants.nih.gov/policy/reproducibility/index.htm>.
- **BEST (Biomarkers, EndpointS, and other Tools) Resource** is an online glossary developed by a FDA and NIH joint committee to clarify terms used in translational science and medical product development, with a focus on study endpoints and biomarkers. For information, see <https://www.ncbi.nlm.nih.gov/books/NBK326791/>.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and 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 any academic level (or equivalent) 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 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.

When starting the pre-application, PIs should ensure that they have selected the appropriate application category:

- Research Advancement Award (RAA)
- Research Advancement Award - Biorepository Contribution Option (RAA-BCO)

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.

[FY21 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.
 - State which [FY21 GWIRP Overarching Challenge\(s\)](#), or other overarching challenge, the proposed research will address. If “other,” state the overarching challenge and provide justification within the context of [The Gulf War Illness Landscape](#).
 - Briefly describe how the scope of the proposed research is appropriate for the Qualification phase of the research pipeline. If applicable, state the [FY21 GWIRP Research Advancement Award Area of Emphasis](#) that will be addressed.
 - State the hypothesis and clearly outline the aims/approach to test the hypothesis
 - Describe how the results will lead to a clinical impact for Veterans with GWI even if a clinical impact is not an immediate outcome.
- **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:

- Whether the pre-application addresses at least one of the [FY21 GWIRP Overarching Challenges](#). If a topic outside of the FY21 GWIRP Overarching Challenges is addressed, to what degree the pre-application provides adequate justification within the context of [The Gulf War Illness Landscape](#).
 - To what degree the scope of the proposed research is appropriate for the Qualification phase of the research pipeline. If applicable, how well the proposed research addresses one of the [FY21 GWIRP Research Advancement Award Areas of Emphasis](#).
 - Whether a hypothesis is clearly stated and the extent to which the aims/approach will test the hypothesis.
 - Whether the results of the proposed research will lead to a clinical impact for Veterans with GWI even if a clinical impact is not an immediate outcome.
- **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 | |
| Download application package components for W81XWH-21-GWIRP-RAA 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. | Download application package components for W81XWH-21-GWIRP-RAA from eBRAP (https://ebrap.org/). |

| Extramural Submissions | Intramural DOD Submissions |
|--|--|
| Full Application Package Components | |
| SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information. | Tab 1 – Summary: Provide a summary of the application information. Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative. |
| <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 | 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: <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites 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. |

| 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 prior to 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.

- **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) 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.

Outline for Project Narrative: Describe the proposed project in detail using the outline below.

- **Background:** Describe how the research proposed is appropriate for the Qualification phase of the research pipeline. The PI must clearly demonstrate continued translatability of research to treatment and/or healthcare delivery for 1990-1991 Gulf War Veterans with GWI. Provide preliminary data in the GWI field. Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project. Describe plans to address weaknesses in the rigor of the prior research.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project's specific aims to be funded by this award. If the proposed work is part of a larger study, present only tasks that this award would fund.
- **Research Strategy and Feasibility:**
 - Describe the experimental design, methods, and analyses (including appropriate controls) in sufficient detail for scientific evaluation to include an assessment of overall project feasibility.
 - Describe the established GWI model that will be used and why it is the most appropriate model to support qualification or replication of established concepts.
 - Describe an assessment of endpoints. Applicants should consider endpoints across a variety of domains (molecular, physiological, pain/fatigue, cognition/memory, etc.) as appropriate to the study.
 - Address potential problem areas and present alternative methods and approaches.
 - If applicable, describe how data will support a regulatory filing with the FDA.
 - For applications proposing biomarker research, present a rationale for why the proposed biomarkers would be specific for Gulf War-related exposures and/or have diagnostic potential for GWI.
- **Human Specimens and/or Human Subjects Research (if applicable):**
 - For studies involving the use of banked human specimens, include a detailed plan for the acquisition of samples and/or data. Describe procedures to be used to assess the quality of the materials and identify and correct for effects and/or artifacts of sample processing and storage.
 - For studies involving Gulf War Veterans, include a detailed plan for recruitment. Include a power analysis to demonstrate that the sample size is appropriate to

meet the objectives of the study. Include how data will be handled, criteria for inclusion and exclusion of data, how outliers will be defined and handled, and statistical methods for data analysis.

- For studies involving Gulf War Veterans, both the CDC and Kansas definitions must be used. Describe and justify any additional case definition of GWI, including any targeted illness subgroups that will be defined for the study.
 - For studies involving human subjects, describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects.
 - Describe how the use of GWI CDEs will be incorporated into the collection of clinical data and annotation of clinical samples.
 - Describe how the level of risk to human subjects is minimized and how subject safety is monitored, and measures taken to protect the privacy of human subjects and maintain confidentiality of study data.
- **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. 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.
- 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.
- Inclusion Plan (if applicable): For studies involving human subjects, provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is

a one-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.

- **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:

- Overarching Challenge(s): State the [FY21 GWIRP Overarching Challenge\(s\)](#) that will be addressed or, with adequate justification, another identified overarching challenge related to [The Gulf War Illness Landscape](#).
- Background: Present the scientific rationale behind the proposed work. Demonstrate direct relevance of the project to Veterans of the 1990-1991 Gulf War with GWI. If the application addresses one or more of the [FY21 GWIRP Research Award Areas of Emphasis](#), indicate the area(s) addressed.
- Objective/Hypothesis: State the objective to be reached/hypothesis to be tested. Provide preliminary data in the field of GWI that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design including appropriate controls.
- Impact: Summarize briefly how the proposed project will have an impact on GWI research and/or Veterans with GWI by moving diagnostic or therapeutic concepts closer to clinical application.
- **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.

- Overarching Challenge(s): State the [FY21 GWIRP Overarching Challenge\(s\)](#) that will be addressed or, with adequate justification, another identified overarching challenge related to [The Gulf War Illness Landscape](#).
- Objective and Rationale: 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.
- Applicability: Describe the ultimate applicability of the research.
 - How will this research move diagnostic or therapeutic concepts closer to clinical application?
 - What are the potential clinical applications, benefits, and risks for Veterans with GWI?
 - What is the projected time it may take to achieve a patient-related outcome?
- **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>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the Research Advancement Award, refer to either the “*Suggested SOW Strategy Clinical Research*” or “*Suggested SOW Strategy Generic Research*”, whichever format is most appropriate for the proposed effort, and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.** Summarize how the project addresses one or more of the [FY21 GWIRP Overarching Challenges](#). If the project addresses another overarching challenge, state the overarching challenge and provide justification within the context of [The Gulf War Illness Landscape](#). Explain how the project addresses one or more of the [FY21 GWIRP Research Advancement Award Areas of Emphasis](#) or another critical research area in GWI. Describe how the anticipated outcomes of the project will move diagnostic or therapeutic concepts supported by prior findings closer to clinical application. Describe how the project has the potential to lead to improved health or quality of life for Veterans with GWI in the short and/or long term.
- **Attachment 7: Animal Research Plan (if applicable; three-page limit): Upload as “Animal.pdf”.** If the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as

the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

- Briefly describe the research objective(s) of the animal study.
 - Explain how the animal model of GWI is most appropriate for supporting the research strategy.
 - Summarize the procedures to be conducted. Describe how the study will be controlled.
 - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
 - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
 - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
 - Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
 - Applicants proposing to test FDA-approved drugs in animal models for efficacy must explain why such preclinical testing would be required prior to pilot clinical trials directly in humans.
- **Attachment 8: Use of Hazardous Chemical or Biological Agents (if applicable; no page limit): Upload as “Hazardous.pdf”.** The applicant must submit a plan for acquiring, using, and maintaining hazardous agents if such agents are to be used in the study. The plan must contain all applicable information such as CDC registration, an approved organizational safety plan to use the agent(s), and letters of collaboration, agreement, or approval from government sites issuing any agent(s). Indicate if agents used are purchased commercially, and if so, confirm that the amount is under regulated limits. Include a statement addressing this requirement along with accompanying letters of collaboration, approvals, and certifications.
 - **Attachment 9: 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 9 will be available for programmatic review only.

- **Attachment 10: Biorepository Contribution Statement** (*required for applications submitted under the Biorepository Contribution Option*) (**two-page limit**): **Upload as “BioContribute.pdf”**. If the applicant is not applying to the Biorepository Contribution Option, leave Attachment 10 blank.

Describe the types of datasets and/or Gulf War Veteran biospecimens to be contributed to the BBRAIN, giving the approximate number of each. Provide a detailed accounting of proposed costs (per-sample basis as well as in aggregate). Describe any special preparation required and the facilities and technical capabilities necessary for collection, storage, and transfer of data and/or specimens. Contributing sites must adhere to the standard operating procedures (SOPs), quality assurance measures, and annotation standards for clinical and pathological specimens and data established by the BBRAIN members. Clearly explain how the applicant plans to coordinate with the BBRAIN and provide a plan for resolving any intellectual and material property issues related to contribution of samples and/or data. State whether clinical data will be associated with samples or research datasets and, if applicable, describe how patient data confidentiality will be maintained in compliance with federal and state regulations. Contributing sites must ensure IRB approval and informed consent to share samples and data.

- **Attachment 11: Data and Research Resources Sharing Plan (one-page limit): Upload as “SharingPlan.pdf.”** Describe how data and resources generated during the performance of the project will be shared with the research community. Describe whether the proposed plan for data sharing includes databases most relevant to GWI and whether the plan describes organizational and technical capabilities sufficient to share project data in a timely manner. Refer to the General Application Instructions, Appendix 2, Section K, for more information about CDMRP expectations for making data and research resources publicly available. Include plans for making raw data publicly available in appropriate databases at the time of publication or at the time of conclusion of the funding. The government reserves the right to identify repositories for submission of data for archive. Any costs associated with submission will be addressed during award negotiations.
- **Attachment 12: 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 13: 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 1681(a) 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 NIH 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”.

For extramural submissions, refer to the General Application Instructions, Section III.A.4 for detailed information.

For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

- 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 13](#). (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 April 2022, 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.

Application submissions to the FY21 GWIRP Research Advancement Award with the Biorepository Contribution Option: If applying under the Biorepository Contribution Option, applicants may include additional direct costs up to **\$20,000** associated with the contribution of samples and data to the BBRAIN.

- In this case, the anticipated direct costs budgeted for the entire period of performance will not exceed **\$620,000**. 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 **\$620,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.
- An application submitted under the Biorepository Contribution Option that does not meet the criteria specified for the Biorepository Contribution Option may be funded at the lower maximum direct cost of **\$600,000** as described above for the standard Research Advancement Award.

All direct and indirect costs of any subaward or contract 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 (not all-inclusive) be requested for:

- Veteran subject reimbursement and compensation including:
 - Transportation
 - Lodging
 - Participation incentives
- Travel in support of multidisciplinary collaborations
- Travel costs for one investigator to travel to one scientific/technical meeting per year to present project outcomes or disseminate projects results

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 degree the proposed research is responsive to one or more of the [FY21 GWIRP Overarching Challenges](#) or, with adequate justification, another identified overarching challenge related to [The Gulf War Illness Landscape](#).
 - To what extent the project will make an important contribution to one or more of the [FY21 GWIRP Research Advancement Award Areas of Emphasis](#) or another critical research area in GWI.
 - To what degree the anticipated outcomes of the proposed research will move diagnostic or therapeutic concepts supported by prior findings closer to clinical application.
 - To what extent the proposed project has the potential to lead to improved health or quality of life for Veterans with GWI in the short and/or long term.

- **Research Strategy and Feasibility**

- To what extent the research proposed is appropriate for the Qualification phase of the research pipeline and demonstrates continued translatability of research to treatment and/or healthcare delivery for 1990-1991 Gulf War Veterans with GWI.
- How well the preliminary data in the field of GWI support the hypothesis or objective to be reached.
- Whether the application includes plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project.
- How well the experimental design, methods, and analyses (including appropriate controls) are described and enable assessment of project feasibility.
- Whether an established GWI model is described. Whether the model description explains why it is the most appropriate model to support qualification or replication of established concepts.
- Whether the proposed project describes an assessment of endpoints.
- How well the application addresses potential problem areas and presents alternative methods and approaches.
- If applicable, to what degree the proposed project describes how the data will support a regulatory filing with the FDA.
- If proposing to test FDA-approved drugs in animal models for efficacy, whether the proposed project explains why preclinical testing is required prior to pilot clinical trials directly in humans.
- For applications proposing biomarker research, how well the application presents a rationale for why the proposed biomarkers would be specific for Gulf War-related exposures and/or have diagnostic potential for GWI.
- For studies involving hazardous agents, whether the application includes an appropriate plan for acquiring, using, and maintaining the hazardous agents.
- To what extent the data and resources generated during the performance of the project will be shared with the research community.
- ***For human specimens and/or human subjects research (if applicable):***
 - How well the application demonstrates that the PI will have access to specimens or a suitable 1990-1991 Gulf War Veteran population. For studies involving the use of banked specimens, how clearly the application describes the procedures used to assess the quality of the materials and to identify and correct for effects and/or artifacts of sample processing and storage.

- The extent to which the plan for the recruitment of subjects or the acquisition of samples and/or data is feasible and well developed.
- If applicable, to what degree the GWI CDEs are incorporated into the collection of clinical data and annotation of clinical samples.
- Whether the application describes use of the CDC and Kansas case definitions. If the application proposes use of a case definition in addition to the CDC and Kansas case definitions, how well that case definition is described and justified.
- For studies involving human subjects, to what extent the strategies for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

○ ***For applications submitted to the Biorepository Contribution Option:***

The Biorepository Contribution Statement will be evaluated for applications submitted under the Biorepository Contribution Option.

- How well the types of datasets and/or biospecimens to be contributed to the BBRAIN are described.
- To what extent the application describes any special preparation, facilities and/or technical capabilities necessary for collection, storage, and transfer of data and specimens to BBRAIN.
- How well technical capabilities necessary for collection, storage, and transfer of data and/or Gulf War Veteran specimens to BBRAIN are described.
- Whether plans for adherence to the SOPs, quality assurance measures, and annotation standards for clinical and pathological specimens and data established by the BBRAIN members are adequately detailed.
- How well the application describes plans to coordinate with the BBRAIN for the resolution of any intellectual and material property issues related to contribution of samples and/or data.
- How well the application addresses the informed consent processes and how patient data confidentiality will be maintained in compliance with federal and state regulations, if applicable.

• **Statistical and Data Analysis Plan**

○ ***For animal research:***

- Whether the study provides a sample size estimate for each study arm and the method by which it was derived.

- How well the study describes data handling including criteria for inclusion and exclusion of data, how outliers will be defined and handled, and the statistical methods for data analysis.
- ***For human specimens and/or human subjects research (if applicable):***
 - Adequacy of the power analysis and how well descriptions of data handling and inclusion/exclusion are presented.
 - How well statistical methods for analysis are described, including how outliers will be defined and handled.
- **Personnel**
 - To what degree 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 their 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:

- **Budget**
 - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
 - The degree to which the budget is appropriate for the proposed research.
 - If applicable, the extent the proposed costs for contribution of samples and/or data to BBRAIN are appropriate.
- **Ethical Considerations (for human subjects research)**
 - To what extent the proposed project addresses how the level of risk to human subjects will be minimized, how subject safety will be monitored, and what measures will be taken to protect the privacy of human subjects and maintain confidentiality of study data.
- **Environment**
 - To what extent the scientific environment is appropriate for the proposed research.
 - 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.
- **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 FY21 GWIRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relative impact and innovation
 - Relative outcomes from the PI's previous GWI-related research (if applicable)
 - Program portfolio composition with consideration of the [FY21 GWIRP Research Advancement Award Areas of Emphasis](#) or other GWI research area in the context of the [FY21 GWIRP Overarching Challenges](#).

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 FY21 funds are anticipated to be made no later than September 30, 2022. 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.A.5.

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 [USAMRAA 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.

Inclusion Enrollment Reporting Requirement (*required only for research studies involving human subjects*): Enrollment on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final technical report. The suggested Inclusion Enrollment Report format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP.

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 601a. The program announcement numeric version code will match the General Application Instructions version code 601.

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 FY21 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 FY21 GWIRP Programmatic Panel members can be found at <https://cdmrp.army.mil/gwirp/panels/panels21>.*
- 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 FY21, 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.

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" | |
| | Animal Research Plan: Upload as Attachment 7 with file name "Animal.pdf" if applicable | |
| | Use of Hazardous Chemical or Biological Agents: Upload as Attachment 8 with file name "Hazardous.pdf" if applicable | |
| | Outcomes Statement: Upload as Attachment 9 with file name "Outcomes.pdf" if applicable | |
| | Biorepository Contribution Statement: Upload as Attachment 10 with file name "BioContribute.pdf" if applicable | |
| | Data and Research Resources Sharing Plan: Upload as Attachment 11 with file name "SharingPlan.pdf" | |
| | Representations (extramural submissions only): Upload as Attachment 12 with file name "RequiredReps.pdf" if applicable | |
| | Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 13 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 |
| ACURO | Animal Care and Use Review Office |
| ALS | Amyotrophic Lateral Sclerosis |
| ARRIVE | Animal Research: Reporting <i>In Vivo</i> Experiments |
| BBRAIN | Boston Biorepository, Recruitment, and Integrative Network |
| CDC | Centers for Disease Control and Prevention |
| CDE | Common Data Element |
| CDMRP | Congressionally Directed Medical Research Programs |
| CFR | Code of Federal Regulations |
| CSPEC | Cooperative Studies Program Epidemiology Center |
| DHA | Defense Health Agency |
| DHP | Defense Health Program |
| DIACAP | DOD Information Assurance Certification |
| DMDC | Defense Manpower Data Center |
| DOD | Department of Defense |
| DODGARs | Department of Defense Grant and Agreement Regulations |
| DODSR | DOD Serum Repository (formerly, Armed Forces Serum Repository) |
| DUNS | Data Universal Numbering System |
| eBRAP | Electronic Biomedical Research Application Portal |
| EC | Ethics Committee |
| ET | Eastern Time |
| FAD | Funding Authorization Document |
| FAPIS | Federal Awardee Performance and Integrity Information System |
| FDA | U.S. Food and Drug Administration |
| FGID | Functional Gastrointestinal Disorder |
| FY | Fiscal Year |
| GERD | Gastroesophageal Reflux Disease |
| GI | Gastrointestinal |
| GWECB | Gulf War Era Cohort and Biorepository |
| GWI | Gulf War Illness |
| GWIRP | Gulf War Illness Research Program |
| GWICTIC | Gulf War Illness Clinical Trials and Interventions Consortium |
| GWVIB | Gulf War Veterans' Illnesses Biorepository |
| HRPO | Human Research Protection Office |
| IACUC | Institutional Animal Care and Use Committee |
| IND | Investigational New Drug |
| IOM | Institute of Medicine (now, National Academy of Medicine) |
| IRB | Institutional Review Board |
| M | Million |
| MAVERIC | Massachusetts Veterans Epidemiology Research and Information Center |
| MIPR | Military Interdepartmental Purchase Request |

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| MVP | Million Veteran Program |
| NIH | National Institutes of Health |
| 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 |
| SBCC | Systems Biology Collaboration Center |
| SOPs | Standard Operating Procedures |
| 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 |
| USAMRDC | U.S. Army Medical Research and Development Command |
| USC | United States Code |
| VA | Department of Veterans Affairs |
| VABBB | VA Biorepository Brain Bank |