

Intramural Program Announcement

**for the
Department of Defense
Defense Health Program
Congressionally Directed Medical Research Programs**

Defense Medical Research and Development Program

Defense Health Agency

Clinical Research Intramural Initiative

Military Women's Health Research Award

Funding Opportunity Number: DHA-17-CRII-MWHRA

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), May 31, 2017
- **Invitation to Submit an Application:** July 7, 2017
- **Application Submission Deadline:** 11:59 p.m. ET, September 5, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, September 11, 2017
- **Peer Review:** October 2017
- **Programmatic Review:** November 2017

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2017 (FY17) Clinical Research Intramural Initiative (CRII) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate. As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The CRII was initiated in 2012 to provide support for intramural clinical research in OASD(HA)-directed topic areas. The intent of the CRII is to foster intramural research aimed at protecting, supporting, and advancing the health and welfare of military personnel, families, and communities while supporting the development of military researchers and building Military Health System (MHS) research capabilities.

The management agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP) through the Defense Medical Research and Development Program (DMRDP). Additional information about CDMRP and DMRDP can be found on the website at <http://cdmrp.army.mil/>.

THIS IS AN INTRAMURAL AWARD; BEFORE APPLYING, PLEASE NOTE:

- 1. This Program Announcement/Funding Opportunity is intended for intramural investigators and organizations only. An intramural investigator is defined as a Department of Defense (DoD) military or civilian employee working within a DoD laboratory or military treatment facility (MTF), or working in a DoD activity embedded within a civilian medical center.***
- 2. Funding to intramural organizations for selected applications 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.***
- 3. Extramural entities ARE NOT eligible to apply to this Program Announcement/ Funding Opportunity and submissions from extramural investigators will be rejected. Should an intramural organization propose collaboration with an extramural entity for a subset of the research effort, the intramural organization will receive all funds and is responsible for funding awards to collaborating partners through their agency's contracting procedures.***
- 4. It is expected that the work funded through this Program Announcement/ Funding Opportunity will be performed within a DoD laboratory or MTF. Regardless of location, any work that is to be performed by associated non-DoD organizations must be limited to work performed under existing service or research contracts, or Cooperative Agreements. The Government reserves the right to administratively withdraw any application that does not meet these eligibility criteria. Applications***

that require work to be performed by a non-DoD organization under a new service or research contract will not be considered for funding.

5. *Applicants must provide a detailed Federal Agency Financial Plan after the budget justification information in the Detailed Budget and Justification form. Applications must provide a plan delineating how all FY17 funds will be obligated by September 30, 2018. The plan must include the funding mechanism(s) and contractual arrangements that will be used to carry over funds between fiscal years, if applicable.*

Funds for this award are FY17 DHP RDT&E Program Element (PE) 6.3 dollars. Any FY17 funding not obligated by September 30, 2018 may be withdrawn by the issuing comptroller.

6. *Applicants must provide Letters of Organizational Support from the following:*
 - a. *Resource Manager/Comptroller: Provide a letter of support from the applicant institution's Resource Manager/Comptroller Office (or appropriate financial point of contact) assuring that the institution will be able to accept these funds, if awarded. If funds are to be sent to multiple sites, include a letter from each site.*
 - b. *Commander(s): Provide a letter (or letters) of support from appropriate MTF, Installation Commander, or equivalent Commanders/Directors to ensure access to the facility, research population, and other necessary resources. The Commander should be aware of all submissions and should confirm that the proposed work is both feasible from a technical perspective and relevant from a programmatic and Command perspective.*

B. FY17 CRII Military Women's Health Research Award Priority Areas

Applications must be relevant to at least one of the following FY17 CRII Military Women's Health Research Award (MWHRA) Priority Areas:

- **Psychological Health and Resilience:** Address psychosocial/psychological health challenges unique to military women and develop interventions, programs, and policies that promote and preserve their psychological health and resilience.
 - Determine whether there are any factors unique to women that need to be accounted for in developing predictive models and metrics for psychological health and resilience
 - Determine best practices for supporting military women during transitions (e.g., reintegration following deployment, separation from the military, reserve component transitions)
 - Evaluate sex-associated factors influencing the neuro-pathophysiology, assessment, treatment response (to include adherence/retention), rehabilitation, and clinical outcome for psychological health issues, such as post-traumatic stress disorder (PTSD), suicidality, sleep disturbances, and substance abuse/misuse
 - Assess barriers to healthcare utilization, such as military workplace stress, sexual harassment and assault, PTSD, and pre-military trauma

- **Injury Prevention, Reduction, Treatment, and Rehabilitation:** Promote and preserve operational readiness through injury prevention and reduction strategies, and develop restorative and rehabilitative care that resets injured Service members for return to duty (RTD), reclassification, or transition from service with optimal clinical outcomes with the highest quality of life.
 - Develop and validate preventative strategies to reduce risk of injury and optimize performance of military women in training and operational environments
 - Develop and validate sex-associated assessment metrics for what constitutes successful RTD, reclassification, and transition from service after injury
 - Evaluate pain management therapeutics dosing considerations for military women
 - Assess injury prevalence, incidence, natural history, occupational and gender-related differences, and clinical outcomes
 - Develop short- and long-term evidence for new and existing support and reintegration strategies, specifically for wounded female Service members
- **Physiological Health and Readiness:** Develop biomedical countermeasures to sustain Service member physiological health and operational effectiveness throughout the military lifecycle, including training, deployment, reset, and injury recovery.
 - Assess sex-dependent differences in nutritional and physiological homeostasis under military training- and combat-relevant conditions
 - Evaluate dietary supplements and nutritional and behavioral interventions to mitigate threats to readiness, operational health, and performance for military women
 - Assess effects of hormonal contraceptive use, and vehicle of delivery, on the physiological health and performance of women in military settings
- **Environmental Health and Protection:** Develop standards and tools for monitoring health, readiness, and operational effectiveness of Service members exposed to extreme operational environments including heat, cold, and altitude, as well as exposure to industrial chemical and airborne hazards.
 - Develop and validate standards and predictive models for measuring physical performance of military women in extreme environments
 - Develop standards and tools to detect, prevent, and mitigate degraded physical and cognitive performance of female Service members in extreme environments
 - Develop standards and tools for individualized environmental exposure monitoring that provide actionable information on the health and readiness of female Service members

- **Combat Casualty Care:** Develop casualty management capabilities for the acute and early management of combat-related trauma, including point-of-injury, en route, and facility-based care to optimize survival and recovery from combat-related injury in current and future operational environments.
 - Evaluate sex-associated differences in the physiological responses to acute trauma/injury that influence mortality rates
 - Identify sex-associated differences in mechanisms of fatal battlefield injuries, wounding patterns, and injury severity
 - Develop point-of-injury, acute care, and treatment strategies for traumatic injuries suffered by women

- **Medical Simulation and Training:** Develop combat casualty care medical simulation and training technologies that sufficiently replicate the anatomical and physiological differences between male and female Service members, and reflect lifelike responses to stimuli and treatment (e.g., tissue, organ, wound responses/feedback).
 - Develop adaptable, flexible, and interoperable female physiological models for medical training with specific focus on the genitourinary system that reflect physiological responses to combat-related injuries as well as dynamic physiological responses to different treatments
 - Develop virtual models integrating various anatomical datasets where accurate physiological algorithms and appropriate behavioral responses are incorporated for pre-intervention rehearsal training for healthcare professionals from common complaints to complex scenarios

C. Award Information

The FY17 CRII MWHRA seeks to support intramural research to promote the health, readiness, and performance of the woman Service member and Joint Force across the full range of military operations, to include all training and operational environments. Moreover, it seeks to support research toward the preservation of operational capabilities through definitive and rehabilitative care that resets wounded or injured women Service members for return to duty or optimal clinical outcomes with the highest quality of life. ***Preliminary data are not required. However, logical reasoning and a sound scientific rationale for the proposed research must be demonstrated.*** Applications should include a well-formulated, testable hypothesis based on strong scientific rationale.

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity. A clinical trial is defined as a prospective accrual of patients where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. For more information on clinical trials and clinical research overall, a Human Subject Resource Document is provided on the electronic Biomedical Research Application Portal (eBRAP) system at <https://ebrap.org/eBRAP/public/Program.htm>.

Research Resources: Applicants are encouraged to consider leveraging resources available through existing DoD and/or Department of Veterans Affairs (VA) resources, if retrospectively collected human anatomical substances and correlated data are relevant to the proposed research. These resources include:

- **DoD Cancer Centers of Excellence:** The DoD funds three Cancer Centers of Excellence, which focus on breast, prostate, and gynecologic cancers, enabling cutting-edge treatment and research on cancers in our Warfighters and other beneficiaries.
- **DoD Serum Repository (<https://health.mil/Military-Health-Topics/Health-Readiness/Armed-Forces-Health-Surveillance-Branch/Data-Management-and-Technical-Support/Department-of-Defense-Serum-Repository>):** The DoD Serum Repository (DoDSR) was established in 1989 as the Army/Navy Serum Repository for storing serum that remained following mandatory HIV testing within the active and reserve components of the Army, Navy, and Marines. Since that time, the mission of the DoDSR has expanded to include the collection and storage of operational deployment specimens as well as Air Force specimens. Specimens contained in the DoDSR are available to researchers and other investigators within the DoD for the purposes of conducting militarily relevant investigations.
- **Millennium Cohort Program (<http://millenniumcohort.org>):** The Millennium Cohort Study (MCS) and the Millennium Cohort Family Study together make up the Millennium Cohort Program (MCP) at the Naval Health Research Center, San Diego, CA. The MCS is the largest prospective health study in U.S. military history, and has approximately 200,000 participants. The purpose of the MCS is to evaluate the impact of military experiences, including deployment, on long-term health outcomes of Service members, and to provide strategic policy recommendations that inform leadership and guide interventions. The MCS provides the DoD with unique data capabilities given the ability to: collect data via survey that is not collected elsewhere; to assess temporal sequence of exposures and outcomes or disease; to track Service members after they leave military service; and to link survey data with other enterprise data sources. Access to MCS data and biospecimens requires collaboration with one of the MCS investigators and approval of the MCS oversight committee by way of a preproposal/proposal process.
- **Million Veteran Program (<http://www.research.va.gov/MVP/default.cfm>):** The VA's Million Veteran Program (MVP), with over 445,000 enrolled veterans, 32 percent of whom have reported a cancer diagnosis, provides a potential rich clinical database for genetic exploration and analyses.

Multi-Institutional Research: A partnership with a DoD training installation or local academic institution or Federal/national laboratory is allowed. Note, regardless of location, any work that is to be performed by associated non-DoD organizations must be limited to work performed under existing service contracts, under Cooperative Agreements, CRADAs, or Material Transfer Agreements. An awardee may, in accordance with his/her research project, use the funds to collaborate with Federal (DoD and non-DoD) and non-Federal entities in order to execute the research. If the proposed research is multi-institutional, plans for communication, funding, and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, must be included in the appropriate sections of the application. *A separate intellectual and material property plan agreed upon by*

all participating institutions is also required for multi-institutional research. A letter of support from an authorized representative of each respective organization must be enclosed with the submitted application. Participating institutions must be willing to resolve potential intellectual and material property issues and to remove any barriers that may interfere with achieving high levels of cooperation to ensure successful completion of this award.

Military Relevance: Relevance to the healthcare needs of military Service members and other beneficiaries is a key feature of this award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate military relevance:

- Explanation of how the project has direct relevance to DoD healthcare personnel, recipients, and other beneficiaries
- Use of military populations or data in the proposed research
- Collaboration among DoD investigators
- Involvement of military consultants (Army, Air Force) or specialty leaders (Navy, Marine Corps) to the Surgeons General in a relevant specialty area

Use of Military and VA Populations or Resources: If the proposed research involves access to military and/or VA population(s) and/or resource(s), the Principal Investigator (PI) is responsible for establishing access. If possible, access to target military and/or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest-ranking person with approval authority, should be included for studies involving military Service members, Veterans, military, and/or VA-controlled study materials, and military and/or VA databases. *If access cannot be confirmed at the time of application submission, the DHA reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.*

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 Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. *Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.* Refer to [Appendix 3.B.2](#), and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. Specific

documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” *Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies*. Refer to [Appendix 3.B.1](#), for additional information.

Rigor of Experimental Design: All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards were written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in research and should be applied consistently across basic and translational studies. Projects that include research on animal models are required to submit [Attachment 9, Animal Research Plan](#), as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at https://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf.

Data Sharing: The DHA and CDMRP expect that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity will 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 [Appendix 2, Administrative Information](#).

Federal Interagency TBI Research (FITBIR) Informatics System: For studies that will enroll TBI subjects, the DoD requires that the awardees make data available to the TBI research community by depositing de-identified research data into the FITBIR Informatics System on a quarterly basis. The FITBIR Informatics System is a free resource to the TBI community designed to accelerate comparative effectiveness research on brain injury diagnosis and treatment. Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and collaborate with others performing similar research. While use of the informatics system presents no direct cost to the user, a *project estimation tool* (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate indirect cost and manpower needs associated with data submission.

- In order to facilitate FITBIR compliance, it is recommended that investigators contact the FITBIR Operations Center (FITBIR-ops@mail.nih.gov) during the application development phase to discuss submission requirements and potential IRB submission modifications.
- All reasonable efforts should be made to ensure that data elements are reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI Common Data Elements (CDEs), which are housed within the FITBIR data dictionary

(<https://fitbir.nih.gov/content/data-dictionary>). Use of these TBI CDEs, as published, is required to facilitate data sharing and collaboration through the usage of standard definitions across studies. *If the proposed research data cannot be entered in CDE format, the investigators must supply a proposal for an alternative data submission or data sharing vehicle and justification for its use.* FITBIR Operations can provide assistance in mapping study variables to specific CDEs. If necessary, FITBIR Operations will work with researchers to create new, unique data elements when suitable data elements are not available in the FITBIR data dictionary.

Additional information, including the advantages of FITBIR use to the researcher, is detailed at the FITBIR website (<http://fitbir.nih.gov/>).

If the project includes systems biology (SB)-related research, the PI may be required to make SB data available to the research community by depositing research data into the SysBioCube system (<https://sysbiocube-abcc.ncifcrf.gov/>).

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

D. Eligibility Information

- **Organization:** Intramural DoD organizations are eligible to submit applications. An intramural DoD organization is defined as a DoD laboratory, MTF, or activity embedded within a civilian medical center. Submissions from extramural (non-DoD) organizations will be rejected.
- **Principal Investigator:** Independent intramural investigators are eligible to apply. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory, MTF, or activity embedded within a civilian medical center. Submissions from extramural (non-DoD) investigators will be rejected. The majority of work funded through this Program Announcement/Funding Opportunity is required to be performed within the intramural DoD organization. It is permissible, however, for an extramural investigator to be named as a collaborator in a submission from an intramural investigator. In such cases, the intramural organization will receive all funds and is responsible for executing all necessary awards to collaborating partners through their agency's procedures. Note, regardless of location, any work that is to be performed by associated non-DoD organizations must be limited to work performed under an existing service or research contract or Cooperative Agreement,. FY17 CRII MWHRA funding will not be used to support new awards to extramural organizations.

E. Funding

Submissions selected for funding will be processed for funding by the USAMRMC and funds will be transferred to organizations, not individuals. Funding to intramural organizations will be executed through the MIPR or 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.

- The maximum period of performance is **3** years.
- The anticipated total costs budgeted for the entire period of performance will not exceed **\$750,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$750,000** total costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs associated with an intramural or extramural collaboration 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.
- Regardless of the period of performance or number of collaborators proposed, the applicant may not exceed the maximum allowable total costs.
- Institutions funded through this Program Announcement/Funding Opportunity must ensure that all FY17 funds will be obligated by September 30, 2018.

For this award mechanism, direct costs must be requested for:

- Travel costs for the PI to disseminate project results at one DoD In Progress Review (IPR) per year. The dates for these meetings will be determined during the performance period. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary, including contract personnel (Federal salaries paid by the parent organization may not be reimbursable)
- Research supplies
- Equipment
- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations, including travel

- Travel costs for up to one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above.
- Travel costs are intended for the PI or his/her designee only. Justification must be provided if other personnel are included in the travel budget.

The DHA expects to allot approximately \$5.0M of the anticipated FY17 DHP RDT&E appropriation to fund approximately seven Military Women’s Health Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission and (2) application submission through the electronic Biomedical Research Application Portal (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. It is the applicant’s responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

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

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

A. Pre-Application Submission Content

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

All pre-application components must be submitted by the initiating 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, collaborators, 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:

- **Tab 1 – Application Information**
- **Tab 2 – Application Contacts**
 - Enter contact information for the PI. Enter the organization’s resource manager/ comptroller or equivalent Business Official and Authorized Business Official responsible for sponsored program administration. The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
 - Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, and click on “*Add Organizations to this Pre-application.*” The organization(s) must either be selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.
 - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Tab 3 – Collaborators and Key Personnel**
 - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
 - To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For 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.shtml>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government.
- **Tab 4 – Conflicts of Interest (COIs)**
 - 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).

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

The Preproposal Narrative should include the following:

- **Alignment with Priority Areas:** Identify the FY17 MWHRA Priority Area(s) that the proposed research addresses. Explain how the proposed research is relevant to the identified Priority Area(s) and the intent of the award mechanism with respect to military women’s health.
- **Research Plan:** Concisely state the ideas and reasoning on which the proposed work is based. State the project’s hypotheses, objectives, specific aims, and briefly describe the experimental approach.
- **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research project.
- **Impact and Military Relevance:** Describe, if successful, the extent to which study could impact research and improve military women’s health and promote the health, readiness, and performance of women Service members and the Joint Force. Describe how well the proposed study will directly or indirectly benefit military Service members and other beneficiaries.

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

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- **Key Personnel Biographical Sketches (six-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.
- **Quad Chart:** Complete the Quad Chart template, a one-page PowerPoint file that must be downloaded from the CDMRP eBRAP System at <https://ebrap.org/eBRAP/public/Program.htm>, and save using Adobe Acrobat Reader as a PDF file.

- **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 CRII, pre-applications will be screened based on the following criteria:

- **Alignment with Priority Areas:** Whether the proposed research addresses at least one of the FY17 CRII MWHRA Priority Areas and meets the intent of the award mechanism.
- **Research Plan:** How well the rationale, hypotheses, objectives, specific aims, and experimental design support the research idea.
- **Personnel:** To what extent the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research project.
- **Impact and Military Relevance:** If successful, to what extent the study could improve military women’s health and promote the health, readiness, and performance of women Service members and the Joint Force. Whether the proposed study will directly or indirectly benefit military Service members and other beneficiaries.

- **Notification of Pre-Application Screening Results**

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

B. Full Application Submission Content

The pre-application process in eBRAP must be completed before the application can be submitted. After pre-application submission, go to “My Applications” and click on “Start Full Application” for the log number under which the pre-application was submitted.

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

All application components must be submitted by the indicated application deadline by the PI through eBRAP (<https://eBRAP.org/>). Material submitted after the deadline, unless specifically requested by the Government, will not be forwarded for processing. *The organization’s Business Official or Authorized Organization Representative (or resource manager/ comptroller) must approve/verify the full application submission prior to the verification/approval deadline.*

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

eBRAP application package components: For the FY17 CRII MWHRA, the eBRAP application package includes the following components, which are organized in eBRAP by separate tabs. **To access these tabs, go to “My Applications” and click on “Start Full Application”** for the log number under which the pre-application was submitted.

Tab 1 – Summary: Provides a summary of the application information.

Tab 2 – Application Contacts: This tab will be populated by eBRAP. Add Authorized Organization Representative.

Tab 3 – Full Application Files: Under each Application Component in eBRAP, upload each as an individual PDF file. Refer to [Appendix 1](#), for detailed formatting guidelines.

1. Application Component: Attachments. Each attachment must be uploaded as an individual PDF file unless otherwise stated.

- **Attachment 1: Project Narrative (20-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. ***This award may not be used to conduct clinical trials.***

- **Relevance:** Identify the required FY17 CRII MWHRA Priority Area(s) to be addressed by the proposed project. Explain the study’s relevance to the applicable Priority Area(s) and military women’s health.
- **Background:** Describe in detail the rationale for the study and include a literature review, preliminary studies, and preliminary data (if applicable) that led to the development of the proposed project. The background section should clearly explain the basis for the study questions and/or study hypotheses.
- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
- **Research Strategy and Feasibility:** Describe the research strategy, methods, and analyses, including appropriate controls, in sufficient detail for analysis of appropriateness and feasibility. Address potential problem areas and present alternative methods and approaches. If animal research is proposed, describe the model and its relevance to military women’s health and the proposed research. If cell line or animals are to be used, justify why the proposed cell lines(s) or animal model(s) were chosen. If human subjects or human

anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.

- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives as appropriate to the type of study. For research involving human subjects, specify the approximate number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size (animal or human) is appropriate to meet the objectives of the study. Address potential problem areas and present alternative methods and approaches.
- **Attachment 2: Supporting Documentation. Start each document on a new page.** Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.*
 - **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
 - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
 - **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
 - **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
 - Intangible property acquired, created, or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315.
 - **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. If relevant, PIs may be required to report research data

to the FITBIR informatics system (<http://fitbir.nih.gov/>) or to the SysBioCube (<https://sysbiocube-abcc.ncifcrf.gov/>). See Appendix 2 for additional information.

- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The technical abstract should be written using the outline below.

- **Background:** Present the ideas and reasoning behind the work.
- **Objective/Hypothesis:** State the objectives/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design including appropriate controls.
- **Impact:** Identify the FY17 CRII MWHRA Priority Area(s) to be addressed, and briefly describe how the proposed research will impact those area(s) toward improving military women’s health.

- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.***

- Clearly describe the objectives and rationale for the proposed study in a manner readily understood by readers without a background in science or medicine.
- Identify the FY17 CRII MWHRA Priority Area(s) to be addressed and briefly describe how the proposed research will impact those area(s). State how the proposed studies are relevant to military women’s health.
- Clearly describe the problem or question to be addressed and the ultimate applicability and impact of the research.
 - Who will it help, and how will it help them?
 - What are the potential applications and benefits?
 - What is the projected time it may take to achieve an actionable outcome?
 - If the research is too basic for immediate fielding or clinical applicability, describe the interim outcomes.

- **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>). There is no limit to the number of specific aims, tasks, or subtasks to be described within the SOW page limit.
- **Attachment 6: Quad Chart: Upload as “Quad.ppt.”** Provide an updated Quad Chart for the proposed project. The format for the quad chart is available on eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
- **Attachment 7: Impact and Military Relevance (1-page limit): Upload as “Impact.pdf.”** State explicitly how the proposed work will impact military women’s health. Describe the anticipated short- and/or long-term outcomes of the proposed project and their potential impact on improving military women’s health. Describe how the proposed materiel or knowledge product represents an improvement to currently available pharmacology agents, devices, or clinical guidance. Describe how the proposed work will directly or indirectly benefit military women Service members and other beneficiaries.
- **Attachment 8: Letters of Support (limit each letter to two pages): Combine and upload as a single file named “Letters.pdf.”** Start each document on a new page.
 - Resource Manager/Comptroller: Provide a letter of support from the applicant institution’s Resource Manager/Comptroller (or appropriate financial point of contact) assuring that the institution will be able to accept and obligate FY17 DHP RDT&E PE 6.3 funds by 30 September 2018, if selected for funding. If funds are to be sent to multiple sites, include a letter from each site.
 - Commander(s): Provide a letter(s) of support from appropriate Installation Commander or equivalent Commander/Director to ensure access to the facility, research population, and other necessary resources. The Commander should be aware of all submissions and should confirm that the proposed work is both feasible from a technical perspective and relevant from a programmatic and command perspective. The letter(s) should provide clear evidence of organizational commitment for the coordinating administrative tasks and for the use of facilities and resources necessary for the proposed work at each participating study site.
 - Partnership/Collaboration (if applicable):
 - If the project includes partnership/collaboration with a non-DoD entity, provide a signed letter from each partner/collaborator that describes their contribution to the project and demonstrates support and availability of any resources necessary for the proposed work.
 - If the project involves collaboration with another DoD researcher, provide a letter from the commanding officer or military facility director authorizing his/her participation in the research project.

- Access to Military or VA Populations and/or Resources (if applicable): If the proposed research plan involves access to active duty military and/or VA populations, patients, data or resources, include letter(s) of support, signed by the lowest-ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.
- **Attachment 9: Animal Research Plan (if applicable, two-page limit per animal study):** Start each animal study on a new page headed by the name of the PI and title of the animal study. Combine and upload as a single file named **“AnimalResearchPlan.pdf.”**

When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study’s relevance to human biology.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Attachment 10: Human Subject Recruitment and Safety Procedures (if applicable, required for all studies recruiting human subjects; no page limit): Upload as “HumSubProc.pdf.”** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
 - a. **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent

demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical studies (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided. ***For clinical studies proposing to include military personnel as volunteers, refer to [Appendix 3.B.9](#), for more information.***

- b. Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical study. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

Inclusion of Women and Minorities in Study. Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical study.

- c. Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, and healthcare provider identification).

- Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
- Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
- Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

- d. Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.

- Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects’ questions will be addressed during the consent process and throughout the study.
- Include information regarding the timing and location of the consent process.

- Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
 - Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
 - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
 - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical study to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>).
 - **Assent.** If minors or other populations that cannot provide informed consent are included in the proposed clinical study, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- e. **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.
- f. **Risks/Benefits Assessment:**
- **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical study. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

- **Risk management and emergency response:**
 - Describe how safety surveillance and reporting to the IRB and U.S. Food and Drug Administration (FDA) (if applicable) will be managed and conducted.
 - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
 - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
 - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, and pregnancy prevention).
 - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
 - For a study in which the IRB determines there is greater than minimal risk to human subjects, the DoD requires an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol. If applicable, refer to [Appendix 3](#) for more information on study reporting authorities and responsibilities of the research monitor.
- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.

2. Application Component: Key Personnel

- Each of these application components should be included for the PI and each individual identified as Key Personnel. Each attachment must be uploaded as an individual PDF file unless otherwise stated.
 - **Research & Related Senior/Key Person Profile (Expanded) Form:** Upload the completed Research & Related Senior/Key Person Profile (Expanded) Form as “Key Personnel.pdf.”
 - **PI Biographical Sketch (six-page limit):** Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The five-page NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

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

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

3. Application Component: Budget. Use the DoD Military Budget Form available on the “Funding Opportunity and Forms” page in eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). Refer to [Appendix 4](#) for detailed information on completing this form.

- Upload the DoD Military Budget Form as “Budget_LastName.pdf.”
- Budget Justification (no page limit): Upload as “BudgetJustification_LastName.pdf.” The budget justification must include a Federal Agency Financial Plan, as described in [Appendix 4](#).
- Subaward Budget: Include all Subaward budgets. Describe in detail funding arrangements with extramural partners (if applicable). Complete a separate detailed budget using the DoD Military Budget Form including a budget justification for each subaward (subgrant or subcontract) in accordance with the instructions listed above. Title each individual subaward, “Budget,” and “Budget Justification,” with the name of the subawardee/subrecipient organization,

4. Application Component: Project/Performance Site Location(s) Form. Use the Project/Performance Site Location(s) Form available on the “Funding Opportunity and Forms” page in eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). Upload as “Performancesites.pdf.”

On the Project/Performance Site Location(s) Form, indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. Add more sites as necessary using the “Next Site” button. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach it to this form. Each additional research site requesting funds will require a subaward budget.

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.

Tab 5 – Submit/Request Approval Full Application

Once all components have been uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here”

and press the “Submit Full Application” button. eBRAP will validate files against the Program Announcement/Funding Opportunity requirements and discrepancies will be noted. If no discrepancies are noted, press the “Confirm Submission” button to complete the application submission. **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 Approval deadline.**

C. Submission Dates and Times

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

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the 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 CRII, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section III.B.2, Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization’s application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Process

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

- **Impact and Military Relevance**

- How well the proposed study addresses at least one of the FY17 CRII MWHRA Priority Areas.
- To what degree the anticipated short- and long-term outcomes of the proposed project will impact the advancement of military women's health research and MHS healthcare.
- How well the anticipated research outcomes directly or indirectly address the healthcare needs of military Service members, Veterans, and/or other MHS beneficiaries.

- **Research Strategy and Feasibility**

- To what degree the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, logical reasoning, presentation of background information, and preliminary data (if applicable).
- How well the study aims, hypotheses, objectives, experimental design, methods, data collection procedures, and analyses are designed to clearly answer research objective.
- If applicable, whether the proposed animal model is appropriate.
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
- How well the PI acknowledges potential problems and addresses alternative approaches.
- How well the PI has outlined a plan for management and sharing of research data as appropriate for the study.
- Whether the statistical analysis plan, including sample size projections and power analysis, is adequate to achieve the study objectives and is appropriate for the proposed study.

For applications proposing research involving human anatomical substances or human subjects:

- How well the sample population represents the targeted population that might benefit from the research.
- How well the PI addresses the availability of human subjects or samples.
- Whether the PI has demonstrated access to the proposed subject population or samples.

- **Personnel**
 - Whether the research team’s background and expertise are appropriate to accomplish the proposed work.
 - Whether the levels of effort by the PI and other key personnel are appropriate to ensure the successful conduct of the project.
 - If applicable, to what extent the proposed partnership or collaboration represents a significant contribution to the proposed research project.
 - Whether the proposed work supports the intent of the award mechanism by supporting research at MTF’s.
- **Environment**
 - The degree to which the scientific environment is appropriate for the proposed research.
 - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
 - To what degree the quality and extent of institutional support are appropriate.
 - Whether there is sufficient evidence of a plan to resolve intellectual and material property issues, if applicable.

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

- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
 - Whether there is a plan for supporting non-DoD collaborations needed for research.
 - Whether there is a sufficient plan outlining how all FY17 funds will be obligated by September 30, 2018.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.

2. Programmatic Review: To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

a. Ratings and evaluations of the peer reviewers

b. Relevance to the mission of the DHP and the CRII as evidenced by the following:

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Programmatic relevance to the FY17 CRII MWHRA Priority Areas
- Relative military benefit and impact

C. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

D. Notification of Application Review Results

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications and applications from eBRAP, the following administrative actions may occur:

A. Rejection

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

- Preproposal Narrative is missing.
- Preproposal Narrative exceeds page limit.
- Preproposal was submitted by an ineligible organization; see [Section I.D., Eligibility Information](#), for details.

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 is missing.
- Project Narrative exceeds page limit.
- Budget is missing.

B. Modification

- Pages exceeding the specific limits will be removed prior to review.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents. The missing documents

must be provided by the deadline specified. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

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

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Total costs as shown on the DoD Military Budget Form exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Letters of support are missing.
- 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).
- The PI does not meet the eligibility criteria.
- 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.shtml>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government.

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 CDMRP for a determination of the final disposition of the application.

V. ADMINISTRATIVE INFORMATION

A. Notice

Funds will be transferred no later than September 30, 2018. Refer to [Appendix 2](#) for additional award administration information.

B. Administrative Requirements

Refer to [Appendix 2](#) for general information regarding administrative requirements.

C. Reporting

Refer to [Appendix 2](#) for general information on reporting requirements.

Quarterly, annual, and final technical progress reports and quad charts will be required.

In addition to written progress reports, in-person presentations may be requested.

D. Transfers

Transfer of funding for this project to a non-DoD institution is not allowed. The award may be transferred to another PI within the same institution. Approval of a PI transfer request will be on a case-by-case basis at the discretion of the FY17 CRII MWHRA Program Manager.

F. Site Visits

DHA and CDMRP personnel may, at their discretion, perform site visits during the award period of performance.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

B. FY17 CRII MWHRA Point of Contact

Questions regarding award mechanism intent and requirements should be directed to the FY17 CRII MWHRA Program Manager, CDR Alexis Mosquera.

Phone: 301-619-7906

Email: Alexis.Mosquera.mil@mail.mil

VII. APPLICATION SUBMISSION CHECKLIST

Application Components	Upload Order	Action	Completed
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Quad Chart: Upload as Attachment 6 with file name "Quad.ppt."	
	7	Impact and Military Relevance: Upload as Attachment 7 with file name "Impact.pdf."	
	8	Letters of Support: Upload as Attachment 8 with file name "Letters.pdf."	
	9	Animal Research Plan (if applicable): Upload as Attachment 9 with file name "AnimalResearchPlan.pdf."	
	10	Human Subject Recruitment and Safety Procedures: Upload as Attachment 10 with file name "HumSubProc.pdf" (if applicable; required for all studies recruiting human subjects).	
Key Personnel		Research & Related Senior/Key Person Profile (Expanded): Upload as "Key Personnel.pdf."	
		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Budget		Upload Budget (Budget_LastName.pdf) and Budget Justification (BudgetJustification_LastName.pdf), and Subaward Budgets and Budget Justifications as applicable.	
Project/Performance Site Location(s) Form		Complete form as instructed.	

APPENDIX 1 FORMATTING GUIDELINES

All pre-application and application documents must be legible and should conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on a computer screen.

Document Format: All attachments must be in PDF.

Font Size: 12 point, 10 pitch.

Font Type: Times New Roman.

Spacing: Single space or no more than six lines of type within a vertical inch (2.54 cm).

Page Size: No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).

Margins: At least 0.5 inch (1.27 cm) in all directions.

Print Area: 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).

Color, High-Resolution, and Multimedia Objects: Project narratives and pre-application files may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects should not exceed 15 seconds in length and a size of 10 MB. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.

Scanning Resolution: 100 to 150 dots per inch.

Internet URLs: URLs directing reviewers to websites that contain additional information about the proposed research are not allowed in the application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. However, links to publications referenced in the application are encouraged.

Language: All documents must be submitted in English, unless otherwise specified in the Program Announcement (e.g., foreign transcripts submitted with English translations).

Headers and Footers: Should not be used. Pre-existing headers and footers on required forms are allowed.

Page Numbering: Should not be used.

Recommended Component Size: Each attachment should not exceed 20 MB.

APPENDIX 2 ADMINISTRATIVE INFORMATION

A. Reporting Requirements

Reporting requirements and deliverables will be determined prior to funding and may vary depending on the research being conducted. Anticipated reporting requirements and deliverables may include the following:

Progress Reports: Quarterly, annual, and final reports will be required. These reports will present a detailed summary of scientific issues and accomplishments. A final report will be submitted within 30 days of the end of the performance period and will detail the findings, their potential impact to the military or Veteran population, and other issues for the entire project. The format for the progress reports is available on eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.

Quad Charts: Quad Charts that outline the specific aims, approach, timeline and costs, and goals/milestones will be required with every quarterly report. The format for the quad chart is available on eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.

B. Publication, Acknowledgement, and Public Release

Publication of Findings: Publication of findings is a requirement of this submission. It is expected that at study completion researchers will submit their findings to an appropriate peer-reviewed journal for publication. Copies of all scientific publications, presentations, and reports resulting from this funding mechanism shall be submitted to CDMRP when published or completed even if beyond the period of performance to allow reporting to the DHP and Congress on the accomplishments of the program.

Acknowledgment: The recipient agrees that in the release of information relating to this funding such release shall include the statements below, as applicable. “Information” includes, but is not limited to, news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.

- “This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency J9, Research and Development Directorate through the Clinical Research Intramural Initiative. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.”
- “In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture.” Include required assurances, approvals, documents and information specified on the Animal Care and Use Review Office (ACURO) website (https://mrmc.detrick.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1).
- “In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules.” (<http://www.nih.gov>)

- “In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.” (<http://www.cdc.gov/biosafety>)

C. Sharing of Data and Research Resources

It is the intent of the Department of Defense that data and research resources generated by this funded research be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.

Expectations for sharing of data and research resources apply to all basic research, clinical studies, surveys, and other types of research funded through this award. This includes all data and research resources generated during the project’s period of performance through grants, cooperative agreements, or contracts. It is critically important to share unique data and research resources that cannot be readily replicated, including but not limited to the following:

- **Unique Data**¹ are defined as data that cannot be readily replicated. Examples of unique data include large surveys that are expensive to replicate; studies of unique populations, such as patients to whom access is not widely available; studies conducted at unique times, such as during military conflict; studies of rare phenomena, such as rare diseases.
- **Final Research Data**² are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not the summary statistics or tables; rather, final research data are the data on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.
- **Research Resources**³ include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.

Data and research resources generated from this funded research should be made as widely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data, and third-party intellectual property. By sharing and leveraging data and research resources, duplication of very expensive and time-consuming efforts can be avoided, allowing for the support of more investigators with Federal funds. Such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health.

¹ Adapted from http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique

² Adapted from http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique

³ Adapted from <http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf>

The PI may be required to participate in the following:

- Traumatic Brain Injury: If the project includes traumatic brain injury (TBI) research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) informatics System (<https://fitbir.nih.gov>).
- Systems Biology: If the project includes systems biology (SB)-related research, the PI may be required to make SB data, generated via an award, available to the research community by depositing research data into the SysBioCube system (<https://sysbiocube-abcc.ncifcrf.gov/>).

For additional information on data-sharing, refer to the document titled “Congressionally Directed Medical Research Programs: Policy on Sharing Data and Research Resources,” available on eBRAP under Reference Material at <https://ebrap.org/eBRAP/public/Program.htm>.

APPENDIX 3 REGULATORY REQUIREMENTS

A. Surety, Safety, and Environmental Requirements

Based on recent changes to Department of Defense (DoD) compliance requirements (DA PAM 385-69, **DA PAM 385-10**, 32 CFR 651 6 September 2012), provisions previously requested for Safety and Environmental Compliance have been removed. However, in certain instances, compliance review may require submission of additional documentation prior to the awarding of any assistance agreement. Such instances may include use of Army-provided infectious agents or toxins, select biological agents or toxins, select chemical agent(s), or pesticides outside of an established laboratory. The U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Surety, Safety, and Environment will identify any need for compliance review and documents must be submitted upon request.

B. Research Protections Review Requirements – Use of Human Subjects, Human Anatomical Substances, Human Data, Human Cadavers, and Animals

The USAMRMC Office of Research Protections (ORP) ensures that research conducted, contracted, sponsored, supported, or managed by the USAMRMC and involving human subjects, human anatomical substances, human data, human cadavers, and animals are conducted in accordance with Federal, DoD, Army, USAMRMC, and international regulatory requirements.

Principal Investigators (PIs) and applicant organizations **may not commence performance** of research involving the above, **or expend funding** on such efforts, until and unless regulatory documents are submitted and approved by the USAMRMC ORP to ensure that DoD regulations are met. All expectations described below are consistent with the DoD Instruction (DoDI) 3216.01, “Use of Animals in DoD Programs,” as issued 13 September 2010, available at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_regulations and DoDI 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research,” as issued on 8 November 2011, and available at <http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>.

The ORP Animal Care and Use Review Office (ACURO) is responsible for administrative review, approval, and oversight of all animal research protocols, including all changes made during the life of the protocol.

The ORP Human Research Protection Office (HRPO) is responsible for administrative review, approval, and oversight of research involving human subjects, human anatomical substances or data, and use of human cadavers. ***Research involving use of human data and/or specimens that is anticipated to be exempt from human subjects protections regulations requires a determination from the PI’s institution as well as the ORP HRPO at USAMRMC.*** A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

1. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO, a component of the

USAMRMC ORP, must review and approve all animal use prior to the start of working with animals. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the Animal Use Appendix titled “Research Involving Animals.” For guidance on which version of the appendix to use, as well as links to both, visit the ACURO website at: https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_Animalappendix. *Allow at least 3 to 4 months for regulatory review and approval processes for animal studies.*

For additional information, send questions via email to ACURO (usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil).

2. Use of Human Cadavers or Human Anatomical Substances Obtained from Human Cadavers

Research, development, test and evaluation (RDT&E), education or training activities involving human cadavers shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview). The USAMRMC ORP is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy. Award recipients must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Written approvals to begin the activity will be issued under separate notification to the recipient. Questions regarding submission of cadaver research for USAMRMC ORP review and approval should be directed to the ORP at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil.

3. Research Involving Human Subjects, Human Subjects Data, or Human Anatomical Substances



In addition to local Institutional Review Board (IRB) review, investigators must submit all USAMRMC-funded research protocols involving human subjects and human anatomical substances for review and approval by the USAMRMC ORP HRPO prior to implementation of the research. The focus of this review is to validate IRB review as appropriate and ensure that DoD, Army, and USAMRMC regulatory requirements have been met.

Human subject research definitions, categories, and resource information may be found in the Human Subject Resource Document on the eBRAP website (<https://ebrap.org/eBRAP/public/Program.htm>). This information is a guide only; it is not intended to be a source for human subject protection regulations. Questions regarding applicable human subject protection regulations, policies, and guidance should be directed to the local IRB, the ORP HRPO (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), and/or the U.S. Food and Drug Administration (FDA) as appropriate. For in-depth information and to access HRPO protocol submission forms, refer to the ORP HRPO website (https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo).



ORP HRPO-required language must be inserted into the consent form, and compliance with DoD regulations may require additional information be included in the protocol.

The ORP HRPO ensures that DoD-supported and/or -conducted research complies with specific DoD laws and requirements governing research involving human subjects. These laws and requirements may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the ORP HRPO requirements must be addressed, and any changes to the already approved protocol must be approved as an amendment by the local IRB. It is strongly recommended that investigators carefully read the “Information for Investigators” found at https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_Animalappendix. The time to approval depends greatly on adherence to the requirements described within. If the protocol has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission.

Documents related to the use of human subjects or human anatomical substances will be requested if the application is recommended for funding. ***Allow at least 2 to 3 months for regulatory review and approval processes for studies involving human subjects.***

Specific requirements for research involving human subjects or human anatomical substances can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

4. **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current Department of Health and Human Services Office for Human Research Protection (OHRP) Federal-wide Assurance (FWA) or DoD Assurance.
5. **Training:** Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming completion of appropriate instruction may be required during the regulatory review process.
6. **Informed Consent Form:** The following must appear in the consent form:
 - A statement that the U.S. Department of Defense is providing funding for the study.
 - A statement that representatives of the DoD are authorized to review research records.
 - In the event that a Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DoD must be listed as one of the parties to whom private health information may be disclosed.
7. **Intent to Benefit:** The requirements of Title 10 of the United States Code Section 980 (10 USC 980), which are applicable to DoD-sponsored research, must be considered. 10 USC 980 requires that “Funds appropriated to the Department of Defense may not be used for research involving a human being as an *experimental subject* unless (1) the informed consent of the subject is obtained ***in advance***; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject.”

An individual not legally competent to provide informed consent (e.g., incapacitated individuals, cognitively impaired, minors) may not be enrolled as an ***experimental subject*** in a DoD-supported study unless the research is intended to benefit each subject enrolled in

the study, to include subjects enrolled in study placebo arms. Studies designed in a manner that permits all subjects to potentially benefit directly from medical treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements. Note that the definition of experimental subject as defined in the DoDI 3216.02 has a much narrower definition than human subject. Research with experimental subjects must involve an intervention or interaction where the primary purpose of the research is to collect data regarding the effects of the intervention or interaction.



10 USC 980 is only applicable to certain intervention studies. It does not apply to retrospective studies, observational studies, studies that involve only blood draws, and tissue collections. Contact the HRPO at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil if further clarification regarding applicability of 10 USC 980 to the proposed research project is required.

8. **Research Monitor Requirement:** *For research determined to be greater than minimal risk, DoDI 3216.02 requires that the IRB approve, by name, an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol.* The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities.

The research monitor's duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report his/her observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI's institution. Research monitor functions may include:

- Observing recruitment and enrollment procedures and the consent process for individuals, groups or units;
- Overseeing study interventions and interactions;
- Reviewing monitoring plans and Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO) reports; and/or
- Overseeing data matching, data collection, and analysis.

There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board. At a minimum, the research monitor:

- May discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
- Shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report; and,
- Shall have the responsibility for promptly reporting his or her observations and findings to the IRB or other designated official and the HRPO.

A curriculum vitae or biographical sketch and human subjects protection training for the research monitor must be provided. There should be no apparent conflict of interest, and the research monitor cannot be under the supervision of the PI, other investigators, or research staff associated with the proposed research project. If the duties of the research monitor could require disclosure of subjects' Protected Health Information outside a covered entity (i.e., the research monitor is not an agent of the covered entity), the PI's institution may require the identity and location of the research monitor to be described in the study HIPAA authorization. It is acceptable to provide appropriate compensation to the research monitor for his or her services.

9. Military Personnel Volunteers: The following is important information for research projects proposing to include military personnel as volunteers.

- **Recruitment of Military Personnel:** Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator familiar with service-specific requirements.

A letter of support from Commanders of military units in which recruitment will occur or the study will be conducted will be requested by the HRPO. Some military sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies.

Special consideration must be given to the recruitment process for military personnel. The Chain of Command must not be involved in the recruitment of military personnel and cannot encourage or order Service members to participate in a research study.

For greater than minimal risk research, an ombudsman must be employed when conducting group briefings with active duty personnel to ensure that volunteers understand that participation is voluntary; this ombudsman may be recommended in other situations as well, especially when young enlisted Service members, who by virtue of their age and enlistment status are trained to follow orders, are being recruited. Service members are trained to act as a unit, so peer pressure should also be considered and minimized, if possible.

- **Payment to Federal Employees and Military Personnel:** Under 24 USC 30, payment to Federal employees and active duty military personnel for participation in research while on duty is limited to blood donation and may not exceed \$50 per blood draw. These individuals may not receive any other payment or non-monetary compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.
- **Confidentiality for Military Personnel:** Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties and/or discharge from active duty. Information regarding alcohol or drug abuse, drunk driving, and sexual or spousal abuse can lead to actions under the Uniform Code of Military Justice, including incarceration and dishonorable discharge.

10. Site Visits: The USAMRMC ORP HRPO conducts site visits as part of its responsibility for compliance oversight.

Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.



Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

- 11. Protocol Submission Format:** The ORP HRPO accepts protocol submissions in the format required by the local IRB. The IRB protocol application, if separate from the protocol itself, should be included with protocol submissions. A HRPO protocol submission form should be completed and submitted with each protocol.

APPENDIX 4 BUDGET FORM INSTRUCTIONS

Complete the DoD Military Budget Form and Justification Form. Begin by entering the PI name, eBRAP Log number, and period of performance fields at the top of the DoD Military Budget Form. **DoD Civilian and Military Personnel:** Personnel involved in the project should be listed in this section; however, this award is not intended to provide salary support for any Federal employee, as those costs were to have been included in infrastructure costs. If salary support is requested, sufficient justification must be provided in the budget justification section.

- **Name:** Beginning with the PI, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, mentor (if applicable) and support staff.
- **Role on Project:** Identify the role of each personnel listed. Describe his/her specific functions in the proposed research in the budget justification.
- **Type of Appointment (Months):** List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The Government assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time (e.g., 50%), note this with an asterisk (*) and provide a full explanation in the budget justification. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.
- **Annual Base Salary:** Enter the annual organizational base salary (based on a full-time appointment) for each individual listed for the project.
- **Effort on Project:** List the percentage of each appointment to be spent on this project for all staff members including unpaid personnel.
- **Salary Requested:** Enter the salary for each position for which funds are requested. This is calculated automatically from the data provided. If you do not wish this to be calculated for you, uncheck the small "Calculate Salary" checkbox in the bottom of the field. Calculate the salary request by multiplying an individual's organizational base salary by the percentage of effort on the project.
- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines.
- **Totals:** Calculated automatically from the data provided.
- **Major Equipment:** Provide an itemized list of proposed equipment, showing the cost of each item. Equipment is any article of nonexpendable tangible property having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit.

- **Materials, Supplies, and Consumables:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies.
- **Travel Costs:** PIs are responsible for budgeting for all costs associated with travel, including airfare, hotel, etc., associated with the trip. Anticipated travel costs should be built into the budget at current or projected DoD per diem rates. Travel costs must include:
 - Travel costs for the PI to attend the required IPR meeting each year.
 Travel costs may include:
 - Travel costs for up to 1 investigator to travel to 1 scientific/technical meeting per year.
 - Travel costs between collaborating organizations.
- **Research-Related Subject Costs:** Include itemized costs of subject participation in the proposed research. These costs are strictly limited to expenses specifically associated with the proposed research.
- **Other Direct Costs:** Itemize other anticipated direct costs such as publication and report costs, equipment rental (provide hours and rates), communication costs, and organizationally provided services. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution. Organizationally provided services should be supported by the organization's current cost/rate schedule. These items should be described in detail and clearly justified.
- **Subcontract Costs (Partnership/Collaboration Costs):** Should an intramural organization propose collaboration with an extramural entity for part of the research effort, the intramural organization will receive all funds and is responsible for executing all necessary contractual or assistance funding awards to collaborating partners through the agency's procedures. **All direct and indirect costs of any partnership/collaboration costs must be included in the total direct costs of the primary award.** The nature of the partnership/collaboration should be described in the Budget Justification section.
- **Total Direct Costs:** Calculated automatically from the data provided for the initial budget period on page F-2 and for the entire proposed period of support on page F-3.
- **Total Indirect Costs:** If funds for indirect costs are requested, sufficient justification must be provided in the budget justification section. The Government reserves the right to disallow any indirect costs not sufficiently justified. All direct and indirect costs of any proposed collaborator must be included in the total direct costs of the primary award. (See [Section I.E., Funding.](#))
- **Total Costs:** This section is calculated automatically from the data provided.

- **Fee:** A profit or fixed fee is not allowable on awards or on subawards.
- **Budget Justification Instructions:** Provide a clear budget justification for each item in the budget over the entire period of performance in the Justification section of the DoD Military Budget Form. Itemize direct costs within each budget category for additional years of support requested beyond year one.
- **Federal Agency Financial Plan (required):** Provide a detailed Federal Agency Financial Plan after the budget justification information in the DoD Military Budget Form. The plan delineates how all FY17 funding will be obligated by **September 30, 2018**. The plan must include the funding mechanism(s) or contractual arrangements that will be used to carry over funds between fiscal years, if applicable. Any FY17 funding not obligated by September 30, 2018 may be withdrawn by the issuing Comptroller.