# FY23 HRRP Funding Opportunity FAQ

### 1. Can one Principal Investigator (PI) submit more than one application?

There are no limitations on the number of applications for which an investigator may be named as a PI.

# 2. Are commercial organizations eligible to apply? And clinical researchers?

Commercial organizations and clinical researchers can apply if they are registered in SAM (<u>https://www.sam.gov</u>) and meet the eligibility criteria.

# 3. Can international applicants apply? If so, is having a partner researcher in the U.S. recommended?

International applicants can apply if they are registered as an entity in SAM (<u>https://www.sam.gov</u>) and receive confirmation of an "Active" status. Once registered, the same eligibility criteria apply to domestic and international applicants. Please refer to Section II.C, Eligibility Information, in the program announcement. For eligible international applicants, having a U.S. partner is neither required nor a review criterion.

# 4. I am a postdoctoral fellow. Can I apply?

Only independent investigators may be named as PI. Please refer to Section II.C.1.b, Principal Investigator, in the Focused Research Award program announcement, for additional eligibility information specific to PIs.

#### 5. Can I submit a revised proposal after it was rejected?

A project can be submitted again after it was rejected, as long as the new submission meets all the requirements of the new funding opportunity (such as alignment with current Focus Areas). All submissions will be treated as new submissions.

# 6. What are the topic areas that the HRRP is interested in?

Applications submitted to the FY23 HRRP must address at least one of the following Focus Areas:

- Improvement and acceleration of the translation of biological regeneration/repair mechanisms into clinical applications. Research addressing the damage, repair, and regeneration of the auditory system after military-relevant injuries is strongly encouraged.
- Development of diagnostic tests that differentiate sensory, neural, synaptic, and central processing disorders, that may inform applicability and outcomes for current or future hearing restoration therapeutics.

• Development of reliable in-vitro human models to facilitate the understanding, derivation, and characterization of human auditory cells, and/or to facilitate the evaluation of hearing restoration therapies.

### 7. How do I know which funding level to submit to?

When submitting the pre-application, it is the responsibility of the applicant to select the funding level that is most appropriate for the research proposed. The funding level should be selected based on the stage and maturity level of the research project, rather than the amount of the budget. Please refer to Section II.B, Award Information, of the Focused Research Award program announcement for a detailed description of the purpose and key features of each funding level.

### 8. Do I need to be invited in order to submit a full application?

*(New for FY23)* Applicants to the FY23 HRRP Focused Research Award should submit a Letter of Intent (LOI) as part of their pre-applications. Submission of a LOI is required prior to full application submission. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. An invitation to submit a full application is NOT provided after LOI submission and applicants are NOT required to have such an invitation in order to proceed to submitting a full application.

Please refer to II.D.2.a. Step 1: Pre-Application Submission Content, in the Focused Research Award program announcement, for additional details on LOI.

#### 9. What is a pilot clinical trial and how is it different from a clinical trial? A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

While both pilot clinical trials and full-scale clinical trials involve an intervention (or interventions) and the evaluation of the effects of the intervention(s) in human subjects, they differ in purpose. In contrast to full-scale clinical trials that are designed to determine safety or efficacy, the purpose of a pilot clinical trial is to inform the feasibility, rationale, and design of subsequent clinical trials through limited clinical testing of a novel intervention. The scale and design of the pilot clinical trial should serve and reflect such purpose.

# 10. What are the success rates for invited applications, i.e., submissions that have successfully moved beyond the pre-application stage?

The success rates vary by fiscal year. Details on the success rates in FY22 can be viewed in the FY22 HRRP Information Paper.

### 11. Where can I view recent awardees' research topics?

You may search past CDMRP awards by program and other parameters, and view an award's public abstracts at <u>https://cdmrp.health.mil/search.aspx</u>.

Note: FY22 HRRP awards are currently under negotiation and are not in the database; information will be searchable after September 2023.