

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Defense Medical Research and Development Program

Joint Program Committee-8/Clinical and Rehabilitative Medicine Research Program

Hearing and Balance Research Award

Funding Opportunity Number: W81XWH-17-DMRDP-CRMRP-HBRA
**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), December 12, 2016
- **Invitation to Submit an Application:** January 20, 2017
- **Application Submission Deadline:** 11:59 p.m. ET, March 29, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, April 3, 2017
- **Peer Review:** May 2017
- **Programmatic Review:** July 2017

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from [Grants.gov](https://www.grants.gov).

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2017 (FY17) Joint Program Committee-8/Clinical and Rehabilitative Medicine Research Program (JPC-8/CRM RP) are being solicited for the Defense Health Agency (DHA) Research and Development (J9), by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), DHA Research and Development manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) provides Defense Medical Research and Development Program (DMRDP) execution management support for DHP core research program areas, including JPC-8/CRM RP. This Program Announcement/Funding Opportunity and subsequent awards will be managed and executed by the CDMRP with strategic oversight from JPC-8/CRM RP.

The JPC-8/CRM RP is one of the major program areas within the DHA and seeks to implement long-term strategies to develop knowledge and materiel products to reconstruct, rehabilitate, and provide definitive care for injured Service members. The ultimate goal is to return Service members to duty and improve their quality of life. Additional information about the JPC-8/CRM RP can be found at: <https://crmrp.amedd.army.mil/>.

B. FY17 Hearing and Balance Research Award Capability Gaps and Focus Areas

Capability Gaps

The FY17 JPC-8/CRM RP Hearing and Balance Research Award is intended to provide support for research of exceptional scientific merit that has the potential to make a significant impact on improving the function, wellness, and overall quality of life for injured military Service members, Veterans, their caregivers and family members, and the American public. To address Sensory Systems Requirements as defined in the CRM RP Initial Capabilities Document and the Combat Casualty Care Research Program Capability Based Assessment, the Hearing and Balance Research Award Programmatic Panel identified the following four major Capability Gaps for FY17.

To meet the intent of the award mechanism, all applications must specifically address one or more of the FY17 JPC-8/CRM RP Hearing and Balance Research Award Capability Gaps listed below. Applications proposing research outside of these Capability Gaps should not be submitted in response to this Program Announcement/Funding Opportunity. (Note: Capability gaps are not listed in priority order.)

- Lack of knowledge of the prevalence, incidence, natural history, occupational and gender-related differences of tinnitus and its possible relation to individual blast/noise exposure
- Lack of standardized metrics for hearing and/or vestibular assessment and monitoring in clinical and operational environments

- Lack of understanding of the primary/secondary (e.g., mechanical/injury progression) effects of blast exposure leading to the neuronal dysfunction of auditory and/or vestibular systems
- Lack of knowledge and effective strategies and products for hearing and/or vestibular restoration

Focus Areas

Translational preclinical research: It is highly encouraged that applications to the FY17 JPC-8/CRM RP Hearing and Balance Research Award address one or more of the Focus Areas below.

- Characterize the progression of auditory and vestibular dysfunction in small and large animal blast models to support future research for the development of treatments or diagnostics
- Develop, evaluate, and/or validate improved technology to conduct reproducible auditory and/or vestibular assessments in operational environments (with considerations for portability and ruggedization). Ideally, this effort could lead to Investigational Device Exemption (IDE) submission of a device.
- Propose, evaluate, and/or validate techniques demonstrating the regeneration of functional hair cells which has the potential to lead to a U.S. Food and Drug Administration (FDA)-approved therapeutic.

Clinical trials and observational studies: It is highly encouraged that applications to the FY17 JPC-8/CRM RP Hearing and Balance Research Award address one or more of the Focus Areas below.

- Leverage multiple data bases to identify prevalence, incidence and potential risk factors/variables for service-induced tinnitus to increase provider awareness, inform diagnostic and treatment strategies, and create clinical practice guidelines.
- Develop, evaluate and/or validate assessment measures to evaluate individuals with vestibular and/or hearing impairments performing operational/functional tasks to inform diagnostic and treatment strategies and create clinical practice guidelines.
- Propose and validate novel personalized treatment strategies to restore auditory and vestibular function with the potential to inform clinical practice and/or lead to an FDA-approved treatment or device.
- Systematically examine the impact of blast exposure (include those with normal hearing thresholds and temporary threshold shifts) on listening tasks to inform development of advanced screening techniques.

C. Award Information

The FY17 JPC-8/CRM RP Hearing and Balance Research Award is intended to support translational preclinical research, observational studies, and early-stage clinical trials addressing auditory and vestibular dysfunction associated with military service. The intent of the award is to advance treatment/assessment strategies and evidence-based practice to optimize the

rehabilitation of vestibular and hearing dysfunction resulting from military service-related injuries. Ultimately, the goal is to develop and transition knowledge and materiel products to restore Service member's form, function, and quality of life, benefitting Service members, Veterans, their caregivers and family members, and the American public.

Two different research levels, based on the type of study proposed, are available under this Program Announcement/Funding Opportunity. ***It is the responsibility of the Principal Investigator (PI) to correctly identify and select the research level that is most appropriate for the research proposed based on the following descriptions.***

Translational research, observational studies, and clinical trials are allowed in the FY17 Hearing and Balance Research Award. PIs should note that preclinical research, observational studies, and clinical trials have different submission requirements. ***It is the responsibility of the PI to correctly identify the type of research proposed and to comply with the relevant submission requirements.***

Research Level 1 includes translational preclinical research.

- Translational preclinical research includes, but is not limited to, studies evaluating new therapeutic modalities using established or validated preclinical systems; developing pharmacological agents through absorption, distribution, metabolism, excretion, and toxicity studies; or other Investigational New Drug (IND)/IDE-enabling research projects.

Research Level 2 includes observational studies and clinical trials.

- A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction.
- An observational study is a type of clinical study in which individuals are observed or certain outcomes are measured. No attempt is made to affect the outcome (for example, no treatment is given or diagnosis tested). Retrospective studies analyzing existing clinical data are also clinical studies. These types of studies are not considered clinical trials. All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of research.

Research Involving Animals: All Department of Defense (DoD)-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC Office of Research Protections (ORP) Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use

protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 6, for additional information.

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 USAMRMC ORP, Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 6, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

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

Research Involving an FDA-Regulated Drug, Biologic, or Device: If the study proposed involves the use of a drug that has not been approved by the FDA for the proposed investigational use, then an IND application to the FDA that meets all requirements under the Code of Federal Regulations, Title 21, Part 312 (21 CFR 312) may be required and must be submitted to the FDA ***prior to the application submission deadline.*** If the investigational product is a device, evidence that an IDE application that meets all requirements under 21 CFR 812 has been submitted to the FDA ***prior to the application submission deadline,*** or that the device is exempt or qualifies for an abbreviated IDE, is required. 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 grant submission deadline, or if documented status of the IND or IDE has not been obtained within 12 months of the award date.

Multi-Institutional Studies: If the proposed study is multi-institutional, plans for communication and data transfer among the collaborating institutions, as well as how specimens and/or imaging products obtained during the study will be handled, should be included in the appropriate sections of the application. A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional studies.

Federal Interagency Traumatic Brain Injury (TBI) Research (FITBIR) Informatics

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

To contribute to FITBIR, researchers should contact the FITBIR Operations Center ahead of time to arrange for data entry support and to ensure all data have been made compatible with the system. FITBIR guidance and policies, as well as the considerable advantages of FITBIR use to the researcher, are detailed at [FITBIR: Federal Interagency Traumatic Brain Injury Research Informatics System](http://fitbir.nih.gov/) (<http://fitbir.nih.gov/>).

FITBIR allows for de-identification and storage of data (medical imaging clinical assessment, environmental and behavioral history, etc.) of various types (text, numeric, image, time series, etc.). Use of FITBIR's Global Unique Identifier (GUID) system facilitates repeated and multi-user access to data without the need to personally identify data sources. FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards.

Data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI Common Data Elements (CDEs) or entered into the FITBIR data dictionary as new, unique data elements. For the most current version of the NINDS TBI CDEs, go to <http://www.commondataelements.ninds.nih.gov>. Assistance will be available to help the researchers map their study variables to specific CDEs and ensure the formats of the CDEs collected are compatible with the FITBIR informatics system. If the proposed research data cannot be entered in CDE format, the investigators must supply a proposal for an alternative data submission or data sharing vehicle and justification for use. Use of the TBI CDEs is required wherever possible in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical research of TBI.

TBI Outcomes Reporting: PIs are highly encouraged to use the Neurobehavioral Symptom Inventory (NSI), a measure of post-TBI symptom severity, and the Patient Global Impression of Change (PGIC), a global outcome measure of patient experience of care. The NSI and PGIC achieved unanimous concurrence by DoD and Department of Veterans Affairs (VA) TBI stakeholders in September 2013 as core TBI outcome measures. More information on the NSI and PGIC is available at the respective links below:

NSI: [http://dvbic.dcoe.mil/sites/default/files/DVBIC - NSI Information Paper Final.pdf](http://dvbic.dcoe.mil/sites/default/files/DVBIC_-_NSI_Information_Paper_Final.pdf)

PGIC: [http://dvbic.dcoe.mil/sites/default/files/DVBIC - PGIC Information Paper Final.pdf](http://dvbic.dcoe.mil/sites/default/files/DVBIC_-_PGIC_Information_Paper_Final.pdf)

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

- Explanation of how the project addresses an aspect of the target disease/condition/technology that has direct relevance to military Service members, Veterans, and/or other military health system beneficiaries
- Description of how the knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to benefit the civilian population and also address a military need
- Use of military or Veteran populations or datasets in the proposed research

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with DoD or VA investigators is also encouraged. The extent to which the proposed research integrates and/or aligns with DoD and/or VA research laboratories and programs will be evaluated during programmatic review. The following websites may be useful in identifying ongoing areas of DoD and/or VA research interest within the FY17 Hearing and Balance Research Award Capability Gaps.

Air Force Research Laboratory
<http://www.wpafb.af.mil/afrl>

Center for Neuroscience and
Regenerative Medicine
<http://www.usuhs.mil/cnrm/>

Clinical and Rehabilitative Medicine
Research Program
<https://crmrp.amedd.army.mil>

Combat Casualty Care Research Program
<https://ccc.amedd.army.mil>

Congressionally Directed Medical
Research Programs
<http://cdmrp.army.mil>

Defense Advanced Research
Projects Agency
<http://www.darpa.mil>

Defense Technical Information Center
<http://www.dtic.mil>

Military Infectious Diseases
Research Program
<https://midrp.amedd.army.mil>

Military Operational Medicine
Research Program
<https://momrp.amedd.army.mil>

National Center for Telehealth
and Technology
<http://t2health.org/>

National Museum of Health and Medicine
<http://www.medicalmuseum.mil/index.cfm>

Naval Health Research Center
<http://www.med.navy.mil/sites/nhrc>

Navy and Marine Corps Public
Health Center
<http://www.med.navy.mil/sites/nmcphc>

Office of Naval Research
<http://www.med.navy.mil>

Office of the Under Secretary of Defense
for Acquisition, Technology and Logistics
<http://www.acq.osd.mil/>

U.S. Army Medical Research
Acquisition Activity
<https://www.usamraa.army.mil/>

U.S. Army Medical Research and Materiel Command
<http://mrmc.amedd.army.mil/>

U.S. Army Research Laboratory
<http://www.arl.army.mil>

U.S. Department of Defense Blast Injury Research Program
<https://blastinjuryresearch.amedd.army.mil/>

U.S. Naval Research Laboratory
<https://www.nrl.navy.mil/>

U.S. Department of Veterans Affairs, Office of Research and Development
<http://www.research.va.gov>

Walter Reed Army Institute of Research
<http://wrair-www.army.mil>

Use of Military and VA Populations or Resources: If the proposed research involves access to military and/or VA population(s) and/or resource(s), the PI is responsible for establishing access. Access to target military and/or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the appropriate organizational official with approval authority, should be included as part of Attachment 2 for studies involving Service members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. See [Section II.C., Full Application Submission Content; Supporting Documentation](#) for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity 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 4, Section K.

D. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit an application.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. *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.*
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

The requested funding should be based on the type of research proposed. Investigators are highly encouraged to submit budgets appropriate to the scope of work proposed. This will be evaluated and [scored at peer review](#). The below funding levels are listed as maximums. Note: all awards will be fully funded with FY17 dollars (contingent upon funding availability).

Research Level 1 - Translational Preclinical Research:

- The maximum period of performance is **3** years.
- The anticipated total costs (direct and indirect) budgeted for the entire period of performance will not exceed **\$2 million (M)**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$2M** total costs or using an indirect rate exceeding the organization's negotiated rate.

Research Level 2 – Observational Studies or Clinical Trials:

- The maximum period of performance is **4** years.
- The anticipated total costs (direct and indirect) budgeted for the entire period of performance will not exceed **\$4M**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$4M** total costs or using an indirect rate exceeding the organization's negotiated rate.

Both Funding Levels:

- All direct and indirect costs of any subaward subcontract must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum allowable period of performance for the selected funding level.

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

- Travel costs for the PI to disseminate project results at one In-Progress Review meeting during the period of performance. For planning purposes, it should be assumed that the meeting will be a 1-day meeting held in the National Capital Area.
- Travel costs for the PI to disseminate project results at one DoD-sponsored scientific meeting (e.g., Military Health System Research Symposium) during the period of performance. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies and equipment

- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for up to two investigators to attend two scientific/technical meetings per year in addition to the required meetings described above

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

The JPC-8/CRM RP expects to allot approximately \$13M of the anticipated FY17 DHP RDT&E appropriation to fund approximately three to four Research Level 1 and one to two Research Level 2 Hearing and Balance Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program. Note: all awards will be fully funded with FY17 dollars (contingent upon funding availability).

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II.A., for registration and submission requirements for eBRAP and Grants.gov.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity 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/Funding Opportunity.

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

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

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-17-DMRDP-CRMRP-HBRA in Grants.gov (<http://www.grants.gov/>).

B. Pre-Application Submission Content

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

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>).

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

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

- **Tab 1 – Application Information**

- **Tab 2 – Application Contacts**

- Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
- Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on “Add Organizations to this Pre-application.” The organization(s) must either be selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.
- It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

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

- Enter the name, organization, and role of all collaborators and key personnel associated with the application.
- FY17 JPC-8/CRM RP Hearing and Balance Research Award Programmatic Panel members should not be involved in any pre-application or application including, but not limited to, concept design, application development, budget preparation, and the development or provision of any supporting documentation, to include letters of recommendation. A list of the FY17 JPC-8/CRM RP Hearing and Balance Research Award Programmatic Panel members can be found at <http://cdmrp.army.mil/dmr dp/panels/HBR Apanel17>. For questions related to Panel members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

- **Tab 4 – Conflicts of Interest**

- List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to Appendix 1, Section C, of the General Application Instructions for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

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

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

The Preproposal Narrative must include the following:

- **Rationale:** State the ideas and reasoning on which the proposed research is based. Briefly describe how the preliminary data and rationale support the research idea. State how this project meets the intent of the award mechanism.
- **Alignment:** Note specifically which of the [FY17 JPC-8/CRM RP Hearing and Balance Research Award Capability Gaps and Focus Areas](#) the proposed research addresses. Describe how the proposed research addresses those Capability Gaps and Focus Areas. State and justify which Research Level to which the application is submitted.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Strategy:** Clearly describe the research being proposed and indicate the phase of trial and/or class of device and regulatory status as appropriate. Describe the intervention, if applicable. Concisely state the project's objectives, specific aims, and ultimate endpoints. If applicable, briefly describe the proposed recruitment strategies and methods, how they will accomplish the project's aims, and the outcome measures that will be used.
- **Research Team:** Provide a description of the research team that clearly demonstrates appropriate background and expertise to accomplish the proposed work.
- **Military Benefit:** Describe how the proposed work would impact the healthcare needs of military Service members and/or Veterans recovering from hearing and balance dysfunction resulting from military service.
- **Intramural Collaboration:** Describe how the proposed work involves, collaborates with, or aligns with DoD and/or VA research laboratories and programs (see list on pages 8-9).
- **Budget:** Provide an overall estimated total budget for the work proposed.

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

- References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
 - PI Biographical Sketch (five-page limit). *The biographical sketch should be uploaded as a single file.* The biographical sketch 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 JPC-8/CRM RP, pre-applications will be screened based on the following criteria:

- **Alignment with Capability Gaps:** How well the project addresses at least one of the FY17 JPC-8/CRM RP Hearing and Balance Research Award Capability Gaps and Focus Areas
 - **Military Benefit:** How the proposed work would benefit the healthcare needs of military Service members and/or Veterans recovering from hearing and balance dysfunction.
 - **Objective/Hypothesis and Rationale:** How well the objective/hypothesis is stated and supported through preliminary data, scientific rationale, and referenced literature.
 - **Research Strategy:** To what degree the rationale, objectives, and specific aims support the research idea. How well the endpoints are defined and are appropriate for the proposed study. Whether the proposed recruitment strategies (if applicable) and methodology are appropriate for accomplishing the research aims.
 - **Intramural Collaboration:** To what degree does the proposed work involve, collaborate with, or align with DoD and/or VA research laboratories and programs (see list on pages 8-9).
- **Notification of Pre-Application Screening Results**

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

[title page](#) of this Program Announcement/Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

C. Full Application Submission Content

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant's organization's Entity registration in the SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

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

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

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

Each application submission must include the completed Grants.gov application package for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

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

If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID *prior to the application submission deadline*.

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

Grants.gov application package components: For the FY17 Hearing and Balance Research Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

- 1. SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 2. Attachments Form**

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the

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

The Project Narrative is NOT the formal clinical trial protocol. Instead, all essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 8, 10, and 11 described below, if applicable. Failure to submit these attachments as part of the application package will result in rejection of the entire application.

- **Attachment 1: Project Narrative: 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, etc.) 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 type of study the application proposes:
 - **Research Level 1/Translational Preclinical Research:** 12-page limit
 - **Research Level 2/Observational Studies or Clinical Trials:** 20-page limit

Describe the proposed project in detail using the outline below.

- **Background:** Describe in detail the rationale for the research. Provide a literature review and clearly describe the preliminary studies and/or preclinical data that led to the development of the proposed research. Clearly articulate how prior work in the field supports the proposed research. If proposing a clinical study, provide a summary of other relevant ongoing, planned, or completed clinical studies and describe how the proposed study differs and include a discussion of current clinical use of the proposed intervention and/or details of its study in clinical trials for other indications (as applicable).

If a proposed observational study or clinical trial was initiated using other funding prior to this application, explain the history and background of the observational study or clinical trial and declare the source of prior funding. Specifically identify the portions of the study or trial that would be supported with funds from this award.

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims to be funded by this award.

- **Research Strategy:** Describe the research, type of study (e.g., correlative or epidemiological), or type of trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
 - Identify the intervention to be tested, if applicable, and describe the projected outcomes.
 - Define the study variables, outline why they were chosen, and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
 - For all clinical trials and for observational studies as applicable:
 - Describe the study population and inclusion and exclusion criteria that will be used.
 - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).
 - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
 - If using psychometric measures, describe their reliability and validity.
- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the research objectives. If applicable, specify the approximate number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the research objectives. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study or trial.
- **Attachment 2: Supporting Documentation. Start each document on a new page. Combine and upload as a single file named “Support.pdf.”** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.*
- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support (recommended two-page limit per letter): 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/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable) (recommended two-page limit per letter): 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. For applications that include an intramural collaborator, include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.
- Letters of Commitment (if applicable) (recommended two-page limit per letter): 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, and support for the indication to be tested.
- Approval for Access to Military and VA Populations or Resources (if applicable, recommended one-page limit per site): A letter of support, signed by the lowest-ranking person with approval authority, should be included for studies involving active duty military, Veterans, or military family members; military-controlled study materials; databases; and/or restricted facilities (e.g., biological or chemical containment facilities). If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.
- Intellectual Property
 - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315.

Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:

- Clearly identify all such property;
 - Identify the cost to the Federal government for use or license of such property, if applicable; or
 - Provide a statement that no property meeting this definition will be used on this project.
- 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. PIs are required to report data to the FITBIR informatics system (<http://fitbir.nih.gov/>) for studies proposing patient populations diagnosed with TBI. For projects involving clinical trials, PIs may be required to register their clinical trials on Clinicaltrials.gov (<https://clinicaltrials.gov/>). Refer to the General Application Instructions, Appendix 4, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
 - Current Quad Chart: Complete and upload the Quad Chart template available from the eBRAP “Funding Opportunities and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>).
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below.

- **Background:** Present the ideas and rationale behind the proposed research.
- **Relevance:** State the relevance of the project to at least one of the FY17 JPC-8/CRM RP Hearing and Balance Research Award Capability Gaps and Focus Areas
- **Hypothesis or Objective:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State the specific aims of the study.
- **Research Strategy:** Briefly describe the study design, including appropriate controls.

- **Military Benefit and Impact:** Briefly explain how the proposed project will have an immediate or potential long-term impact on the health and well-being of Service members, Veterans, and/or their family members.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. *Do not include proprietary or confidential information.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

- Describe the objectives and rationale for the proposed project in a manner that will be *readily understood by readers without a background in science or medicine.*
- Describe the ultimate applicability and potential impact of the research.
- Describe the types of patients that will be helped by the research and how it will help them. Include currently available statistics to the related injury/condition.
- Describe potential clinical applications, benefits, and risks.
- Describe the projected timeline to achieve the expected patient-related outcome.
- Describe how the proposed project will benefit Service members, Veterans, and/or their family members.
- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.”** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Hearing and Balance Research Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.
- **Attachment 6: Military Benefit and Impact (one-page limit): Upload as “MilBen.pdf.”**
 - Describe how the proposed study is responsive to the healthcare needs of Service members and/or Veterans recovering from auditory and/or vestibular injury. Provide information about the incidence and/or prevalence of the disease or condition to be studied in Service members and/or Veterans, if appropriate and available. Show how the proposed study complements ongoing DoD and/or VA areas of research interest.
 - If active duty military and/or Veteran population(s) will be used in the proposed research project or clinical trial, describe the population(s), the appropriateness of the population(s) for the proposed study, the feasibility of accessing the population and potential benefit from the research. If a non-military population

will be used for the proposed research project or clinical trial, explain how the population simulates the targeted population (i.e., Service members or Veterans).

- Describe the short-term impact: Detail the anticipated outcomes that will be directly attributed to the results of the proposed research.
 - Describe the long-term impact: Explain the long-range vision for implementation of the anticipated research outcomes in the clinic or field, and describe the anticipated long-term benefits for the targeted population.
 - Describe how the research has the potential to advance the field of hearing and balance research.
 - If applicable, describe how the proposed intervention represents an improvement over currently available interventions and/or standards of care.
 - If applicable, describe how the research contributes to the development or validation of evidence-based policy or guidelines for patient evaluation and care.
 - Describe any relevant controversies or treatment issues that will be addressed by the proposed research.
 - Describe any potential issues that might limit the impact of the proposed research.
- **Attachment 7: Transition Plan (two-page limit): Upload as “Transition.pdf.”**

A key feature of the intent of this award mechanism is to bring materiel solutions and key knowledge products to the injured Warfighter. Applications must include a Transition Plan that clearly describes how this will be accomplished. Describe/discuss the methods and strategies proposed to move the anticipated research outcomes to the next phase of development or implementation (e.g., next phase clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Outline the regulatory strategy. The post-award transition plan should include the components listed below.

 - The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication.
 - Details of the funding strategy to transition the anticipated research outcomes to the next phase of development, implementation, and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for).
 - For Knowledge Products, a description of collaborations and other resources that will be used to provide continuity of development 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. *A “Knowledge Product” is a non-materiel product that addresses an identified need, topic area, or capability gap, is based on current evidence and research, aims to transition into medical practice, training, tools, or to*

support materiel solutions (systems to develop, acquire, provide, and sustain medical solutions and capabilities), and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.

- A schedule for transitioning the anticipated research outcomes to the next phase of development (next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by the FDA). This should include estimated timelines and cost to deliver products to the Warfighter outlining specific metrics and milestones that will be used to verify the results of the proposed work. Include identification of the FDA regulatory strategy (if appropriate). Identify existing or potential commercial partner(s) for transitioning materiel solutions (if appropriate).
- 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 8: IND/IDE Documentation (if applicable; required for Research Level 2): Upload as "IND-IDE.pdf." If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "IND-IDE.pdf."**
 - Complete the IND/IDE Documentation Form, which is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity on Grants.gov.
 - If an IND or IDE has been submitted, an explanation of the status of the IND or IDE should be provided (e.g., beyond 30-day waiting period, pending response to questions raised by the Agency, on clinical hold.) Inclusion of a copy of the Agency meeting minutes is encouraged but not required.
 - If the IND or IDE application is not yet submitted, provide evidence that an IND or IDE will be submitted within 60 days of award. Examples include a pre-IND or pre-IDE meeting with the FDA, a pre-IND/pre-IDE meeting request to the FDA, or other communication with the FDA. Provide the anticipated date of IND/IDE submission.
 - If an IND or IDE is not required for the proposed study, provide evidence in the form of communication from the FDA or the IRB of record to that effect.
- **Attachment 9: Animal Research Plan (if applicable; required for all studies utilizing animals; three-page limit per animal study): Upload as "AnimRschPln.pdf."**

When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should

not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
 - Summarize the procedures to be conducted. Describe how the study will be controlled.
 - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
 - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
 - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
 - Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Attachment 10: Human Subject Recruitment and Safety Procedures (if applicable; required for all studies recruiting human subjects; no page limit): Upload as "HumSubProc.pdf."** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
 - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from whom the sample will be recruited/drawn). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous observational studies and/or clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.
 - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical study. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.
 - ***Inclusion of Women and Minorities in Study.*** Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and Congressional legislation, special attention is given to

inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical study.

- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, healthcare provider identification).
 - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
 - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
 - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.
 - **For the proposed study, provide a draft, in English, of the Informed Consent Form.**
 - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
 - Include information regarding the timing and location of the consent process.
 - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
 - Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
 - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
 - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a

clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical study to be in compliance with Title 10 United States Code Section 980 (10 USC 980)

(<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>). If applicable, refer to the General Application Instructions, Appendix 6, for more information.

- ***Assent for minors or other populations that cannot provide informed consent:*** If these populations are included in the proposed clinical study, describe a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.
- **Risks/Benefits Assessment:**
 - **Foreseeable risks:** Clearly identify all study risks. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical study. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
 - **Risk management and emergency response:**
 - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
 - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
 - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
 - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
 - **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.

- **Attachment 11: Data Management (if applicable; required for all studies recruiting human subjects; no page limit): Upload as “Data_Manage.pdf.”** The Data Management attachment should include the components listed below.
 - **Data management:** Describe all methods used for data collection to include the following:
 - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
 - **Confidentiality:**
 - Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
 - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
 - Address requirements for reporting sensitive information to state or local authorities.
 - **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored. See [Section I.C.](#) for information regarding particular data repository requirements.
 - **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
 - **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.
 - **Laboratory Evaluations:**
 - Specimens to be collected, schedule, and amount: All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
 - Evaluations to be made: Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
 - Storage: Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.

- Labs performing evaluations and special precautions: Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.
 - **Attachment 12: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information.
- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.
- Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf.”
 - **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch_LastName.pdf.”
 - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.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.
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.

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

Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 12, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity 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/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

E. Submission Dates and Times

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

F. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All extramural applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA J9 – R&D Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and JPC-8/CRM RP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section III.B.2., Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

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

B. Application Review Process

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:
 - **Research Strategy and Feasibility**
 - How well the preliminary data and scientific rationale support the research project.
 - How relevant and applicable the proposed research and findings are to at least one of the FY17 JPC-8/CRM RP Hearing and Balance Research Award Capability Gaps and at least one of the Focus Areas.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
 - How consistent the methods and procedures are with sound research design.
 - How well the potential problems and alternative approaches are addressed.

- Whether the research can be completed within the proposed period of performance.
- To what degree the statistical model and data analysis plan are suitable for the planned study.
- How well a plan for management and sharing of research data is outlined as appropriate for the type of study.
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
- For research involving human subjects:
 - How well the population(s) of interest is (are) described, access to these populations is demonstrated, viable plans for recruitment, consent, screening, and retention of appropriate subjects are outlined, and sampling methods are identified to gain a representative sample from the population(s) of interest.
 - How well plans for addressing ethical and regulatory considerations have been developed, including mitigation of risk, consideration of privacy issues, and the process for obtaining informed consent.
 - If applicable, whether there is evidence demonstrating availability of the device/intervention from its source for the duration of the proposed study.
 - If required, whether an IDE/IND has been or could be acquired in the required timeline. If not required, how well the justification adequately describes a valid exemption.
- For applications involving animal studies:
 - How well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.
 - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
- **Military Benefit and Impact**
 - How well the potential immediate and long-term effects on patient care are described.
 - The potential immediate or long-term benefit and usability of the proposed research on the health and well-being of Service members and Veterans.
 - Potential for changing the standard of care in the treatment of auditory and/or vestibular injury.
- **Transition Plan**
 - Whether the funding strategy described to bring the outcome(s) to the next level of development and/or delivery to the military or civilian market is appropriate.

- Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
- How the schedule for bringing the outcome(s) to the next level of development are appropriate.
- How well the potential risk analysis for cost, schedule, manufacturability, and sustainability is developed.
- How well the application identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this Program Announcement/Funding Opportunity.
- **Budget (see [Section I.E., Funding](#) for budget details)**
 - Whether the budget is appropriate for the proposed research.
 - How well the funding level requested is justified.
 - How well the expenses are justified.

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

- **Environment**
 - To what degree the scientific environment and the accessibility of institutional/organizational resources support the proposed research.
 - Whether the quality and extent of institutional support are appropriate for the proposed project.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.

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

- a. Ratings and evaluations of the peer reviewers**
- b. Relevance to the mission of the DHP and JPC-8/CRM RP, as evidenced by the following:**
 - Programmatic relevance in relation to FY17 JPC-8/CRM RP Hearing and Balance Research Award Capability Gaps and Focus Areas.
 - Program portfolio composition
 - Military relevance and impact
 - Alignment/integration with DoD and/or VA research laboratories and programs

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

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

E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

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 including animal studies:
 - Attachment 9, Animal Research Plan, is missing.
- For applications recruiting human subjects:
 - Attachment 10, Human Subject Recruitment and Safety Procedures, is missing.
 - Attachment 11, Data Management, is missing.

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.

C. Withdrawal

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

- An FY17 Hearing and Balance Research Award Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY17 Hearing and Balance Research Award Programmatic Panel members can be found at <http://cdmrp.army.mil/dmrp/panels/HBRApanel17> .*
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The invited application does not propose the same research project described in the pre-application.
- For studies proposing a clinical trial, documentation of IND/IDE submission and/or approval is not provided.

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.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 4, Section H, for general information on reporting requirements.

Quarterly technical progress reports and quad charts and in-person presentations will be required.

E. Award Transfers

An organizational transfer of an award is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants Officer. 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 4, Section L, for general information on organization or PI changes.

VI. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code 20160210k. The numeric sequence of the Program Announcement/Funding Opportunity version code will match the General Applications Instructions version code 20160210.

B. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

C. Grants.gov Contact Center

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

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

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity 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.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
SF-424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Military Benefit and Impact: Upload as Attachment 6 with file name "MilBen.pdf."	
	7	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf."	
	8	IND/IDE Documentation: Upload as Attachment 8 with file name "IND-IDE.pdf." Required for Research Level 2.	
	9	Animal Research Plan: Upload as Attachment 9 with file name "AnimRschPln.pdf," if applicable.	
	10	Human Subject Recruitment and Safety Procedures: Upload as Attachment 10 with file name "HumSubProc.pdf," if applicable.	
	11	Data Management: Upload as Attachment 11 with file name "Data_Manage.pdf," if applicable.	
	12	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 12 with file name "MFBudget.pdf," if applicable.	
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		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	