

## **I. OVERVIEW OF THE FUNDING OPPORTUNITY**

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Hearing Restoration Research Program**

**Focused Research Award**

**Announcement Type: Initial**

**Funding Opportunity Number: W81XWH-19-HRRP-FRA**

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

### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 16, 2019
- **Invitation to Submit an Application:** August, 2019
- **Application Submission Deadline:** 11:59 p.m. ET, November 14, 2019
- **End of Application Verification Period:** 5:00 p.m. ET, November 19, 2019
- **Peer Review:** January 2020
- **Programmatic Review:** March 2020

*This Program Announcement must be read in conjunction with the General Application Instructions, version 20190218. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”*

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## **II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY**

### **II.A. Program Description**

Applications to the Fiscal Year 2019 (FY19) Hearing Restoration Research Program (HRRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The HRRP was initiated in 2017 to support innovative and impactful research that pursues the treatment of auditory system injuries and the restoration of hearing. Appropriations for the HRRP from FY17 through FY18 totaled \$20 million (M). The FY19 appropriation is \$10M.

It is estimated that more than 30 million Americans over the age of 12 have hearing loss in both ears and an estimated 48 million have hearing loss in at least one ear. The most recent data from the Department of Veterans Affairs (VA) indicates that there are 1.1 million Veterans with Service-connected disability due to hearing loss. The HRRP will fund innovative research that has the potential to maximize operational performance, medical readiness, and quality of life for Service members, Veterans, and others living with significant auditory system injuries.

#### **II.A.1. FY19 HRRP Focused Research Award (FRA) Focus Areas**

**To meet the intent of the award mechanism, all applications to the FY19 HRRP FRA must address research in one or more of the following Focus Areas:**

- Develop or validate techniques/methods to assess, diagnose, or treat auditory dysfunction as related to synaptopathy, hidden hearing loss, and central auditory processing disorders. Examples include, but are not limited to:
  - Diagnostic tests that help differentiate sensory, neural, synaptic, and central processing disorders
  - Diagnostic tools for use in forward or remote deployed settings to assess hidden hearing loss and to inform whether the individual's hearing capability is sufficient to perform the duties of the job or work assignment
  - Treatments for the various types of damage that result in the auditory dysfunction leading to decreased ability to adequately perform the duties of the job or work assignment
- Accelerate translation of biological regeneration/repair mechanisms into therapies that restore auditory function. Examples include, but are not limited to:
  - Treatments to enhance synaptic plasticity
  - Hair cell regeneration/repair/recovery

- Neural regeneration/repair/recovery
- Develop reliable in-vitro human models for evaluating hearing restoration therapies

**Tinnitus or vestibular-related research is excluded.**

## **II.A.2. Award History**

The HRRP FRA Award mechanism was first offered in FY17. Since then, 15 FRA applications have been received, and 6 have been recommended for funding.

## **II.B. Award Information**

The FY19 HRRP FRA mechanism is intended to support promising research that will accelerate drug discovery and therapeutic development for hearing restoration or accelerate advances in the assessment, diagnosis, and treatment of auditory dysfunction. The proposed research must be relevant to active duty Service members, Veterans, military beneficiaries, and/or the American public. Applications involving multidisciplinary collaborations among academia, industry, the military Services, the VA, and other Federal Government agencies are highly encouraged.

Compared to the general public, military personnel face higher risks of noise-induced hearing loss and auditory system injury. Service members are exposed to high levels of noise (e.g., gunshots, helicopters, explosions, aircraft take-off from carrier deck, etc.) unique to military operating and training environments. In contrast with exposure to noise in construction, agriculture, and recreation, encountering combat noise is not predictable, and protection against combat noise is further complicated by the need for Warfighters to hear sound and to communicate. Exposure to loud noise triggers hearing loss and auditory dysfunction that not only put the affected Service member at increased risk on the battlefield, but may also endanger others in the unit and the mission.

Currently, no drug has been approved by the U.S. Food and Drug Administration (FDA) to treat hearing loss. Although significant progress has been made in the molecular and cellular understanding of hearing loss and regeneration mechanisms in the inner ear, the majority of research is preclinical, and the findings need to be verified in more clinically relevant research and translated to clinical applications.

Noise exposure may induce auditory dysfunction such that an individual's hearing sensitivity is within normal limits but the capacity to listen and understand speech is substantially impaired. This type of auditory dysfunction is often referred to as "hidden hearing loss" because it is not readily diagnosed through typical hearing tests. The underlying cause for hidden hearing loss is not well understood; proposed causes include synaptopathy and central auditory processing disorder. If a Service member cannot effectively hear battlefield communication and sounds, s/he may pose a danger to self, others in the unit, and the mission. There is a great need for validated and reliable techniques and methods to detect and assess this type of auditory dysfunction, especially techniques and methods that can be applied by a non-specialist (e.g., physician assistant, medic, or corpsman) in the operational/austere environment (e.g., Forward Operating Base or Battalion Aid Station) to quickly screen Service members for combat

readiness. Techniques and methods are further needed to identify the damaged component(s) of the auditory system or pathway. The ability to diagnose and measure sensory, neural, synaptic, or central auditory integrity/function is crucial for the design and implementation of successful clinical trials and hence for the development of therapeutics and intervention.

To support research projects at different stages and the exploration/development of ideas of different maturity levels, two different funding levels are available under this Program Announcement. ***When submitting the pre-application, it is the responsibility of the applicant organization to select the funding level that is most appropriate for the research proposed. The funding level should be selected based on the stage and maturity level of the research project, rather than the amount of the budget.***

- **Funding Level 1** supports exploratory, high-risk/high-reward research that is in the earliest stages of idea development. Research must have the potential to yield new avenues of investigation, such as new approaches, new research tools, or new paradigms.
  - No preliminary data is required. However, applicants must provide solid rationale of the research idea, supported by literature.
  - The investigating team must have sufficient expertise to test the research idea.
- **Funding Level 2** supports the advancement of more mature research toward clinical translation.
  - ***Preliminary data supporting the readiness and feasibility of the proposed research are required.***

The FY19 HRRP FRA may be used to support preclinical studies in animals and/or clinical research involving human subjects and human anatomical substances. **The FY19 HRRP FRA Funding Level 2 also allows funding for a pilot clinical trial component, where limited clinical testing of a novel intervention is necessary to inform the feasibility, rationale, and design of subsequent clinical trials.** Such pilot clinical trial studies should be small in scale, represent only a portion of the proposed Statement of Work, and be utilized to establish feasibility of a potential approach or to aid in intervention refinement. Applications that do include a pilot clinical trial as part of the proposed research will have additional submission requirements and review criteria.

***New FY19 definition:*** A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. The interventions may be in the form of a device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other. The effects may be related to safety, effectiveness, and/or efficacy. For more information on how to distinguish clinical research from clinical trials, see the Human Subject Resource Document at <https://ebrap.org/eBRAP/public/Program.htm>.

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available Federal website in accordance with Federal requirements described in the Code of Federal Regulations, Title 32, Part 219 (32 CFR 219).

The anticipated direct costs budgeted for the entire period of performance for an **FY19 HRRP FRA Funding Level 1 will not exceed \$250,000**. The anticipated direct costs budgeted for the entire period of performance for an **FY19 HRRP FRA Funding Level 2 will not exceed \$1,000,000 or \$1,250,000 for applications with a pilot clinical trial option**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

*The CDMRP expects to allot approximately \$8.8M to fund approximately nine HRRP FRA applications. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.*

Awards will be made no later than September 30, 2020. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of the Department of Defense (DoD) during project performance is the key factor in determining whether to award a grant or cooperative agreement.

An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305) and the award will identify the specific substantial involvement. Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

**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 (<https://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 8, 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.nc3rs.org.uk/sites/default/files/documents/Guidelines/NC3Rs%20ARRIVE%20Guidelines%202013.pdf>.

**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.*** Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Applications that involve recruitment of human subjects must indicate the quarterly enrollment targets across all sites in [Attachment 5: Statement of Work \(SOW\)](#). Successful applicants will work with USAMRAA to establish milestones for human subjects recruitment. Continued support for the project will be based upon satisfactory progress in meeting the established milestones. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

**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. Principal Investigators (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 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

**Use of DoD or VA Resources:** If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD

resource(s) or database(s) should be confirmed by including a letter of support signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs/co-PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information.

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

## **II.C. Eligibility Information**

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

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

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

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

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

**Intramural DoD Organization:** A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center.

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

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

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

Independent investigators at all academic levels (or equivalent) are eligible to be named by the recipient organization as PI on the applications.

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

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

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

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

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

There are no limitations on the number of applications an investigator may submit.

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

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

## **II.D. Application and Submission Information**

***Extramural Submission:*** An application submitted by an organization to Grants.gov.

***Intramural DoD Submission:*** An application submitted by a DoD organization to eBRAP.

### **II.D.1. Address to Request Application Package**

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

#### ***Extramural Submissions:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](https://eBRAP.org).
- Full application packages must be accessed and submitted at Grants.gov.

#### ***Intramural DoD Submissions:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](https://eBRAP.org).
- Full application packages must be accessed and submitted at [eBRAP.org](https://eBRAP.org).

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

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

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

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

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

***Extramural Organization Submissions:*** Full applications from extramural organizations must be submitted through Grants.gov Workspace. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in [Section II.C.1, Eligible Applicants](#).

***Intramural DoD Organization Submissions:*** Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP.

***For Both Extramural and Intramural Applicants:*** eBRAP allows an organization’s representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement requirements, and discrepancies will be noted in an email to the PI and in the “Full Application Files” tab in eBRAP. It is the applicant’s responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

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

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

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

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

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

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

The applicant organization and associated PIs 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](mailto:help@eBRAP.org) or 301-682-5507.

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

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

- **Tab 1 – Application Information**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://eBRAP.org/eBRAP/public/>

[Program.htm](#). Note that the codes have recently been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

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

Enter the name, organization, and role of all collaborators and key personnel associated with the application.

[FY19 HRRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

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

The Preproposal Narrative should include the following:

- **Research Idea/Rationale**
  - **Funding Level 1:** Describe the research idea to be explored and the rationale. Concisely explain how the idea may yield new avenues of investigation, such as new approaches, new research tools, or new paradigms.
  - **Funding Level 2:** Describe the proposed research and the preliminary data supporting its readiness and feasibility. Concisely explain how the proposed research has the potential to make significant advancements toward clinical translation.
  - **Both Funding Levels:** Explain how the research idea meets the intent of the FY19 HRRP FRA and addresses an important problem within the FY19 HRRP FRA Focus Areas.
- **Objective(s)/Hypothesis(es), Specific Aims, and Approaches:** Concisely state the project’s objective(s)/hypothesis(es), specific aims, and describe the scientific approaches. Include a description of controls, as appropriate. As applicable, identify the animal models to be studied, the data to be analyzed, and/or the human subject population to be engaged during the study.
  - If applicable, clearly identify which aims involve preclinical or clinical studies and which aim involves a pilot clinical trial. Describe how the outcome of the pilot clinical trial will inform the feasibility, rationale, and design of subsequent clinical trials.
- **Impact:** Describe the anticipated short- and long-term impact of this study on the field of hearing restoration. Explain how the outcome of the proposed research will lead to better diagnosis and/or treatment of military-relevant hearing loss and auditory dysfunction.
- **Personnel:** Briefly state the qualifications of the PI and key personnel. Clearly demonstrate that the investigating team has sufficient expertise that is appropriate for the research idea and the proposed phase/type of study.
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to the following:
  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

- **Key Personnel Biographical Sketches (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.

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

- **Research Idea/Rationale:**

- **Funding Level 1:** How well the research idea is supported by rationale. To what extent it is designed to yield new avenues of investigation.
- **Funding Level 2:** How well the proposed research is supported by preliminary data and rationale. To what extent it is designed to make significant advancements toward clinical translation.
- **Both Funding Levels:** How well the research idea meets the intent of the FY19 HRRP FRA and addresses an important problem within the FY19 HRRP FRA Focus Areas.

- **Objective(s)/Hypothesis(es), Specific Aims, and Approaches:** Whether the proposed research has clear objective(s)/hypothesis(es). To what extent the specific aims and approaches, including controls if applicable, form a coherent research plan to address the objective(s)/hypothesis(es).

- **Impact:** To what extent the short- and long-term outcomes of the proposed study, if successful, will advance diagnosis and/or treatment of military-relevant hearing loss and auditory dysfunction.

- **Personnel:** To what extent the investigating team has sufficient qualification and expertise to perform the proposed research.

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

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated in [Section I, Overview of the Funding](#)

Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

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

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

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

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

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

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

**Table 1. Full Application Submission Guidelines**

Extramural Submissions	Intramural DoD Submissions
<b>Application Package Location</b>	
Download application package components for W81XWH-19-HRRP-FRA from Grants.gov ( <a href="https://www.grants.gov/">https://www.grants.gov/</a> ) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-19-HRRP-FRA from eBRAP ( <a href="https://ebrap.org/">https://ebrap.org/</a> ).

Extramural Submissions	Intramural DoD Submissions
<b>Full Application Package Components</b>	
<p><b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.</p>	<p><b>Tab 1 – Summary:</b> Provide a summary of the application information.</p> <p><b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a> (if applicable)</li> </ul>	<p><b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <p><b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>
<b>Application Package Submission</b>	
<p><b>Create a Grants.gov Workspace.</b> Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b> An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><b>Note:</b> If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline.</p>	<p><b>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</b></p> <p><b>Tab 5 – Submit/Request Approval Full Application:</b> After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email.</p>

Extramural Submissions	Intramural DoD Submissions
<b><u>Application Verification Period</u></b>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research &amp; Related Budget Form</i>.</p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI(s) will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research &amp; Related Budget Form</i>. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>
<b>Further Information</b>	
<p><b>Tracking a Grants.gov Workspace Package.</b> After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

**Both Extramural and Intramural Organizations:** Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. *The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.* Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

**Attachments:**

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

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

- **Attachment 1: Project Narrative (page limit varies by funding level; see below for 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.
  - **Page Limit:** Page limits for the Project Narrative are correlated with the application’s funding level:
    - **Funding Level 1:** Six-page limit
    - **Funding Level 2:** Twelve-page limit

Describe the proposed project in detail using the outline below.

- **Background/Rationale:** Provide a sound scientific rationale for the proposed research. To establish why the proposed research is needed, explain the problem it will solve and critically summarize relevant completed and ongoing studies in the field. Explain how the proposed research meets the intent of the FY19 HRRP FRA and aligns with the FY19 HRRP FRA Focus Areas.
  - **Funding Level 1:** Provide a solid rationale for the research idea, supported by literature. Explain how the proposed research has the potential to yield new

avenues of investigation, such as new approaches, new research tools, or new paradigms. *Preliminary data are allowed but not required.*

- **Funding Level 2:** Present sufficient preliminary data to support the proposed work, including the soundness of the hypothesis(es), the readiness of the objective(s), and the feasibility of the approach(es). Describe the proof-of-concept preclinical finding(s) that the proposed research aims to move forward to the next phase of development. Explain how the proposed research has the potential to make significant advancements toward clinical translation.
- **Objective(s) or Hypothesis(es):** State the objective(s) to be reached or the hypothesis(es) to be tested.
- **Specific Aims:** Concisely explain the project’s specific aims. As applicable, clearly identify which aims involve preclinical or clinical studies and which aim involves a pilot clinical trial.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate randomization, blinding/masking, and controls. Provide sufficient detail so that the appropriateness and feasibility of the research strategy can be fully evaluated.
  - Explain how the research strategy will meet research goals and milestones.
  - Address potential problems that may arise and present alternative methods and approaches.
  - If the methodology is new or unusual, provide sufficient justification and details for evaluation.
  - Describe the statistical plan and the rationale for the statistical methodology. Provide a sample size estimate and the method by which it was derived, including power analysis calculation, if applicable.
  - Describe how data will be reported and how it will be assured that the documentation will support potential regulatory filing with the FDA.
  - If cell lines or animals are to be used, justify the selection of the proposed cell line(s) or animal model(s). Be specific as to why the cell line or animal model was chosen over other cell lines or models and how it is optimal for addressing the study aims and is relevant to human auditory biology. Describe how animal research will be conducted in accordance with the ARRIVE guidelines (<https://www.nc3rs.org.uk/sites/default/files/documents/Guidelines/NC3Rs%20ARRIVE%20Guidelines%202013.pdf>). Further details of research involving animals will be required in [Attachment 8, Animal Research Plan](#), as applicable.
  - If human subjects or human biological samples will be used, describe the study population and include a detailed plan for the recruitment of subjects or the

acquisition of samples. Further details of research involving human subjects or human biological substances will be required in [Attachment 9, Human Subjects/Samples Acquisition and Safety Procedures](#), as applicable.

- As applicable, describe how the pilot clinical trial is linked to the preclinical and/or clinical studies that will also be performed through this award.
- **Pilot Clinical Trial Plan (if applicable):** Describe the plans for initiating and conducting the pilot clinical trial during the course of this award.
  - Describe the design of the pilot clinical trial and outline the proposed methodology in sufficient detail to show a clear course of action. Briefly identify the intervention to be tested, projected outcomes, study variables, controls, and endpoints.
  - Describe how the pilot clinical trial is an appropriate pilot for subsequent clinical trials (e.g., how it is limited in scale and scope; how it will be utilized to inform the feasibility, rationale, and design of subsequent clinical trials).
  - Describe potential challenges and alternative strategies, where appropriate.
  - As appropriate for the proposed pilot clinical trial, describe the statistical model and data analysis plan. If applicable, include power analysis calculations.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use.

If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support (two-page limit per letter is recommended): Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable) (two-page limit per letter is recommended): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.
- Letter of Commitment (if applicable) (two-page limit per letter is recommended): If the proposed study involves use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating availability of the product for the duration of the study, support for the proposed phase of research.
- Intellectual Property: Information can be found in 2 CFR 200.315, “Intangible Property.”
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
  - All Traumatic Brain Injury (TBI) clinical research projects are required to report data to the Federal Interagency TBI Research (FITBIR) informatics system (<https://fitbir.nih.gov/>) on a quarterly basis.

- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.
- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. *Do not include proprietary or confidential information.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

*Members of the Programmatic Panel typically rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.*

Technical abstracts should include the following elements:

- Research Idea/Rationale: Present the ideas and scientific rationale behind the proposed research project. Clearly indicate whether the proposed project is exploring early ideas with the potential to yield new avenues of investigation or is advancing more mature research toward clinical translation.
- Objective(s) and/or Hypothesis(es): Clearly state the objective(s) to be reached and/or the hypothesis(es) to be tested.
- Specific Aims: State the specific aims. As applicable, clearly identify which aims involve preclinical or clinical studies and which aim involves a pilot clinical trial.
- Study Design: Briefly describe the study design, including appropriate controls.
- Impact: Briefly describe how the proposed project, if successful, will impact the field of hearing restoration research and the auditory health of Service members, Veterans, and the American public.
- **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.

The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community. Lay abstracts should be written using the outline below in a manner *readily understood by readers without a background in science or medicine*. Minimize use of acronyms and abbreviations, where appropriate. Do not duplicate the technical abstract.

- Clearly describe the rationale, objective, and aims of the application.
- Describe the anticipated short-term and long-term outcomes of the proposed research. Explain how the outcomes will help Service members, Veterans, and the American Public suffering from hearing loss or auditory dysfunction.
  - If applicable, how will the proposed research open new avenues of investigation? Why is that important?
  - If applicable, how will the proposed research make significant advancements toward clinical translation?
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the FRA mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.

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

- Include the name(s) of the key personnel and contact information for each study site/sub award site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
- Identify cell line(s) and commercial or organizational source(s) to be used.
- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug [IND] and Investigational Device Exemption [IDE] applications) by the FDA or other Government agency.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.** Describe the anticipated short- and long-term impact of the proposed work on hearing restoration research and/or patient care.
  - **Funding Level 1:** Explain how the proposed work will open new avenues of investigation.
  - **Funding Level 2:** Explain how the proposed research will lead to significant advancement toward clinical translation.
- **Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as “Military.pdf”.** Explain how the proposed research is applicable to the operational performance, medical readiness, and quality of life of Service members and Veterans with auditory system injuries and/or to their family members and caregivers.
  - Identify any element(s) or special consideration(s) related to the applicability of the ultimate outcome of the research in the military operational environment (e.g., battlefield, Battalion Aid Stations, Forward Support Medical Battalions).
  - If active duty military, Veteran, or military family member population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research, and the feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population.
  - If applicable, provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to both benefit the civilian population and address a military need.
- **Attachment 8: Animal Research Plan (required if the proposed research involves the use of animals; no page limit): Upload as “AnimalResPlan.pdf”.** Describe 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. Identify the ages, sex, and total number of animals by species to be used.
  - Describe the randomization and blinding procedures, 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 potential regulatory filing with the FDA, if applicable.
- **Attachment 9: Human Subjects/Samples Acquisition and Safety Procedures (required if the proposed research involves human subjects or human biological samples; no page limit): Upload as “HumProc.pdf”.** Include the components listed below, as applicable.
  - **Study Population and Recruitment Process:** Describe the study population (i.e., Service members/Veterans/civilians, approximate number, age ranges, gender, ethnic groups, and other pertinent demographic characteristics), criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects.
    - Demonstrate that the research team has access to the proposed study population. If applicable, discuss past efforts in recruiting human subjects from the target population for previous clinical studies.
    - Address any potential barriers to accrual and plans for addressing unanticipated delays.
    - Describe how the subject-to-group assignments process will be conducted (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable.
    - Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender.
    - *For clinical studies proposing to recruit military personnel, refer to the General Application Instructions, Appendix 1, for more information.*
  - **Informed Consent Process:** Describe the plan for obtaining informed consent from human subjects. Include relevant draft process documents. **Provide a draft, in English, of the Informed Consent Form.**
  - **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.
  - **Risks/Benefits Assessment:** Identify all foreseeable study risks (physical, psychological, social, legal, and other). Discuss the importance of the knowledge to

be gained in relation to the risks to subjects. Clearly describe measures of risk management and plans for emergency response. Describe known and potential benefits, which may or may not be direct to subjects, in relation to risks.

***Note: Payment and/or other compensation for participation are not considered benefits and must be addressed in Study Population and Recruitment Process.***

- **Human Sample:** Describe the types and source(s) of specimens, records, or data to be collected and evaluated. Include information about specimen storage (i.e., location, duration, special handling conditions). Describe the identifiers that will be associated with the human specimens and data and provide a list of who has access to subjects' identities. Describe how individually identifiable private information will be protected.
- **Attachment 10: Regulatory Strategy (required only if proposing a pilot clinical trial; no page limit):** If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “Regulatory.pdf”. Answer the following questions and provide supporting documentation as applicable.
  - State the name of the product/intervention to be tested.

**For products/interventions that do not require regulation by the FDA or an international regulatory agency:**

- Explain why the product/intervention is exempt from FDA oversight. Provide confirmation in writing from the IRB of record or the FDA that the pilot clinical trial does not require regulation by the FDA. If the pilot clinical trial will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements. No further information for this Attachment is required.

**For products/interventions that require regulation by the FDA and/or an international regulatory agency:**

- State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States.
- If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).
- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor

- commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.
- If an IND or IDE is required, provide documentation of submission (e.g., a copy of the FDA acknowledgment letter to include submission date and receipt date, status of the application) or a timeline for planned submission. Submission must be made prior to the award date. ***The Government reserves the right to withdraw funding if an IND or IDE is necessary but has not been submitted to the FDA prior to the award date, or if documented status of the IND or IDE has not been obtained within 6 months of the award date.***
  - The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed pilot clinical trial.
  - If a technical or a protocol amendment to an IND/IDE is necessary to conduct the pilot clinical trial, provide a copy of the FDA acknowledgment letter and meeting minutes (pre-IND/pre-IDE and/or Type C) that confirm the FDA's concurrence to the proposed regulatory approach. Documents must demonstrate clear evidence that the proposed investigational drug or device will not require new IND/IDE submission pertaining to the indication and formulation to be used in the pilot clinical trial.
  - Provide a current status for manufacturing development (e.g., manufacturer's name, Good Manufacturing Practice (GMP)-compliant lots available, status of stability testing), non-clinical development (e.g., test facility name, status of pivotal Good Laboratory Practice (GLP) toxicology studies to support Phase I testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).
  - Describe the overall regulatory strategy and product development plan that will support the planned product indication. Include considerations for compliance with current GMP, GLP, and Good Clinical Practice (GCP) guidelines.
  - **Attachment 11: Post-Award Transition Plan (required only for Funding Level 2; three-page limit): Upload as "Transition.pdf".** Applicants are strongly encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the Post-Award Transition Plan. PIs are encouraged to explore developing relationships with industry, DoD advanced developers, and/or other funding agencies to facilitate moving the anticipated research outcomes into the next phase of development. The Post-Award Transition Plan should include the components listed below as applicable.
    - The next phase of development (e.g., transition to industry, clinical trials, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by the FDA) after the successful completion of the proposed study.
    - The methods and strategies to move the anticipated research outcomes to the next phase of development.

- A brief schedule and milestones for transitioning the anticipated research outcomes to the next phase of development.
- The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication (e.g., Target Product Profile). Describe in detail the FDA regulatory strategy, including the number and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings to be held, the submission filing strategy, and considerations for compliance with GMP, GLP, and GCP guidelines (if appropriate).
- Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., specific potential industry partners, internal/external funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.
- If applicable, a description of collaborations and other resources that will be used to provide continuity of development for knowledge products, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications.
- Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government’s ability to access such products or technologies in the future.
- If applicable, a risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 12: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 13: DoD Military Budget Form(s), if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.
- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able

to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

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

**Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- PI Biographical Sketch (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 National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
- Key Personnel Biographical Sketches (six-page limit each): Upload as “Biosketch\_LastName.pdf”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.

**Research & Related Budget:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

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

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

- **Extramural Applications Only**

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 13. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

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

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

### **II.D.4. Submission Dates and Times**

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

### **Applicant Verification of Full Application Submission in eBRAP**

Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement requirements, and discrepancies will be noted in both the email and in the “Full Application Files” tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

***Extramural Submission:*** The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the

application verification period, the full application package, *with the exception of the Project Narrative and Budget Form*, may be modified.

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

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

#### **II.D.5. Funding Restrictions**

*The requested funding level should be based on the stage and maturity level of the research project, rather than the amount of the budget.*

##### **Funding Level 1:**

- The maximum period of performance is **2** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$250,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$250,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

##### **Funding Level 2:**

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$1M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$1M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

##### **Funding Level 2 with Pilot Clinical Trial Option:**

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$1.25M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. The combined budgeted direct costs

approved by the Government will not exceed **\$1.25M** or use an indirect cost rate exceeding each organization's negotiated rate.

**For All Funding Levels:**

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

For Funding Level 2, direct costs must be requested for:

- Travel costs for the PI to present project information or disseminate results at one DoD-sponsored meeting to be specified by the program office during award negotiations (e.g., the Military Health System Research Symposium). For planning purposes, it should be assumed that the meeting will be held in the Central Florida Area. Costs associated with travel to this meeting should be included in Year 2 or 3 of the budget. This is in addition to the annual scientific/technical meeting described below.

For both Funding Levels, direct costs may be requested for (not all-inclusive):

- Salary
- Research supplies
- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for one investigator to travel to one scientific/technical meeting per year to present project information or disseminate project results from the FY19 HRRP Focused Research Award
- Costs associated with FITBIR data submission. A project estimation tool (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate FITBIR submission costs.

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

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations***

*collaborating with Federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.*

Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

## **II.D.6. Other Submission Requirements**

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

## **II.E. Application Review Information**

### **II.E.1. Criteria**

#### **II.E.1.a. Peer Review**

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

- **Impact**
  - To what extent the proposed research will impact hearing restoration research and/or patient care.
  - **Funding Level 1:** If successful, to what extent the proposed work will open new avenues of investigation.
  - **Funding Level 2:** If successful, to what extent the proposed research will lead to significant advancement toward clinical translation.
- **Research Rationale and Strategy**
  - **Funding Level 1:** To what extent the idea of the proposed research, including the objective(s) and/or hypothesis(es), is based on sound rationale and critical analysis of literature.
  - **Funding Level 2:** To what extent the idea of the proposed research, including the objective(s) and/or hypothesis(es), is based on sound rationale and critical analysis of literature and/or preliminary data.
  - How well the proposed research meets the intent of the selected Funding Level of the FY19 HRRP FRA.
  - How well the proposed research aligns with at least one of the FY19 HRRP Focus Areas.

- To what extent the specific aims are appropriate to address the objective(s) and/or hypothesis(es) of the proposed research.
- To what extent the experimental design is feasible and appropriate and describes adequate controls, sample sizes, blinding/masking, randomization, and data handling, as applicable.
- How well the application acknowledges potential problems and addresses alternative approaches.
- If applicable, how well the use of new or unusual methodology is justified and appropriate.
- To what extent the statistical plan and power analysis are appropriate.
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
- Whether the research can be completed within the proposed period of performance.
- For applications involving cell line(s) or animals:
  - Whether the choice of cell line(s) or animal model(s) is justified. To what extent the cell line(s) or animal model(s) is relevant to human biology.
  - Whether the number of animals is appropriate.
  - To what extent the proposed endpoints/outcome measures are appropriate.
  - Whether the design of animal studies demonstrates adequate planning in accordance with the ARRIVE guidelines and supports adequate reporting of animal research.
- For all applications involving human subjects or human samples:
  - How well the study population(s) or sample(s) of interest is (are) described, access to the population(s) or sample(s) is demonstrated, and viable plans for subject recruitment or sample acquisition, consent, screening and retention are outlined.
  - How well plans for addressing ethical and regulatory considerations have been developed, including consideration of risks and benefits, protection against risks, justification for limited inclusion, privacy issues, and the process for obtaining informed consent.
- For applications including *pilot clinical trials*, the following **additional** criteria apply:
  - To what extent the pilot clinical trial has a clear and sound design, including appropriate controls, study variables, endpoints, etc.

- To what extent the pilot clinical trial is an appropriate pilot for subsequent clinical trials, and how well it will inform the feasibility, rationale, and design of subsequent clinical trials.
- To what extent the application demonstrates availability of, and access to, the intervention to be tested.
- To what extent the Regulatory Strategy provides sufficient evidence for IND/IDE exemption or, if IND/IDE is required, an appropriate plan/timeline for applying for and obtaining IND/IDE status (or other FDA approvals).
- **Post-Award Transition Plan (for Funding Level 2 applications)**
  - Whether the identified next phase of development and/or commercialization is rational.
  - Whether the methods and strategies to move the anticipated research outcomes to the next phase of development and/or commercialization are feasible.
  - Whether the schedule and milestones for bringing the anticipated research outcomes to the next level of development are achievable.
  - If the ultimate goal is to produce an FDA-regulated product (e.g., drug, biologics, or device), whether the regulatory strategy and product development plan are appropriate to support a regulatory filing with the FDA.
  - Whether the funding strategy to bring the anticipated research outcomes to the next level of development is reasonable and realistic.
  - As applicable, whether the proposed collaborations and other resources for providing continuity of development are established and/or achievable.
  - As applicable, whether the applicant has identified intellectual property ownership, demonstrated appropriate access to all intellectual property rights necessary for development and/or commercialization, and described an appropriate intellectual and material property plan among participating organizations for products or technologies supported by this award.
  - As applicable, whether the risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
- **Personnel**
  - To what extent the backgrounds, expertise, and past accomplishments of the PI and key personnel are appropriate to accomplish the proposed research project.
  - Whether the levels of effort by the PI and key personnel are appropriate for the successful conduct of the proposed work.

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

- **Environment**

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

- **Budget**

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

- **Application Presentation**

- To what extent the writing, clarity, and presentation of the application components influence the review.

### **II.E.1.b. Programmatic Review**

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY19 HRRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Relative impact
  - Relevance to military health
  - Program portfolio composition

### **II.E.2. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of

other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA). *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.army.mil/about/2tierRevProcess>. A PI Information Paper describing the funding recommendations and review process for the award mechanisms for the HRRP will be provided to the PI and posted on the CDMRP website. .

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

### **II.E.3. Integrity and Performance Information**

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

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

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

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

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

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

## **II.F. Federal Award Administration Information**

### **II.F.1. Federal Award Notices**

Awards supported with FY19 HRRP funds are anticipated to be made no later than September 30, 2020. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

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

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

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

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

Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

### **II.F.2. Administrative and National Policy Requirements**

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

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

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

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

### **II.F.3. Reporting**

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

Annual and final technical progress reports will be required.

Annual and final quad charts will be required. Refer to the eBRAP “Funding Opportunities & Forms” web page at <https://ebrap.org/eBRAP/public/Program.htm> for the format of the quad chart.

Quarterly technical progress reports and/or quad charts may be required.

Award Expiration Transition Plan (applicable to Funding Level 2 Awards only): An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template “Award Expiration Transition Plan,” available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) under the “Progress Report Formats” section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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

## **II.G. Federal Awarding Agency Contacts**

### **II.G.1. CDMRP Help Desk**

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

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **II.G.2. Grants.gov Contact Center**

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

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

Email: [support@grants.gov](mailto:support@grants.gov)

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

## **II.H. Other Information**

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

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20190218e. The Program Announcement numeric version code will match the General Application Instructions version code 20190218.

### **II.H.2. Administrative Actions**

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

#### **II.H.2.a. Rejection**

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- ***For applications containing a pilot clinical trial:*** Human Subjects/Samples Acquisition and Safety Procedures ([Attachment 9](#)) is missing.
- ***For applications containing a pilot clinical trial:*** Regulatory Strategy ([Attachment 10](#)) is missing.

#### **II.H.2.b. Modification**

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

#### **II.H.2.c. Withdrawal**

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

- An FY19 HRRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***A list of the FY19 HRRP Programmatic Panel members can be found at <https://cdmrp.army.mil/hrrp/panels/panels19>.***
- The application fails to conform to this Program Announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY19, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- The invited application proposes a different research project than that described in the pre-application.
- The application proposes tinnitus or vestibular-related research.

#### **II.H.2.d. Withhold**

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

### II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance ( <b>Extramural submissions only</b> )	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) ( <b>Intramural submissions only</b> )	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Relevance to Military Health Statement: Upload as Attachment 7 with file name "Military.pdf"	
	Animal Research Plan: Upload as Attachment 8 with the file "AnimalResPlan.pdf" if applicable	
	Human Subjects/Samples Acquisition and Safety Procedures: Upload as Attachment 9 with file name "HumProc.pdf" if applicable	
	Regulatory Strategy: Upload as Attachment 10 with file name "Regulatory.pdf" if applicable	
	Post-Award Transition Plan: Upload as Attachment 11 with file name "Transition.pdf"	
	Representations (Extramural submissions only): Upload as Attachment 12 with file name "RequiredReps.pdf" if applicable	
DoD Military Budget Form(s): Upload as Attachment 13 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed	

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

## **APPENDIX 1: ACRONYM LIST**

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
ARRIVE	Animal Research: Reporting In Vivo Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research
FRA	Focused Research Award
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HRPO	Human Research Protection Office
HRRP	Hearing Restoration Research Program
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NPC	Non-Profit Corporation

OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TBI	Traumatic Brain Injury
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs