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
Biorepository Resource Network Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-17-GWIRP-BRNA

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), June 30, 2017
- Invitation to Submit an Application: August 2017
- Application Submission Deadline: 11:59 p.m. ET, September 28, 2017
- End of Application Verification Period: 5:00 p.m. ET, October 3, 2017
- Peer Review: November 2017
- Programmatic Review: January 2018
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. OVERVIEW OF THE FUNDING OPPORTUNITY</td>
<td>1</td>
</tr>
<tr>
<td>II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY</td>
<td>3</td>
</tr>
<tr>
<td>II.A. Program Description</td>
<td>3</td>
</tr>
<tr>
<td>II.A.1. The Gulf War Illness Landscape</td>
<td>3</td>
</tr>
<tr>
<td>II.B. Award Information</td>
<td>3</td>
</tr>
<tr>
<td>II.C. Eligibility Information</td>
<td>10</td>
</tr>
<tr>
<td>II.C.1. Eligible Applicants</td>
<td>10</td>
</tr>
<tr>
<td>II.C.2. Cost Sharing</td>
<td>11</td>
</tr>
<tr>
<td>II.C.3. Other</td>
<td>11</td>
</tr>
<tr>
<td>II.D. Application and Submission Information</td>
<td>11</td>
</tr>
<tr>
<td>II.D.1. Address to Request Application Package</td>
<td>12</td>
</tr>
<tr>
<td>II.D.2. Content and Form of the Application Submission</td>
<td>12</td>
</tr>
<tr>
<td>II.D.3. Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM)</td>
<td>27</td>
</tr>
<tr>
<td>II.D.4. Submission Dates and Times</td>
<td>27</td>
</tr>
<tr>
<td>II.D.5. Funding Restrictions</td>
<td>28</td>
</tr>
<tr>
<td>II.D.6. Other Submission Requirements</td>
<td>29</td>
</tr>
<tr>
<td>II.E. Application Review Information</td>
<td>30</td>
</tr>
<tr>
<td>II.E.1. Criteria</td>
<td>30</td>
</tr>
<tr>
<td>II.E.2. Application Review and Selection Process</td>
<td>33</td>
</tr>
<tr>
<td>II.E.3. Integrity and Performance Information</td>
<td>33</td>
</tr>
<tr>
<td>II.E.4. Anticipated Announcement and Federal Award Dates</td>
<td>34</td>
</tr>
<tr>
<td>II.F. Federal Award Administration Information</td>
<td>34</td>
</tr>
<tr>
<td>II.F.1. Federal Award Notices</td>
<td>34</td>
</tr>
<tr>
<td>II.F.2. Administrative and National Policy Requirements</td>
<td>35</td>
</tr>
<tr>
<td>II.F.3. Reporting</td>
<td>35</td>
</tr>
<tr>
<td>II.G. Federal Awarding Agency Contacts</td>
<td>36</td>
</tr>
<tr>
<td>II.G.1. CDMRP Help Desk</td>
<td>36</td>
</tr>
<tr>
<td>II.G.2. Grants.gov Contact Center</td>
<td>36</td>
</tr>
<tr>
<td>II.H. Other Information</td>
<td>37</td>
</tr>
<tr>
<td>II.H.1. Program Announcement and General Application Instructions Versions</td>
<td>37</td>
</tr>
<tr>
<td>II.H.2. Administrative Actions</td>
<td>37</td>
</tr>
<tr>
<td>II.H.3. Application Submission Checklist</td>
<td>39</td>
</tr>
<tr>
<td>APPENDIX 1: ACRONYM LIST</td>
<td>40</td>
</tr>
</tbody>
</table>

DoD FY17 Gulf War Illness Biorepository Resource Network Award
II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2017 (FY17) 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 FY16 totaled $129 million (M). The FY17 appropriation is $20M.

Gulf War Illness (GWI) is characterized by multiple diverse symptoms that typically include widespread pain, cognitive difficulties, debilitating fatigue, gastrointestinal problems, respiratory symptoms, chronic headache, sleep problems, and other abnormalities that are not explained by established medical diagnoses or standard laboratory tests. The population of Veterans affected by GWI is a subset of the nearly 700,000 who served during the Gulf War. Specifically, these Gulf War Veterans were deployed to the theatre of operations in Southwest Asia, including Iraq, Kuwait, and Saudi Arabia. Studies indicate that approximately 25% to 33% (or 175,000 to 210,000) of Gulf War Veterans continue to experience symptoms associated with their deployment as described above.

The GWIRP challenges the scientific community to design high-impact research that will provide a better understanding of the pathobiology underlying GWI, identify objective markers for improved diagnosis, and develop treatment and healthcare strategies for the complex of GWI symptoms. The GWIRP’s vision is to make a significant impact on GWI and improve the health and lives of affected Veterans and their families.

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 pathobiology and symptoms. Applicants are strongly encouraged to read and consider The Gulf War Illness Landscape before preparing their applications. The Landscape may be found at http://cdmrp.army.mil/gwirp/pdfs/GWIRP_Landscape.pdf.

II.B. Award Information

The Biorepository Resource Network Award (BRNA) is being offered for the first time in FY17.
The anticipated direct costs budgeted for the entire period of performance for an FY17 GWIRP BRNA will not exceed $2,500,000. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The FY17 GWIRP BRNA is intended to provide infrastructure support for the development of a GWI biorepository comprised of a network of institutions that will collect, process, annotate, store, and distribute high-quality biospecimens and data from Veterans of the 1990-1991 Persian Gulf War. In addition to biospecimens, this biorepository is intended to house biological data from previous studies (e.g., imaging or -omics data without specimens attached). The development of the biorepository resource network will enable the GWI research community to conduct research that will address the mission of the GWIRP.

Institutions must demonstrate a commitment to secure additional funds and/or operating arrangements from other agencies or funding sources to continue operations of the proposed biorepository after the end of the GWIRP award performance period.

Investigators with experience and expertise in human biospecimen procurement, annotation, storage, and distribution and in developing and operating a biospecimen repository are encouraged to apply. Institutions must demonstrate access to Gulf War Veterans, Gulf War Veteran samples, and/or Gulf War Veteran data from previous studies.

Applicants intending to recruit Veterans are encouraged to leverage existing cohorts recruited in other GWIRP-supported studies and can refer to the Research Resources link (http://cdmrp.army.mil/gwirp/resources/gwirpresources) on the GWIRP website. These applicants are also encouraged to consider the “Outreach and Recruitment Best Practices” available on the GWIRP website http://cdmrp.army.mil/gwirp/pdfs/General%20_Guidance_for_Gulf_War_Veteran_Outreach_and_Recruitment.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. Researchers are not required to use any of the following limited examples or any one particular dataset.

- Defense Manpower Data Center (DMDC; https://www.dmdc.osd.mil) maintains the largest archive of personnel data in the Department of Defense (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 (Department of Defense 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.afhsc.mil/Home/DoDSR). 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](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** ([http://millenniumcohort.org](http://millenniumcohort.org)). Initiated in 2001, the Millennium Cohort Study is ongoing and comprises 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 Veterans Affairs Biorepository Brain Bank (VABBB)** ([http://www.research.va.gov/programs/tissue_banking/gwvib/](http://www.research.va.gov/programs/tissue_banking/gwvib/) and [https://www.research.va.gov/programs/tissue_banking/als/](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)**; [http://www.research.va.gov/MVP/default.cfm](http://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 (GWECB), CSP#585**. [http://www.research.va.gov/programs/csp/585/repository.cfm](http://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 into the cohort and biorepository. Resources are available to VA and non-VA investigators through the CSPEC-Durham Data and Specimen Repository. Investigators may submit data requests to the CSPEC-Durham Data and Specimen Repository for research under an Institutional Review Board (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.
Organizational Structure: The FY17 GWIRP BRNA will support up to three Resource Sites and one Coordinating Center (which may also be the location of one of the Resource Sites). Together these are referred to collectively as the “Network.” All Sites together will be jointly responsible for developing operating and maintaining a biorepository for GWI research. The Coordinating Center and Resource Sites must submit a single application, submitted by the Coordinating Center, with the proposed Resource Sites as subawards.

The Coordinating Center will serve as the nexus for Network information and planning by providing administrative, operational, and data management support to Resource Sites. The Coordinating Center will be responsible for administering Network policies and standard operating procedures (SOPs) to include biological data submission, biospecimen collection (or submission of pre-existing biospecimens), post-collection processing, handling, storage, and shipment best practices. It is expected that the Coordinating Center will provide unique resources that may not necessarily be available at each Resource Site. The Coordinating Center will also be responsible for establishment and management of a communications system to maintain optimal operation of all Network components.

Resource Sites should possess archived biospecimens and data or the ability to collect new biospecimens and data with consideration of capabilities for the derivatization of DNA, RNA, proteins, and lipids for a large range of GWI research studies. All Resource Sites must collaborate with the Coordinating Center to develop policies and SOPs for the entire Network including biospecimen and/or data inventory, tracking, and basic annotation. The Resource Sites should be selected for the contributions that each can make to the Network. The contributions need not be equal but rather of unique value to the Network as a whole. If the contributions vary significantly between/among the Resource Sites, variance in the budgets allocated to the Sites should be well described in the budget justification.

Collective Network Responsibilities:

Biospecimens/Data: The Network will collect, process, annotate, store, and distribute high-quality Gulf War Veteran biospecimens and associated data to include tissues or other samples such as blood, cerebrospinal fluid, saliva, or other such sources of nucleic acids and/or small molecules/metabolites.

Clinical Annotation of Biospecimens and Data Quality Assurance: In addition to the importance of collecting high-quality samples, annotation of samples is critical to the success of research using samples obtained from the Network. The Network must develop a plan to establish common data elements and standardized language to annotate samples within the Network. The extent of the clinical annotation should include data on deployment history, symptom profile, gender, demography, and characterization of individual pathological samples to include biospecimen type, storage conditions, the existence of case-matched normal biospecimens, and other standard parameters. To ensure the quality of the biospecimens and the consistency and accuracy of data in the repository, the Network is expected to develop quality assurance measures for clinical and pathological data and data transmission.
It is standard practice to de-identify samples and data when released for use by investigators; however, the GWI population is a confined pool of potential donor/subjects. As such, it is not unlikely that multiple samples or datasets from the same individual donor might be selected in any random set. To avoid this bias, the Network must retain links between individual personal donor identifiers and the samples and datasets obtained from them and implement procedures to ensure that groups of released samples and datasets are not biased by multiple materials from single donors.

**Informatics and Data Management:** It is expected that the Network will develop a comprehensive data management plan that includes a common informatics system to manage the biorepository resources and provide for ongoing data transfer, security, and integrity. The system should remain current and responsive to the GWI research community so that data can be both retrieved and submitted into the system. The system may include, but is not limited to, ongoing processes to improve and update Network access to resources internal and external to the Network, and developing new informatics strategies to harmonize the biorepository informatics resources with the informatics of other national biorepositories.

**Key Personnel:** The Coordinating Center Principal Investigator (PI) will serve as the Director of the Network and the Chair of the Steering Committee (Steering Committee described below). In addition to the Coordinating Center PI and the Resource Site PIs, other key personnel in the Network include:

- Coordinating Center **Administrative Manager**, who will assist with daily operations of the Coordinating Center;
- Coordinating Center **Data Management Specialist**, who will oversee all informatics and data management within the Network;
- Coordinating Center **Quality Control Specialist**, who will be responsible for implementing established operational procedures to ensure the quality of biospecimens and data derived from them across the Network and the shared information grid; and
- **Resource Site Coordinator** (one for each Resource Site), who will work with the Coordinating Center Administrative Manager on Network-wide functions in addition to site-specific functions.

**Network Committees:** The Network will be required to have a committee structure that allows for an overall quality assurance plan with the responsibility of:

- Coordinating and developing protocols, equipment, and training of personnel;
- Coordinating regulatory issues including compliance with the local Institutional Review Board (IRB) of record;
- Coordinating oversight of privacy and confidentiality of Veteran data; and
- Managing biospecimens and data including processing, annotation, storage, and distribution.
A **Steering Committee** composed of Coordinating Center PI (Chair), Resource Site PIs and/or co-PIs, Coordinating Center key personnel (Administrative Manager, Data Management Specialist, Data Quality Control Specialist), **at least one Gulf War Veteran with GWI** (Consumer), and other personnel with key expertise will assume the role of the governing body with responsibility for operation of the Biorepository Network. This committee will also be responsible for establishing policies that govern SOPs (with consideration of the International Society for Biological and Environmental Repositories [ISBER] “Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research” http://c.ymcdn.com/sites/www.isber.org/resource/resmgr/Files/ISBER_Best_Practices_3rd_Edi.pdf). SOP considerations include, but are not limited to, quality control, specimen collection, processing, annotation, distribution, legal and ethical regulatory issues, policies for prioritization of specimen distribution, and fees for processing, handling, and shipping requests for samples. The Steering Committee will coordinate the development of additional committees as necessary for development of common data elements, protocol coordination, regulatory coordination IRB and bioethics review, intellectual/material property coordination, data collection, data management (data quality, security, and compatibility), and prioritization and distribution of biospecimens.

**Consumer Participation:** The inclusion of one or more Gulf War Veteran with GWI (i.e., consumer) is required, as Gulf War Veteran participation should be an integral part of Network activities. These Veterans must possess a high level of familiarity with current issues in GWI research and should be actively involved in a Gulf War Veteran advocacy or support group. Their role should be independent of their employment, and they cannot be employees of any of the organizations participating in the application. They will have an active role in ongoing Network oversight including discussion and decision making on participant recruitment, project evaluation, and dissemination of information to the GWI Veteran community and/or public. Examples of appropriate integration include membership on the Steering Committee and other Network committee(s) and attendance at Network-related meetings.

**Performance Metrics:** The FY17 GWIRP BRNA recipient(s) will be accountable to the following performance metrics, upon which continued funding will be contingent after the first 12 months of the award:

- The Coordinating Center must develop and meet a defined set of objectives or milestones as set forth in the Statement of Work.

- The Coordinating Center, in collaboration with the Resource Sites, must develop SOPs for biospecimen collection methods (prospective and existing biospecimens), biological data collection, post-collection processing, and storage.

- The Coordinating Center must demonstrate plans for substantive engagement with the GWI research community, including but not limited to, surveys on biorepository specimen types needed and strategies to foster confidence and enhance utility of the biorepository, ongoing documentation of the number of requests received, and the types and timeliness of specimens distributed.
• The Coordinating Center must demonstrate sufficient data quality control and assurance. This may include audits of unacceptable data (clinical and pathological records) returned to Sites for review and correction for data quality assurance.

• Each Resource Site must contribute biospecimens and/or data.

• Each Resource Site must submit quality data and reports in a timely manner as outlined by the Coordinating Center. This includes, but is not limited to, requests for biospecimens, entry of data, and any subsequent information updates.

Informed Consent: Applications for the FY17 GWIRP BRNA are expected to demonstrate plans for obtaining Veteran-informed consent and de-identification of Veteran identities from biospecimens. PIs should also address how informed consent will be handled, particularly for specimens collected during routine medical care that will be used for future research purposes.

Intellectual Property and Material Transfer Agreements: Since the Network will be a collaborative network of institutions, the Coordinating Center and Resources Site PIs will work together to resolve potential intellectual and material property conflicts and remove institutional barriers that might interfere with achieving the high levels of cooperation necessary for the success of the Network. Applications must provide documented evidence of institutional commitment to allowing specimens collected at Resource Sites to be sent to investigators at non-Network institutions for the purpose of conducting GWI research.

All data contributed to the Network or generated from the use of specimens obtained from the Network will be deposited into a common information grid. Investigators will first have the opportunity to publish the data, after which (and according to a prescribed period of time determined by the Network and in accordance with journal policies) the dataset will be released for distribution and shared with the GWI research community through an internet-accessible database. Investigators must agree to share their data in order to use biorepository resources. The Network will control access to all repository data. In addition, protocols and methods that were used to derive data from biorepository specimens should be available through an open source system such as public websites.

During the period of performance, the Coordinating Center must be able to demonstrate the impact of the biospecimens distributed by tracking of the number of publications involving the use of Network biospecimens.

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 Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is not required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied
to the IRB/EC. **Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.** When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. 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.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

Awards will be made no later than September 30, 2018. For additional information refer to Section II.F.1, Federal Award Notices.

**II.C. Eligibility Information**

**II.C.1. Eligible Applicants**

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

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

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

**Extramural Organization:** An eligible non-DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes. *Extramural Submission: Application submitted by a non-DoD organization to Grants.gov.*

**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 who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.*
**Note:** Applications from an intramural organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

The USAMRAA makes awards to eligible organizations, not to individuals.

**II.C.1.b. Principal Investigator:**

Independent investigators at all academic levels (or equivalent) are eligible to apply.

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 [http://orcid.org/](http://orcid.org/).

**II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

**II.C.3. Other**

Extramural 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.

Each investigator may submit only one GWIRP BRNA application as a PI.

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).*

The BRNA mechanism is structured to accommodate three, and up to a maximum of four, sites. The Coordinating Center site PI will be identified as the primary award PI and will be responsible for the administrative tasks associated with application submission. Resource Sites and their respective PI(s), not part of the Coordinating Center institution, will be included in the primary award as subawards or subcontracts. All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award budget.
Extramural Submission is defined as an application submitted by a non-DoD organization to Grants.gov.

Intramural Submission is defined as an application submission by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

II.D.1. Address to Request Application Package

Submitting Extramural and Intramural Organizations: Pre-application content and forms can be accessed at eBRAP (https://eBRAP.org).

Submitting Extramural Organizations: Full application packages can be accessed at Grants.gov.

Submitting Intramural DoD Organizations: Full application packages can be accessed at eBRAP.org.

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 and full application as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-Application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

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.

Full Application Submission: Full applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full applications from extramural organizations must be submitted through Grants.gov. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural
submissions through Grants.Gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

eBRAP allows intramural organizations to submit full applications following pre-application submission.

For both Extramural and Intramural applicants: A key feature of eBRAP is the ability of an organization’s representatives and PIs to view and modify the full application submissions associated with them. 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. It is the applicant’s responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

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 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 deadline.

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

During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the 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 may result in delays in 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.

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

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):
• **Tab 1 – Application Information**

• **Tab 2 – Application Contacts**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must 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 (R&R) 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.

FY17 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.

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 pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Pre-applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

• **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.
• **Tab 5 – Pre-Application Files**

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

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

  − **Organizational Structure:** For both the Coordinating Center and the Resource Sites, describe the organizational structure (a chart format for this information is encouraged). Describe the ability of the performing institution to serve as the Network Coordinating Center and support the development, administration, and fiscal management of a networked biorepository. Describe the experience and resources (including necessary equipment and access to Gulf War Veteran populations, biospecimens, or data) of the PI, personnel, and institution to participate as a Resource Site of the Consortium.

  − **Institutional Resources:** Describe the unique capabilities and strengths of each institution to serve as a Coordinating Center or Resource Site, including adequate resources for ongoing data transfer, expertise for data management, and maintenance of data. Describe how the Network intends to secure funds, resources, or other forms of support from other sources to leverage Network resources to continue operation of the biorepository beyond the performance period for the award.

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

  − **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).

  − **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

  − **Key Personnel Biographical Sketches (five-page limit per individual):** All biographical sketches should be uploaded as a single combined file. Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

• **Tab 6 – Submit Pre-Application.**

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

Pre-Application Screening Criteria

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

- **Organizational Structure:** To what degree the strategies for the development and implementation of the biorepository and each institution involved are well demonstrated and will facilitate its success.

- **Continued Operations:** Whether the PI and/or institution has demonstrated sufficient willingness and capabilities and a feasible plan to secure additional funds, resources, or other forms of support from other sources to support continued operations of the Network.

- **Intent of the Award Mechanism:** Whether the proposed project is sufficiently related to biospecimens and/or biological data representative of the 1990-1991 Gulf War Veteran population.

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 time frame 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 the PI has received notification of invitation.

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

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

Each application submission must include the completed full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (http://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, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

<table>
<thead>
<tr>
<th>Extramural Submissions</th>
<th>Intramural DoD Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Package Location</td>
<td></td>
</tr>
<tr>
<td>Download application package components for W81XWH-17-GWIRP-BRNA from Grants.gov</td>
<td>Download application package components for W81XWH-17-GWIRP-BRNA from eBRAP</td>
</tr>
<tr>
<td>Full Application Package Components</td>
<td></td>
</tr>
<tr>
<td>SF424 (R&amp;R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.</td>
<td>Tab 1 – Summary: Provide a summary of the application information.</td>
</tr>
<tr>
<td>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</td>
<td></td>
</tr>
<tr>
<td>Descriptions of each required file can be found under Full Application Submission Components:</td>
<td></td>
</tr>
<tr>
<td>• Attachments</td>
<td></td>
</tr>
<tr>
<td>• Research &amp; Related Senior/Key Person Profile (Expanded)</td>
<td>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:</td>
</tr>
<tr>
<td>• Research &amp; Related Budget</td>
<td>• Attachments</td>
</tr>
<tr>
<td>• Project/Performance Site Location(s) Form</td>
<td>• Key Personnel</td>
</tr>
<tr>
<td>• R&amp;R Subaward Budget Attachment(s) Form (if applicable)</td>
<td>• Budget</td>
</tr>
<tr>
<td></td>
<td>• Performance Sites</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>Application Package Submission</td>
<td></td>
</tr>
<tr>
<td>If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget need 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.</td>
<td>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 “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline.</td>
</tr>
<tr>
<td>Extramural Submissions</td>
<td>Intramural DoD Submissions</td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td><strong>Application Verification Period</strong></td>
<td></td>
</tr>
<tr>
<td>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, <em>with the exception of the Project Narrative and Budget Form</em>, may be modified.</td>
<td>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller or equivalent Business Official and PI will receive an 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, <em>with the exception of the Project Narrative and Budget Form</em>, may be modified.</td>
</tr>
<tr>
<td><strong>Further Information</strong></td>
<td></td>
</tr>
<tr>
<td>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</td>
<td>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</td>
</tr>
</tbody>
</table>

*The organization’s Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.*

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. *The Project Narrative and Budget cannot be changed after the application submission deadline.* Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

*Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.*

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 (R&R) 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 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 (30-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

1. **Experience and Expertise in Multi-Institutional Collaboration and Biorepository Development**

   For both the Coordinating Center PI and the Resource Site PIs:

   - Describe previous experience and accomplishments in multi-institutional collaboration.
   - Describe expertise, experience, and accomplishments related to the development, administration, and fiscal management of a biorepository.
   - Describe previous experience with establishing communications systems and data management resources for multi-institutional projects.

2. **Organizational Structure**

   For both the Coordinating Center and the Resource Sites, describe the organizational structure, including the following key features and with consideration of the ISBER’s “Best Practices for Repositories” as applicable:

   - The structure of interactions between/among the Coordinating Center and Resource Sites (a chart format for this information is encouraged).
   - Plans for administration and day-to-day management of Network operations.
The communication plan between the Coordinating Center and Resource Sites. Plans should include methods for information dissemination within the Network and information technologies that will be used to facilitate routine multi-institutional communication.

Plans to standardize operations across institutions and the process for development of SOPs.

Training of personnel.

Coordination of regulatory issues.

Oversight of privacy and confidentiality of human subject data.

Procedures for Network approval of all SOPs and laboratory protocols.

Procedures for prioritization of biospecimen distribution to GWI investigators to ensure appropriate and efficient distribution of samples and attention to studies that address the mission of the GWIRP.

Provide a named consumer to serve as a member of the Steering Committee. Describe the consumer advocate’s familiarity with current issues in GWI and how he/she will play an active role in the Network, including oversight, participant recruitment, program evaluation, dissemination of information to GWI communities and/or the public, and interactions with other participants to strengthen the overall Network.

3. Institutional Resources

For both the Coordinating Center and the Resource Sites, describe the institutional resources, including the following aspects:

The unique capabilities and strengths of the applicant institution to serve as a member of the Network.

Provide evidence of institutional support, resources, and facilities for the development of a repository and its operation in the context of a cooperative network of organizations.

Provide evidence of institutional commitment to allow specimens (prospectively collected or pre-existing) and/or data at Resource Sites to be sent to investigators at non-Network institutions for the purpose of conducting GWI research.

Describe the unique capabilities and strengths of the institutions selected to serve as a Resource Site.

Provide documentation of access to Gulf War Veteran populations and/or access to Gulf War Veteran biospecimens and biological data.
4. Operational Management

For both the Coordinating Center and the Resource Sites, describe the plans for operational management, including the following key features and with consideration of the ISBER’s “Best Practices for Repositories,” as applicable:

- Provide evidence of the expertise of all key personnel that will be involved in the Coordinating Center and the Resource Sites, respectively. Describe their expected roles as they relate to the collection, processing, annotation, storage, and distribution of human biospecimens and data. Key personnel must include a named Administrative Manager at the Coordinating Center who will interact with the Sites to coordinate activities; expedite protocols through regulatory approval processes; expedite review, prioritization, and selection of specimen distribution; coordinate personnel training; and coordinate Veteran participation and other biorepository activities across all institutions.

- Describe plans for collection, processing, and annotation of prospective biospecimens, submission and annotation of existing biospecimens and/or collection and annotation of biological data in accordance with SOPs and other standardized operations.

- Include a named Quality Control Specialist at the Coordinating Center who will interact with all Resource Sites and oversee implementation of established operational procedures to ensure the quality of biospecimens and data across the Network and shared information grid.

- Provide a plan for the development and management of procedures for biospecimen inventory control, quality assurance, and quality control measures across the Network institutions, including:

  - A plan for regular monitoring of biospecimen quality, biospecimen clinical and pathological data, and data transmission across the Network as described in the Clinical Annotation of Biospecimens and Data Quality Assurance section above in Section II.B, Award Information);

  - Registration, tracking, and reporting of Veteran participation;

  - Timely review and assessment of biospecimen data, deposited clinical annotated data, and deposited research data for consistency and accuracy; and

  - Development, implementation, and periodic evaluation of quality assurance and control procedures.

- Plans for contribution by each Resource Site of biospecimens and/or data.

- Include a plan for sharing biospecimens and biological data across the Network.
Outline a plan for ensuring public dissemination of data generated by Network investigators and procedures for timely release of data obtained from use of biospecimens.

(Optional) Plans for a workshop to convene Network PIs, other biorepository participants, and other experts in the field of biospecimen science. The proposed workshop should enhance the usefulness of the biorepository in facilitating meaningful and innovative GWI research.

5. Informatics and Data Management

For both the Coordinating Center and the Resource Sites, describe the plans for informatics and data management, including the following key features and with consideration of the ISBER’s “Best Practices for Repositories” as applicable:

- Include a named Data Management Specialist at the Coordinating Center who will interact with all Resource Site Coordinators to optimize informatics and data management within the Network.

- Describe the common informational system to be used in the Network. Include database design, operation, and maintenance; inventory control system(s); access; and searchable functions for biospecimen information and research data.

- Describe the plan for ongoing data transfer, security, and integrity.

- Describe the plan for managing the resources of the Network while remaining current and responsive to non-Network GWI investigators.

- Provide evidence of adequate resources for data transfer and expertise for data management and maintenance of data security/confidentiality.

6. Legal, Ethical, and Human Subject Issues

For both the Coordinating Center and the Resource Sites, describe the plans to manage legal, ethical, and human subject issues, including the following key features and with consideration of the ISBER’s “Best Practices for Repositories,” as applicable:

- Outline the ethical and legal procedures and policies that will be followed for collection or use of biospecimens or data in research.

- Include a description of the methods for demonstrating or obtaining informed consent, how biospecimens will be de-identified prior to being provided to investigators for research purposes, and how research results from the biospecimens will be made available to clinicians of Veteran participants.

- Describe the process through which all Sites in the Network will adhere to a common policy governing legal, ethical, and human subject issues.
- Describe procedures for ensuring compliance with ethical and legal involvement of human subjects and issues involved in the collection and use of biospecimens in research.

7. Financial Management and Marketing of the Network

- Describe how the Network intends to secure funds, resources, and other support from other sources to leverage Network resources to continue operation of the Network beyond the performance period for the GWIRP award.

- Include plans for advertising/marketing for both obtaining and distributing the biospecimens to the GWI research community.

○ 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. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.

- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.

- Letters of Collaboration: Provide a signed letter from each collaborating individual or organization that will demonstrate that the Network PIs have 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.

  - Required (Coordinating Center only): Provide a signed letter from the named GWI consumer advocate that describes his or her familiarity with current issues in GWI research and how he or she will support the PIs and the project.

- Access to Gulf War Veterans or Gulf War Veteran Biospecimens/Data (as applicable): Provide a letter showing approved access to Gulf War Veterans if proposing to access the Veteran population or use biospecimens/data from Veterans (e.g., from collaborating VA investigators, DMDC Data Request System). PIs whose applications will require use of data from VA or military databases should confirm the ability to meet database requirements prior to application submission. A letter of support, signed by the lowest-ranking person with approval authority, should be included for studies involving Veterans, VA- or military-controlled study materials, and/or VA or military databases.


  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

- 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.

  - Expertise: Summarize the key personnel’s (including the PIs, Veteran advocate(s), and other key personnel) commitment to and expertise in GWI research and repository management.

  - Organizational Structure and Operational Management: Briefly outline the overall organizational structure, administration, and model for operational management.
– **Institutional Resources:** Summarize the unique capabilities and strengths of the institutions serving as Coordinating Center and Resource Sites. Include available resources, facilities, and prior experience in multi-institutional collaborations.

– **Gulf War Veteran Populations:** Describe the access to Gulf War Veteran populations that will be recruited for biospecimen acquisition and/or access to existing Veteran specimens/data.

○ **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.

– **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.

– Describe the objective and rationale for the proposed project in a manner that will be readily understood by readers without scientific or medical backgrounds.

– Describe the ultimate applicability of the effort to GWI Research.

○ **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm). For the BRNA mechanism, use the SOW format example titled “SOW for Collaborative PI Projects.” The SOW must be in PDF format prior to attaching.

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

Include the name(s) of the key personnel and contact information for each study site/subaward site.

Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

Briefly state the methods to be used.

For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the U.S. Food and Drug Administration or other Government agency.

- **Attachment 6: DoD Military Budget Form(s), if applicable:** Upload as “MFBudget.pdf.” If a military facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural and Intramural Applications –**

  **Research & Related Senior/Key Person Profile (Expanded):** 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.

  - **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (PDF) that is not editable.

  - **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf.”

  - **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch_LastName.pdf.”
    - Include biographical sketches for collaborators, including consumer advocate(s).

  - **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.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, 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.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- Extramural Applications Only –

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

- Extramural Subaward: Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)

- Intramural DoD Collaborator(s): Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 6. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

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

Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant’s organization’s Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by 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.

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**

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a submitted application. 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 retrieved files against the specific Program Announcement requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. *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 Budget Form cannot be changed after the application submission deadline.

**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 $2,500,000. If indirect costs have been negotiated, indirect costs rates are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the Government exceeding $2,500,000 direct costs or using an indirect cost rate exceeding the organization’s negotiated rate.

Budget amounts for the Resource Sites should reflect the resources to be contributed. If the budgets between/among Resource Sites differ significantly, the differences must be well justified in the budget justification.

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 be requested for (not all-inclusive):

- Salary
- Development of software, databases, inventory systems, websites, and/or other information technologies
- Purchase of equipment, including computers
- Equipment maintenance and operation
- Advertising/marketing costs
• Specimen collection and replenishment
• Specimen processing
• Specimen storage and management
• Specimen distribution
• Other costs associated with planning and developing Network collaborations and resources
• Network meetings including travel among Network PIs and staff
• Travel costs for up to three investigator(s) to travel to one scientific/technical meeting per year

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). 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 fund transfer. Intragovernmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund 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.4, for budget regulations and instructions for the Research & Related Budget. For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.4.

The CDMRP expects to allot approximately $4M of the $20M FY17 GWIRP appropriation to fund approximately one BRNA application, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.

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:

- **Personnel**
  - How well the Coordinating Center PI, Resource Site PIs, and other key personnel have demonstrated the expertise, experience, and accomplishments to enable successful development, administration, and fiscal management of the proposed Network.
  - How well the Coordinating Center PI, Resource Site PIs, and other key personnel have demonstrated previous success in multi-institutional collaborations including past performance of a multi-institutional award.
  - To what degree the named Administrative Manager and Resource Site Coordinators possess the appropriate expertise to coordinate Network activities across all Sites and expedite protocols through regulatory approval processes.
  - To what degree the named Data Management Specialist and Quality Control Specialist possess sufficient expertise in informatics and data management.
  - Whether there are sufficient levels of effort for the successful conduct of the proposed work at each of the institutions involved.

- **Institutional Resources and Commitment**
  - Whether there is evidence of strong commitment from the Coordinating Center and each Resource Site institutions to provide the necessary resources and facilities for the development of the proposed Network, its operation in the context of a cooperative network, and allowing biospecimens and data to be shared with investigators outside the Network.
  - Whether each institution to be involved in the proposed work has unique resources that will benefit the Network as a whole.
  - To what degree the institutions have a demonstrated track record of sharing biospecimens and data and/or suitable plans to do so.
  - How well the willingness and abilities of the institutions to resolve intellectual and material property issues among participating institutions have been demonstrated.
• **Organizational Structure**
  
  ○ Whether the proposed plan for coordinating ongoing communication across the Network is feasible and appropriately robust.
  
  ○ Whether the proposed organizational management plan is appropriate with respect to decision making, allocation of resources, coordination of Network functions, including evaluation and prioritization of requests for biospecimens and conflict resolution among all participating PIs and institutions.
  
  ○ How well one or more Veteran consumer advocate(s) have been incorporated into the overall leadership and interaction with the PIs of the Network.
  
• **Operational Management**
  
  ○ To what degree the strategies for implementation of the SOPs and other standardized operations at each institution are well planned and will facilitate the Network’s success.
  
  ○ The extent to which the plans described for collection, processing, and annotation of new and/or existing biospecimens and data are adequate and appropriate.
  
  ○ Whether the plans for quality assurance and quality control of biospecimens will ensure avoidance of sample variability and efficiency of specimen integrity.
  
  ○ Whether there are appropriate plans for public dissemination of data generated by the Network.
  
  ○ The degree to which the proposed plan for obtaining and marketing biospecimens to the GWI research community will facilitate the success of the Network.
  
  ○ Whether the PIs and/or institutions have demonstrated sufficient planning, willingness, and capabilities to secure additional funds, resources or other support from other sources to support continued operations of the Network.
  
• **Data Management**
  
  ○ Whether the proposed plan for data management will provide appropriate access to data, data security and confidentiality, and data integrity.
  
  ○ The degree to which the informatics structure and data management plans will successfully facilitate GWI research.
  
  ○ Whether the plans for data sharing between the Resource Sites and with the GWI research community, including all data derived from internal and external studies of the biorepository specimens, are sufficient.
• **Legal, Ethical, and/or Regulatory Issues**
  
  ○ Whether there are appropriate plans for addressing regulatory issues associated with the legal and ethical protection of human subjects and the use of human biospecimens in research.
  
  ○ Whether all relevant privacy issues have been addressed appropriately and whether the plans for data acquisition, storage, and dissemination will sufficiently maintain patient confidentiality.
  
  ○ Whether there are appropriate plans for the coordination of regulatory submissions and approvals at participating Sites.
  
  ○ Whether the plans for ensuring informed consent are sufficiently developed.

• **Access to Gulf War Veterans/Specimens**
  
  ○ To what degree the PIs have demonstrated access to Gulf War Veteran specimens and/or there is sufficient evidence of an ability to prospectively collect Gulf War Veteran specimens.
  
  ○ How well the PIs have demonstrated capabilities in obtaining biological data.

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

• **Budget**
  
  ○ Whether the maximum direct costs are equal to or less than the allowable maximum direct costs as published in the Program Announcement.
  
  ○ Whether the budget is appropriate for the proposed work.

• **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 FY17 GWIRP, as evidenced by the following:
  
  ○ Adherence to the intent of the award mechanism
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 of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and GWIRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review. Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization’s application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 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 (currently $150,000) 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, at its option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about itself 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 (DoDGAR), 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 will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

*Extramural Organizations:* An assistance agreement (grant or cooperative 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. 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). Substantial involvement may include 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.

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

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 documents.
**Intramural Organizations:** Awards 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 managers (RM).

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the CDMRP will contact the business official authorized to negotiate on behalf of the PI’s organization.

**II.F.1.a. Award Transfers**

The transfer of a BRNA to another institution is not allowed.

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

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 DoDGAR found in 32 CFR, Chapter 1, 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 [USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations](#) 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.

Quarterly technical progress reports will be required in addition to annual and final reports. Reports must be in the form of a single comprehensive report encompassing activities at the Coordinating Center and all Resource Sites.
In addition to written progress reports, Annual Award Charts will be required. For the BRNA, use the format example titled, “Generic Award Charts,” available on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm).

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 Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations is available in OAR Article I, Section B, in the July 2016 R&D General Terms and Conditions. The applicable Terms and Conditions for for-profit organizations is available in Section 34 of the February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations.

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 20170516a. The Program Announcement numeric version code will match the General Applications Instructions version code 20170516.

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 FY17 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 FY17 GWIRP Programmatic Panel members can be found at http://cdmrp.army.mil/gwirp/panels/panels17.
- The application fails to conform to this Program Announcement description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

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

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.

- 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.

- The invited application does not propose the same research project described in the pre-application.

- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

- An application for which the PI does not meet the eligibility criteria will be withdrawn.

- Applications may be administratively withdrawn from further consideration if the applicant cannot demonstrate access to the relevant study population or resources.

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

<table>
<thead>
<tr>
<th>Application Components</th>
<th>Action</th>
<th>Completed</th>
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<tr>
<td>SF424 (R&amp;R) Application for Federal Assistance (<a href="#">Extramural submissions only</a>)</td>
<td>Complete form as instructed.</td>
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</tr>
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<td>Summary (Tab 1) and Application Contacts (Tab 2) (<a href="#">Intramural submissions only</a>)</td>
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<td>Attachments</td>
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<td>Project Narrative: Upload as Attachment 1 with file name “ProjectNarrative.pdf.”</td>
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<tr>
<td>Supporting Documentation: Upload as Attachment 2 with file name “Support.pdf.”</td>
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<tr>
<td>Technical Abstract: Upload as Attachment 3 with file name “TechAbs.pdf.”</td>
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<tr>
<td>Lay Abstract: Upload as Attachment 4 with file name “LayAbs.pdf.”</td>
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<tr>
<td>Statement of Work: Upload as Attachment 5 with file name “SOW.pdf.”</td>
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<tr>
<td>DoD Military Budget Form(s): Upload as Attachment 6 with file name “MFBudget.pdf,” if applicable.</td>
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<tr>
<td>Research &amp; Related Senior/Key Person Profile (Expanded)</td>
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<td>Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.</td>
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<tr>
<td>Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.</td>
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<tr>
<td>Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.</td>
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<tr>
<td>Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.</td>
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<tr>
<td>Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.</td>
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</tr>
<tr>
<td>Research &amp; Related Budget (<a href="#">Extramural submissions only</a>)</td>
<td>Complete the DoD Military Budget Form and justification.</td>
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<tr>
<td>Budget (<a href="#">Intramural submissions only</a>)</td>
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<tr>
<td>Project/Performance Site Location(s) Form</td>
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<tr>
<td>R&amp;R Subaward Budget Attachment(s) Form, if applicable</td>
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## APPENDIX 1: ACRONYM LIST

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<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACURO</td>
<td>Animal Care and Use Review Office</td>
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<tr>
<td>ALS</td>
<td>Amyotrophic Lateral Sclerosis</td>
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<tr>
<td>BRNA</td>
<td>Biorepository Network Award</td>
</tr>
<tr>
<td>CDMRP</td>
<td>Congressionally Directed Medical Research Programs</td>
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<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
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<tr>
<td>COI</td>
<td>Conflict of Interest</td>
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<tr>
<td>CSPEC</td>
<td>Cooperative Studies Program Epidemiology Center</td>
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<td>DHA</td>
<td>Defense Health Agency</td>
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<tr>
<td>DHP</td>
<td>Defense Health Program</td>
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<td>DIACAP</td>
<td>Defense Information Assurance Certification</td>
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<td>DMDC</td>
<td>Defense Manpower Data Center</td>
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<td>DoD</td>
<td>Department of Defense</td>
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<td>DoDGAR</td>
<td>Department of Defense Grant and Agreement Regulations</td>
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<td>DoDSR</td>
<td>DoD Serum Repository (formerly, Armed Forces Serum Repository)</td>
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<td>DUNS</td>
<td>Data Universal Numbering System</td>
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<td>eBRAP</td>
<td>Electronic Biomedical Research Application Portal</td>
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<td>EC</td>
<td>Ethics Committee</td>
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<td>ET</td>
<td>Eastern Time</td>
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<td>Funding Authorization Document</td>
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<td>FAPIIS</td>
<td>Federal Awardee Performance and Integrity Information System</td>
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<td>FISMA</td>
<td>Federal Information Security Management Act</td>
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<td>Fiscal Year</td>
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<td>GWECB</td>
<td>Gulf War Era Cohort and Biorepository</td>
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<td>Gulf War Illness</td>
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<td>GWIRP</td>
<td>Gulf War Illness Research Program</td>
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<td>GWVIB</td>
<td>Gulf War Veterans’ Illnesses Biorepository</td>
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<td>HRPO</td>
<td>Human Research Protection Office</td>
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<td>IRB</td>
<td>Institutional Review Board</td>
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<td>ISBER</td>
<td>International Society for Biological and Environmental Repositories</td>
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<td>M</td>
<td>Million</td>
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<tr>
<td>MAVERIC</td>
<td>Massachusetts Veterans Epidemiology Research and Information Center</td>
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<td>MIPR</td>
<td>Military Interdepartmental Purchase Request</td>
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<td>MVP</td>
<td>Million Veteran Program</td>
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<td>Office of the Assistant Secretary of Defense for Health Affairs</td>
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<td>ORCID</td>
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<td>ORP</td>
<td>Office of Research Protections</td>
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<tr>
<td>PI</td>
<td>Principal Investigator</td>
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<tr>
<td>RDT&amp;E</td>
<td>Research, Development, Test, and Evaluation</td>
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DoD FY17 Gulf War Illness Biorepository Resource Network Award
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<tr>
<th>Acronym</th>
<th>Description</th>
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<td>RM</td>
<td>Resource Manager</td>
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<td>System for Award Management</td>
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<td>Standard Operating Procedures</td>
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<td>Statement of Work</td>
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<td>U.S. Army Medical Research Acquisition Activity</td>
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<td>USAMRMC</td>
<td>U.S. Army Medical Research and Materiel Command</td>
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