**Program Announcement for the Defense Health Agency**

# Duchenne Muscular Dystrophy Research Program

# Clinical/Translational Research Award

Funding Opportunity Number: HT942526DMDRPCTRA

Pre-Application Due: September 4, 2026

Application Due: September 18, 2026

***This program announcement must be read in conjunction with the General Application Instructions, version CD26_01.***

# Content

## Before You Begin

- **Active SAM.gov, eBRAP.org and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read this funding opportunity announcement in the order it is written before beginning to prepare application materials.** It is the responsibility of the applicant to determine whether the proposed research meets the intent of this funding opportunity and that all parties meet eligibility requirements.
- **To support application preparation, additional resources are available** including an application process FAQ, a Guide for Intragovernmental & Intramural Applicants and a CDMRP Video Series detailing the application process.

## Who to Contact for Support

**eBRAP Help Desk**

301-682-5507
help@eBRAP.org

*Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.*

**Grants.gov Support Center**

800-518-4726
International: 1-606-545-5035
support@grants.gov

*Questions regarding Grants.gov registration and Workspace.*

This document uses internal links; you can go back to where you were by pressing the Alt + left arrow keys (Windows) or command + left arrow keys (Macintosh) on your keyboard.

***Click ⓘ to be taken to additional guidance and instructions within the General Application Instructions (GAI).***

# 1. Basic Information About the Funding Opportunity

**Summary:** The fiscal year 2026 (FY26) Duchenne Muscular Dystrophy Research Program (DMDRP) Clinical/Translational Research Award (CTRA) supports advanced translational research to accelerate promising ideas in Duchenne muscular dystrophy (DMD) research toward clinical applications. Research must address at least one of the FY26 CTRA Focus Areas. ***Research projects investigating therapies that will be efficacious across the life span are strongly encouraged.***

**Distinctive Features:** The FY26 CTRA offers two funding levels:

- Funding Level 1 to support smaller, less complex preclinical and/or clinical research.
- Funding Level 2 to support larger, more complex preclinical and/or clinical research.

The FY26 CTRA also offers a Partnering PI Option (PPIO) to support meaningful and productive partnerships between two investigators collaborating on the proposed research project. The PPIO has **two eligibility categories**:

- Early-Career Partnering PI category for an independent, early-career investigator within 10 years of their first faculty appointment (or equivalent) by the time of application submission.
- Established Interdisciplinary Partnering PI for independent investigators at all academic levels, or equivalent, in an area other than muscular dystrophy, seeking to transition to a career in DMD, thereby bringing their expertise to the field.

Preliminary data are ***required*** for all applications. Pilot clinical trials and clinical trial readiness studies to better inform development of drugs, devices, and other interventions are allowed.

**Funding Details:** The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly **$8.46M** to fund approximately 6 CTRA applications with total cost caps of **$0.91M** per award for Funding Level 1 with single PI**; $1.0M** per award for Funding Level 1 with PPIO; **$1.75M** per award for Funding Level 2 with single PI; and **$1.90M** per award for Funding Level 2 with PPIO. The maximum period of performance is **3** years for Funding Level 1. The maximum period of performance for Funding Level 2 is **4** years. It is anticipated that awards made from this fiscal year 2026 (FY26) funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. Awards supported with FY26 funds will be made no later than September 30, 2027.

## Submission and Review Dates and Times

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern Time (ET), September 4, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, September 18, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, September 25, 2026
- **Peer Review:** December 2026
- **Programmatic Review:** February 2027

**Announcement Type:** Initial

**Funding Opportunity Number:** HT942526DMDRPCTRA

**Assistance Listing Number:** 12.420

# 2. Eligibility Information

## 2.1. Eligible Applicants

### 2.1.1. Organization

Extramural and intramural U.S. Department of War (DOW) organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities***.

### 2.1.2. Principal Investigator

Independent investigators affiliated with an eligible organization are eligible to be named Principal Investigator (PI) on the application, regardless of ethnicity, nationality or citizenship status.

Partnering PI Option (PPIO): In order to be eligible for the PPIO option, the partnering PI must be in one of the two eligibility categories:

- Early-Career Partnering PI: An independent, early-career investigator within 10 years of their first faculty appointment (or equivalent) by the time of application submission. *Lapses in research time or appointments as denoted in the biographical sketch should be explained in the application.*
- Established Interdisciplinary Partnering PI: An independent investigator at all academic levels, or equivalent, in an area other than muscular dystrophy, seeking to transition to a career in Duchenne muscular dystrophy (DMD), thereby bringing their expertise to the field.

## 2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

## 2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions (GAI) for additional recipient qualification requirements.

# 3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the Duchenne Muscular Dystrophy Research Program (DMDRP). The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. Congress initiated the DMDRP in 2011 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the DMDRP from FY11 through FY25 totaled $92.1 million (M). The FY26 appropriation is $12.5M.

The vision of the FY26 DMDRP is to preserve and improve the function and quality of life, across the lifespan of all individuals with DMD. As such, the DMDRP seeks to support discovery, development, and delivery of safe, effective therapeutics for DMD at all stages of the disease for the benefit of military Families and the general public. Additionally, the DMDRP supports the efforts of the National Institutes of Health (NIH) Muscular Dystrophy Coordinating Committee (MDCC) and the 2015 MDCC Action Plan for the Muscular Dystrophies, which prioritizes the need to improve treatments and reduce the disease burden for muscular dystrophies, including DMD.

***The DMDRP seeks to support research that is relevant to the health care needs of Service Members, Veterans, and their Families, and/or Family readiness of Service Members. Musculoskeletal injuries and diseases are the third leading cause of medical encounters for active Service Members. Drug repurposing and development of novel advanced technologies to improve muscle strength and function after injury and disease are relevant to the support of Warfighter readiness and lethality. Additional information on relevance to military health can be found on the Program Summary Sheet on the DMDRP website.***

## 3.1. Intent of the Clinical/Translational Research Award

The FY26 DMDRP Clinical/Translational Research Award (CTRA) mechanism supports advanced translational research that will accelerate the movement of promising ideas in DMD research into clinical applications. Translational research may be defined as an integration of basic science and clinical observations. However, applicants should not view translational research as a one-way continuum from bench to bedside. The research plan must involve a reciprocal flow of ideas and information between applied and clinical research. As such, ***applications must include preliminary and/or published data relevant to DMD to support the proposed research project. Preliminary data may include unpublished results from the laboratory of the PI, research team, or collaborators named on the application.***

This mechanism is intended to support established projects that have moved beyond the realm of basic research and proof-of-concept studies and have the potential to result in a near-term impact in clinical research or the clinic. ***Research projects investigating therapies that will be efficacious in patients across the lifespan, including infants, toddlers, and nonambulatory individuals, are strongly encouraged***.

Pilot clinical trials and clinical trial readiness studies to better inform development of drugs, devices, and other interventions are ***allowed***.

### 3.1.1. Focus Areas for the CTRA

To meet the intent of the funding opportunity, ***applications must address at least one of the following focus areas***:

**Preclinical Translational Research**

- Extension or expansion of existing preclinical data in support of Investigational New Drug (IND) application-enabling studies. For example:
  - Optimizing therapeutic candidate or candidate delivery to target tissues **(Funding Level 1 only)**
  - Drug exposure
  - Independent replication
  - Comparative studies
  - Safety studies
  - Assay development, outcome measures and/or biomarkers (e.g., pharmacodynamic, prognostic, or predictive biomarkers, including potential surrogate markers)

**Clinical Research**

- Prospective/real world data/post-market studies for combination or sequential therapies, and/or long-term safety and efficacy studies
- Clinical studies designed to improve care and quality of life
- Assessment of clinical trial tools and outcome measures across the lifespan:
  - Discovery and qualification of pharmacodynamic, prognostic, and predictive biomarkers, including potential surrogate markers, with emphasis on minimally invasive approaches
  - Novel clinical outcome assessment
  - Patient-centered outcomes (e.g., quality of life, activities of daily living)
  - Secondary data analysis that helps to address clinical research tool validation
- Natural history studies in understudied systems (e.g., cognitive, gastrointestinal [GI], pulmonary, cardiac) or age ranges (e.g., infants, toddlers, and/or nonambulatory), with an aim toward clinical trial readiness

### 3.1.2. Key Elements for the CTRA

**Funding Levels:** The FY26 DMDRP CTRA offers two Funding Levels (refer to Section 3.4, Funding Details). Only one Funding Level category may be chosen per application, and the choice of application category is at the discretion of the applicant. The following are generalized descriptions of the scope of the research appropriate for each Funding Level:

- **Funding Level 1:** Intended to support smaller, less complex preclinical and/or clinical research. Pilot clinical trials are allowed. The proposal/application's ***total*** costs budgeted for the entire period of performance should not exceed **$0.91M** for a single PI, or **$1.0M** for a PPIO.
- **Funding Level 2:** Intended to support larger, more complex preclinical and/or clinical research. Pilot clinical trials are allowed. The proposal/application's ***total costs*** budgeted for

the entire period of performance should not exceed **$1.75M** for a single PI, or **$1.90M** for a PPIO.

**Partnering PI Option:** The FY26 DMDRP encourages applications that include meaningful and productive collaborations between investigators. In an effort to promote enhanced research capacity within the DMD field, the FY26 CTRA includes an option to include a partnering PI. In order to be eligible for the PPIO, the partnering PI must meet one of the two eligibility categories:

- Early-Career Partnering PI: An independent, early-career investigator within 10 years of their first faculty appointment (or equivalent) by the time of application submission. *Lapses in research time or appointments as denoted in the biographical sketch should be explained in the application.*
- Established Interdisciplinary Partnering PI: An independent investigator at all academic levels, or equivalent, in an area other than muscular dystrophy, seeking to transition to a career in DMD, thereby bringing their expertise to the field.

The PPIO is structured to accommodate two PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The Early-Career PI or the Established Interdisciplinary will be identified as the Partnering PI. Both PIs should contribute significantly to the development and execution of the proposed research project. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PI(s), refer to Section 5.3, Submission Instructions.

### 3.1.3. Other Important Considerations for the CTRA

In accordance with the National Defense Authorization Act for Fiscal Year 2026, Section 732, the CDMRP does not support the conduct of painful research (U.S. Department of Agriculture pain category D or E) involving domestic cats or dogs, except for studies relating to military or service animals.

**Clinical trials and clinical research are allowed within this funding opportunity.**

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research, such as those described in the STROBE, CONSORT, SPIRIT and ARRIVE guidelines 2.0.

Applications from investigators within the DOW and applications involving multidisciplinary collaborations among academia, industry, the DOW, the U.S. Department of Veterans Affairs (VA) and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, their Families and the American Public. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

## 3.3. Funding Instrument

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

## 3.4. Funding Details

**CTRA Funding Level 1**

**Period of Performance:** The maximum period of performance is **3** years.

**Cost Caps:**

***Single PI:*** The application's total costs budgeted for the entire period of performance should not exceed **$0.91M.**

***PPIO:*** The combined total costs budgeted for the entire period of performance in the applications of the initiating PI and each Partnering PI should not exceed **$1.0M.**

**CTRA Funding Level 2**

**Period of Performance:** The maximum period of performance is **4** years.

**Cost Caps:**

***Single PI:*** The application's total costs budgeted for the entire period of performance should not exceed **$1.75M.**

***PPIO:*** The combined total costs budgeted for the entire period of performance in the applications of the initiating PI and each Partnering PI should not exceed **$1.90M.**

**All Funding Levels**

If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years for Funding Level 1, or **4** years for Funding Level 2.

The appropriateness of the budget for the proposed research will be assessed during peer review.

**Direct Cost Restrictions:** For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for **one** investigator to travel to **one** scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY26 DMDRP CTRA.

Must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.

# 4. Application Contents and Format

## 4.1. Application Overview

Application submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP) and a ***full application*** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

***Intramural DOW organizations submitting a full application should follow instructions for submission through eBRAP.***

***Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.***

## 4.2. Pre-Application Components

The Initiating PI must submit the following pre-application components.

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted.

LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. ***An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.***

## 4.3. Full Application Components

### 4.3.1. Full Application Components for the PI or Initiating PI

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

**Partnering PI Option:** The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. The application submission process for the Partnering PI uses an abbreviated full application package.

**(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov submissions only)*:**

***IMPORTANT:*** *When completing the SF424 R&R, enter the* ***eBRAP log number*** *assigned during pre-application submission into* ***Block 4a – Federal Identifier****.*

**(b) Attachments:**

Each attachment of the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines in the GAI.

- **Attachment 1: Project Narrative (15-page limit): Upload as "ProjectNarrative.pdf".**

  Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed research. The application must provide a sound scientific rationale to support the proposed project and its feasibility as established through the demonstration of logical reasoning and critical review and analysis of published literature; include relevant literature citations. Include preliminary data to support the scientific rationale and feasibility of the research approaches. Applications ***must*** include preliminary data to support the clinical relevance of the idea. Any unpublished preliminary data provided should originate from the laboratory of the PI(s) or a member(s) of the research team.
- **Hypotheses/Objectives:** State the hypotheses/study questions and overall objective(s) to be reached.
- **Specific Aims:** Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that this award would fund.
- **Research Strategy and Feasibility:** Describe the experimental design, methods, and analyses including appropriate controls, in sufficient detail for evaluation. Clearly describe how data will be collected and analyzed in a manner that is consistent with the study objectives. Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported. Address potential limitations and present alternative methods and approaches. Describe availability of, access to, and quality control for all data and/or critical reagents, and/or cohorts, where relevant.
  - If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines 2.0 to achieve reproducible and rigorous results, including the choice of model and the endpoint/outcomes to be measured.
  - If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.
  - For clinical research, describe the strategy for the inclusion of women and minorities in the clinical research appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, race, and/or ethnicity, and an accompanying rationale for the selection of subjects.
  - If the proposed research involves access to military and/or VA patient populations and/or DOW or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding or other agreements required to access and publish data. Refer to the General Application Instructions, Appendix 4, for additional considerations.
  - ***If funds for a clinical trial are requested, details regarding the Clinical Strategy Statement must be described in Attachment 9.*** *Only those proposed studies measuring safety, effectiveness, and/or efficacy of an intervention are considered clinical trials and should submit a Clinical Strategy Statement.*
- **Statistical Analysis Plan:** Describe the statistical analysis plan for the resulting outcomes. If applicable, include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. Describe how data will be reported and how it will be assured that the documentation will support a

regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

- **Statement of Collaboration (optional; encouraged for PPIO applications):** Describe the composition of the study team, partners, or any collaborations in enough detail to determine whether the team includes relevant DMD subject matter or other relevant expertise to accomplish the proposed work as it relates to the study hypothesis or objective. Describe how the collaboration will augment the PI's expertise to best address the research question.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".**

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

- **References Cited:** List the references cited in the Project Narrative using a standard reference format (include URLs, if available).
- **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; include any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference the original or present government award under which the facilities or equipment items are now accountable. There is not a standardized form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letters of Support (two-page limit per letter is recommended):** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOW collaborator(s) and/or access to military populations, databases or DOW resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.
- **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Data and/or Research Sharing Plan:** Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe the mechanism (e.g., direct sharing, repository, mixed mode) by which data and resources generated

during the period of performance will be shared with the research community and other affected communities, including clinical research participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed study will be archived, if applicable. Identify and provide the rationale for any data or resources that will not be shared (e.g. for intellectual property, feasibility, cost, or other considerations). The plan should also protect participant privacy, confidential and proprietary data, and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

***Do not submit a copy of the NIH Data Management and Sharing Plan or duplicate the Data Management Plan, which will be requested only after a recommendation for funding is made.***

Refer to the CDMRP Directive on Sharing Data and Research Resources for more information about the CDMRP's expectations for making data and research resources publicly available.

- **Inclusion Enrollment Report *(only required if clinical research and/or a clinical trial is proposed)*:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the "Public Health Service (PHS) Inclusion Enrollment Report", a three-page fillable PDF form that can be downloaded from eBRAP. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".**

Write the technical abstract using the outline below. Clarity and completeness within the space limits are highly important.

- **Background:** Present the scientific rationale behind the proposed research project.
- **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached. Provide evidence or scientific rationale that supports the hypothesis/objective(s).
- **Specific Aims:** State the specific aims of the study, ensuring they address at least one of the FY26 CTRA Focus Areas.
- **Study Design:** Describe the study design, including appropriate controls.
- **Impact:** Briefly describe how the proposed project will have an impact on preserving and improving the function and quality of life and extending the lifespan of all individuals with DMD. Describe how the project will translate promising, well-founded laboratory or clinical research findings into clinical applications for patients with or populations at risk for DMD.
- **Military Relevance:** Describe how the study is relevant to military health.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".**

  The lay abstract should address the points outlined below ***in a manner that is readily understood by readers without a background in science or medicine.*** Avoid overuse of scientific jargon, acronyms and abbreviations. ***Do not duplicate the technical abstract.***

  - Summarize the objectives and rationale for the proposed research.
  - State the FY26 CTRA Focus Area(s) the project addresses
  - What population will the research help, and how will it help them?
  - What are the potential applications, benefits and risks of the anticipated outcomes?
  - What is the projected time anticipated to achieve a clinically relevant outcome? What are the likely contributions of this study to advancing the field of DMD research and/or patient care?
  - What is the potential benefit of the proposed study and the anticipated outcomes to Service Members, Veterans and/or their Families?

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the Suggested SOW Format.

  For guidance on preparing the SOW, refer to either the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work or Example: Assembling a Generic Statement of Work, whichever is most appropriate for the proposed effort. Include milestones for data or research resource(s) sharing.

  ***Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and the Partnering PI should be clearly noted for each task.***

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** ***The Impact Statement should be written in plain language with a broad audience in mind, including readers without a background in science or medicine.*** *The Impact Statement should articulate the project's near-term impact to both DMD research and to individuals with DMD, even if clinical impact is not an immediate outcome.*

  - Describe how the proposed research is relevant to at least one of the FY26 CTRA Focus Areas in a way that is consistent with the program's goals. ***The relevance of all research should relate to patient outcomes and how it benefits those affected by DMD.***
  - Describe how the project will translate promising, well-founded laboratory or clinical research findings into clinical applications for patients with or populations at risk for DMD.
  - Explain how the proposed research will make a significant impact on DMD research and/or patient care, including how the new understanding may ultimately contribute to the goal of preserving and improving the function and quality of life, and extending the lifespan of all individuals with DMD.
  - Explain briefly how the proposed research is relevant to the health care needs of Service Members, Veterans, their Families, and/or the readiness of Service Members.

- **Attachment 7: Transition Plan (two-page limit): Upload as "Transition.pdf".** Provide information on potential methods and strategies to feasibly move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award. The transition plan should include the components listed below.
  - A description of the scientific or technical requirements needed to advance the research findings.
  - An assessment of the opportunities available and potential barriers that would impact the progress of commercializing and/or translating the study results into clinical practice.
  - A timeline with defined milestones and deliverables describing the expected post-award progress of the results toward the next phase of development and eventual clinical impact.
  - Details of the funding strategy that will be used to bring the outcomes to the next phase of development. Provide sufficient evidence that the PI has, or can secure, additional funding and describe potential options to secure the additional funding needed to bring the outcomes to the next phase of development (e.g., specific potential industry partners and/or specific funding opportunities to apply for).
  - A description of collaborations and other resources that will be used to provide continuity of development.
  - A plan to distribute the findings or intervention to the DMD community.
- **Attachment 8: Animal Research Plan (five-page limit): Upload as "AnimalResPlan.pdf". (*Attachment 8 is only applicable and required for applications proposing animal studies.*)**

  If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results 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).

- **Attachment 9: Clinical Strategy Statement, *if applicable* (no page limit): Upload as "Clinical.pdf". If funds for a clinical trial are requested, this attachment is required. *Only those proposed studies measuring safety, effectiveness, and/or efficacy of an intervention are considered clinical trials and should include a Clinical Strategy Statement.***

  - Describe the rationale for the proposed clinical trial. Provide a description of the intervention and the endpoints to be measured. Describe the type of clinical 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.
  - If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically, identify the portions of the study that would be supported with funds from this award.
  - Provide detailed plans for initiating the clinical study within the first year, including FDA IND/Investigational Device Exemption (IDE) application submission plans, **prior to the FY26 DMDRP CTRA application submission deadline**, if applicable. 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. The government reserves the right to withhold or withdraw funding if an IND or IDE is necessary but has not been submitted to the FDA by the application submission deadline, or if documented status of the IND or IDE has not been obtained within nine months of the award date.
  - Indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity using the Public Health Service (PHS) Inclusion Enrollment Report, which is a three-page fillable PDF form that can be downloaded from eBRAP.
  - Describe the type of clinical trial to be performed (e.g., prospective, randomized, cohort, case-control, cross-sectional) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate. Describe how the clinical trial will inform the correlative clinical research, if applicable.
  - State how many months into the award the anticipated clinical trial would be initiated, taking into account any clinical trial preparation (IRB and DOW Office of Human Research Oversight [OHRO, previously Human Research Protection Office] approval). Note: The clinical trial must begin within the first year of the award.
  - **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. Include a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed

correlative studies. 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. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

- **Attachment 10: Partnership Statement (one-page limit): Upload as "Partnership.pdf".** ***(Attachment 10 is only applicable and required for applications submitted under the PPIO.)***
  - Describe the experience of the Initiating and Partnering PIs and indicate how the award will help to enhance research capacity within the DMD field. Describe the contribution and time commitment of each PI toward the proposed research project. Describe how the partners' combined experience will better address the research question and explain why the work should be done together rather than through separate efforts.
- **Attachment 11: Representations** ***(Grants.gov submissions only)*****: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.
- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form** ***(if applicable)*****: Upload as "IGBudget.pdf".** If an intramural DOW organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the Suggested Intragovernmental/Intramural Budget form available on eBRAP.

**(c) Additional Application Materials:**

The following are additional forms for application submission. Follow the instructions specific to the submission portal, as found within the GAI.

| Grants.gov | eBRAP.org |
|---|---|

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

- **Biographical Sketch**
- **Current/Pending Support**

  *Intragovernmental applicants must include their internally supported research and development programs.*

**ii. Research & Related Budget**

*Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s), or vice versa, even if they are located within the same organization. Refer to* ***Section 3.4, Funding Details****, for detailed budget information.*

**iii. Project/Performance Site Location(s)**

**iv. Research & Related Subaward Budget Attachment(s)** *(if applicable, Grants.gov submissions only)*

### 4.3.2. Full Application Submission Components for the Partnering PI (If Applying Under the Partnering PI Option)

Refer to the equivalent attachment above for details specific to each of the following application components. See Appendix 1 for a checklist of the full application components required for the Partnering PI.

**(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov Submissions Only)*:**

**(b) Attachments:**

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

**(c) Additional Application Materials:**

The following are additional formsapplication materials for application submission. Follow the instructions specific to the submission portal found within the GAI.

Grants.gov eBRAP.org

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

- **Biographical Sketch**
- **Current/Pending Support**

  *Intragovernmental applicants must include their internally supported research and development programs.*

**ii. Research & Related Budget**

*Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Partnering PI(s) should not include budget information for the Initiating PI, or vice versa, even if they are located within the same organization. Refer to Section 3.4, Funding Details, for detailed budget information.*

**iii. Project/Performance Site Location(s) Form**

**iv. Research & Related Subaward Budget Attachment(s) Form** *(if applicable, Grants.gov submissions only)*

## 4.4. Other Application Elements

If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.

The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

# 5. Submission Requirements

## 5.1. Location of Application Package

Download the application package components for HT942526DMDRPCTRA from Grants.gov or eBRAP, depending on which submission portal will be used.

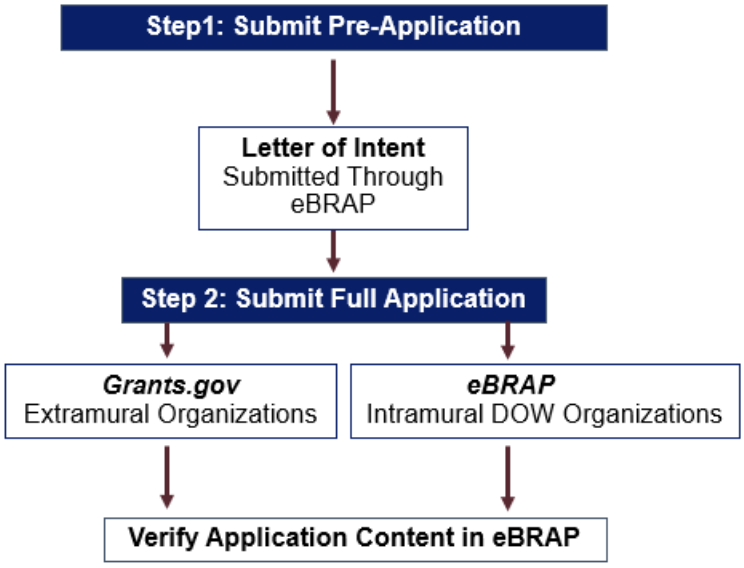
## 5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration.

## 5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions. The workflow below shows which portal system to use for pre- and full application submissions, respectively.

***Application Submission Workflow***




### 5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI or Initiating PI through eBRAP, including the submission of contact information for the Partnering PI if selecting the Partnering PI Option.

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

number, application title and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify and verify the application in eBRAP. Contact the eBRAP Help Desk if any changes need to be made.

**Partnering PI Option**: After the Initiating PI confirms submission of the pre-application, the Partnering PI[(s)] will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI must follow the instructions provided in the email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI must register in eBRAP.

***Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI.*** Partnering PIs are urged to associate the partnering pre-application with their eBRAP account as soon as possible. If this is not completed by the full application deadline:

- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.
- The Partnering PI[(s)] will not be able to view and modify their full application during the verification period in eBRAP.

When starting the pre-application, PIs should select a Mechanism Option appropriate to their pre-application:

| Application Includes: | Select Option: |
|---|---|
| Funding Level 1 and Single PI and NO Clinical Trial | CTRA, Funding Level 1 |
| Funding Level 1 and Single PI and Clinical Trial | CTRA – Clinical Trial, Funding Level 1 |
| Funding Level 1 and Partnering PI Option but NO Clinical Trial | CTRA with Partnering PI Option, Funding Level 1 |
| Funding Level 1 and Partnering PI Option and Clinical Trial | CTRA with Partnering PI Option – Clinical Trial, Funding Level 1 |
| Funding Level 2 and Single PI and NO Clinical Trial | CTRA, Funding Level 2 |
| Funding Level 2 and Single PI and Clinical Trial | CTRA – Clinical Trial, Funding Level 2 |
| Funding Level 2 and Partnering PI Option but NO Clinical Trial | CTRA with Partnering PI Option, Funding Level 2 |
| Funding Level 2 and Partnering PI Option and Clinical Trial | CTRA with Partnering PI Option – Clinical Trial, Funding Level 2 |

### 5.3.2. Full Application Submission

**Grants.gov Submissions:** Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace.

**eBRAP Submissions:** Only intramural DOW organizations may submit full applications through eBRAP.

### 5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the application verification period ends. The full application cannot be modified once the application verification period ends.

## 5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The DHACA cannot make allowances/exceptions for submission problems encountered by the applicant.***

Submission dates and times are specified in Section 1, Basic Information.

## 5.5. Intergovernmental Review

Not applicable for this funding opportunity.

# 6. Application Review Information

## 6.1. Application Compliance Review

***Submitting applications that propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).***

While it is allowable to propose similar research projects to different programs within the CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the CDMRP's Directive on Research Duplication.

Including classified research data within the application and/or proposing research that may produce classified outcomes or outcomes deemed sensitive to national security concerns, may result in application withdrawal.

Members of the FY26 DMDRP Programmatic Panel must not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members ***may*** provide letters to confirm PI eligibility and access to laboratory space, equipment and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). ***A list of the FY26 DMDRP Programmatic Panel members can be found on the CDMRP website.***

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

## 6.2. Review Criteria

### 6.2.1. Pre-Application Screening Criteria

Pre-applications submitted to this funding opportunity are used for program planning purposes only (e.g., reviewer recruitment) and will not be screened.

### 6.2.2. Peer Review Criteria

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

- **Research Strategy and Feasibility**
  - How well studies are designed to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured.
  - How well the scientific rationale for the proposed study and its feasibility is supported by the preliminary data, critical review, and analysis of the literature, and/or laboratory and/or preclinical evidence.
  - How well the hypotheses or objectives, aims, experimental design, methods, analyses, data collection, statistical analysis plan, rationale for the statistical methodology, and power analysis (if applicable) are developed.

- If animal studies are included, how well studies are designed to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured.
- If human subjects or human anatomical samples will be used, how well the plan for the recruitment of subjects or the acquisition of samples is justified and appropriate to accomplish the proposed work.
- If clinical research is proposed, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
- How well the SOW indicates a feasible plan and timeline to conduct the research and provides clearly defined research milestones to be accomplished by the end of each year in the period of performance.
- Whether there is documented availability of, access to, and quality control for all data and/or critical reagents, and/or cohorts, where relevant.
- Whether the proposed plan for data sharing includes databases most relevant to DMD (if applicable), and whether the plan describes organizational and technical capabilities sufficient to share project data in a timely manner.
- How well the application acknowledges potential problems and addresses alternative approaches.
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

- **Clinical Trial Strategy (for applications proposing a clinical trial)**
  - To what extent the application justifies the scientific rationale for the proposed clinical trial.
  - To what degree the proposed clinical trial and proposed intervention are supported by strong preliminary data and relevant literature citations.
  - How well the endpoints to be measured are justified for the described clinical trial.
  - Whether the proposed type of clinical trial to be performed (e.g., randomized, cohort, case-control, cross-sectional) is supported by the methodology to be used.
  - Whether there are detailed plans for initiating the clinical study within the first year, including FDA IND/IDE application submission prior to the FY26 DMDRP CTRA application submission deadline, if applicable.
  - Whether the study population is clearly defined, and whether access to the study population, recruitment plans, and inclusion/exclusion criteria, including justification for the plans and alternatives strategies if issues arise, are sufficient. Whether the informed consent process is clearly articulated.
  - Whether the application describes a strategy for the inclusion of women and minorities that is appropriate for the objectives of the study, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of subjects.
  - Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity is included.

- If applicable, whether the application shows how the data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA.
- To what degree potential challenges and alternative strategies are addressed.
- How well the clinical trial will inform correlative clinical research, if applicable.

- **Statistical Plan**
  - Whether the statistical plan, including sample size projections and power analysis, is adequate for the study (if applicable).
- **Impact**
  - How well the proposed research addresses at least one of the FY26 CTRA Focus Areas.
  - Whether the proposed research project describes how it will lead to major advancements with a significant impact on DMD research and/or patient care, including how the project will translate promising, well-founded laboratory or clinical research findings into clinical applications for patients with or populations at risk for DMD.
- **Transition Plan**
  - How well the application demonstrates feasible methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award.
  - Whether the application appropriately addresses available opportunities and potential barriers that could impact the progress of commercializing and/or translating the study results into clinical practice.
  - Whether the timeline for expected post-award progress is reasonable and contains appropriate milestones and deliverables for advancing the study results toward clinical impact.
  - Whether the proposed transition plan includes sufficient evidence that the PI has or can secure additional funding, or whether the plan clearly describes potential options to secure the additional funding needed to bring the outcomes to the next phase of development.
  - Whether the collaborations and other resources described are sufficient to provide continuity of development.
  - How well the plans are described for distribution of the findings or intervention to the DMD community.
- **Personnel**
  - How the PI has assembled an appropriate and robust research team with their combined backgrounds and DMD-related expertise to enable successful conduct of the project.
  - To what degree the levels of effort by the applicant and other key personnel are appropriate to ensure the success of this research effort.
  - How well the applicant's record of accomplishment demonstrates their ability to accomplish the proposed work.
  - **Partnering PI Option (if applicable):** How the partners' combined expertise will better address the research question, and to what extent the award will help to enhance research capacity within the DMD field.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Research Sharing Plan**
  - To what extent the plan for sharing of project data and research resources is appropriate and reasonable and includes dissemination to affected communities, study participants and/or the scientific community. If applicable, whether specific repository(ies) are named where data and research resources arising from the project will be stored.
  - The expertise and levels of effort are for successful conduct of the proposed work.
- **Budget**
  - Whether the budget is appropriate for the proposed research.
- **Environment**
  - To what extent the scientific environment and level of institutional support is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
- **Application Presentation**
  - To what extent the writing, clarity and presentation of the application components influence the review.

#### 6.2.3. Programmatic Review

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

- Ratings and evaluations of peer reviewers
- Relevance to the priorities of the FY26 DMDRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Impact and relevance to military health

### 6.3. Application Review and Selection Process

#### 6.3.1. Pre-Application

There is no review and selection process for pre-applications submitted to this funding opportunity. ***CDMRP will NOT provide an invitation to submit a full application after pre-application submission***. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.

#### 6.3.2. Full Application

All applications are evaluated by scientists, clinicians and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria

to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are subject to review and approval by a designated official. ***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 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds.

## 6.4. Risk, Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in the Code of Federal Regulations, Title 2, Part 200.1 (2 CFR 200.1), over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the SAM.

An applicant organization may review the SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

In accordance with National Security Presidential Memorandum-33 and all associated laws, all fundamental research funded by the DOW must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

# 7. Federal Award Notices

For each compliant full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the application receipt and review process for the DMDRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website. After all awards are made, the CDMRP includes individual award information in a searchable database.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

***Only an appointed DHACA Grants Officer may obligate the government to the expenditure of funds to an extramural organization.*** No commitment on the part of the government should be inferred from discussions with any other individual. ***The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).***

***Intragovernmental obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.***

Funding obligated to ***intragovernmental and intramural DOW organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD) or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOW investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award.

# 8. Post-Award Requirements

## 8.1. Administrative and National Policy Requirements

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

The GAI contain information regarding administrative requirements and national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the DHACA Terms and Conditions for further information.

***If there are delinquencies in technical reporting requirements for any existing DHA or U.S. Army Medical Research and Development Command awards at the applicant organization, DHACA will not issue any new awards to the applicant organization until all delinquent reports have been submitted.***

Applications recommended for funding that involve animals, human data, human specimens, human subjects or human cadavers must be reviewed for compliance with federal animal and/or human subjects protection requirements and must be approved by the DHA R&D Office of Research and Regulatory Compliance (ORRC), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), IRB or Ethics Committee (EC) review.

## 8.2. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical progress reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

For all awards including prospective accrual of human subjects, quarterly technical progress reports may be required

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

An Award Expiration Transition Plan, using the template available on eBRAP, must be submitted with the final progress report.

PHS Inclusion Enrollment Reporting ***(required for research proposing clinical research and/or clinical trials)***: Enrollment reporting on the basis of sex, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on eBRAP.

Funded clinical trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Additionally, the CDMRP requires all funded clinical trials to register and submit study results on ClinicalTrials.gov.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to the SAM about certain civil, criminal and

administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with their performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil and administrative proceedings as specified in the applicable Representations.

## 8.3. Additional Requirements

Unless otherwise restricted, changes in the PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

An organizational transfer of an award supporting the PI, Initiating PI, or Partnering PI is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants Officer. The organizational transfer of an award supporting a clinical trial is strongly discouraged and, in most cases, will not be allowed. Approval of a transfer request will be on a case-by-case basis 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.

# 9. Other Information

## 9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26_01d.

## 9.2. Administrative Actions

After receipt of full applications, the following administrative actions may occur.

### 9.2.1. Rejection

The following will result in administrative rejection of the full application:

- Pre-application was not submitted.
- The Project Narrative is missing.
- The Budget is missing.

### 9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to reviewing all documents.
- Documents not requested will be removed.

### 9.2.3. Withdrawal

The following may result in administrative withdrawal of the full application:

- A member of the FY26 DMDRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.
- The federal government recipient organization (including an intramural DOW organization): (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or (b) cannot coordinate the use of contractual, assistance or other appropriate agreements to provide funds to collaborators.
- The application fails to conform to this program announcement description.

- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The same research project is submitted to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- The Animal Research Plan (Attachment 8) is missing, for applications proposing animal studies.
- An application proposing a clinical trial where Attachment 9: Clinical Strategy Statement is missing.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

### 9.2.4. 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 DHACA Grants Officer for a determination of the final disposition of the application.

# Appendix 1. Full Application Submission Checklist

| Full Application Components | Uploaded | |
|---|---|---|
| | Initiating PI | Partnering PI |
| **SF424 Research & Related Application for Federal Assistance *(Grants.gov submissions only)*** | ☐ | ☐ |
| **Summary (Tab 1) and Application Contacts (Tab 2) *(eBRAP submissions only)*** | ☐ | ☐ |
| **Attachments** | | |
| **Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"** | ☐ | |
| **Supporting Documentation – Attachment 2, upload as "Support.pdf"** | ☐ | |
| **Technical Abstract – Attachment 3, upload as "TechAbs.pdf"** | ☐ | |
| **Lay Abstract – Attachment 4, upload as "LayAbs.pdf"** | ☐ | |
| **Statement of Work –Attachment 5, upload as "SOW.pdf"** | ☐ | ☐ |
| **Impact Statement – Attachment 6, upload as "Impact.pdf"** | | |
| **Transition Plan – Attachment 7, upload as "Transition.pdf"** | | |
| **Animal Research Plan – Attachment 8, upload as "AnimalResPlan.pdf"** | | |
| **Clinical Strategy Statement – Attachment 9, upload as "Clinical.pdf"** | | |
| **Partnership Statement – Attachment 10, upload as "Partnership.pdf"** | | |
| **Representations *(Grants.gov submissions only)* – Attachment 11, upload as "RequiredReps.pdf"** | ☐ | ☐ |
| **Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 12, upload as "IGBudget.pdf"** | ☐ | ☐ |
| **Additional Application Materials** | | |
| **Research & Related Senior/Key Person Profile (Expanded)** | ☐ | ☐ |
| **Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)** | ☐ | ☐ |
| **Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)** | ☐ | ☐ |
| **Research & Related Budget** | ☐ | ☐ |
| **Project/Performance Site Location(s)** | ☐ | ☐ |
| **Research & Related Subaward Budget Attachment(s) (*if applicable*)** | ☐ | ☐ |

# Appendix 2. Acronym List

| | |
|---|---|
| ARRIVE | Animal Research: Reporting of In Vivo Experiments |
| CDMRP | Congressionally Directed Medical Research Programs |
| CFR | Code of Federal Regulations |
| CONSORT | Consolidated Standards of Reporting Trials |
| CTRA | Clinical/Translational Research Award |
| DHA | Defense Health Agency |
| DHA R&D | Defense Health Agency Research and Development |
| DHACA | Defense Health Agency Contracting Activity |
| DMD | Duchenne Muscular Dystrophy |
| DOD | U.S. Department of Defense |
| DoDGARs | Department of Defense Grant and Agreement Regulations |
| DOW | U.S. Department of War |
| eBRAP | Electronic Biomedical Research Application Portal |
| EC | Ethics Committee |
| ET | Eastern Time |
| FAD | Funding Authorization Document |
| FDA | U.S. Food and Drug Administration |
| FY | Fiscal Year |
| GAI | General Application Instructions |
| IACUC | Institutional Animal Care and Use Committee |
| IDE | Investigational Device Exemption |
| IND | Investigational New Drug |
| IRB | Institutional Review Board |
| LOI | Letter of Intent |
| M | Million |
| MIPR | Military Interdepartmental Purchase Request |
| NIH | National Institutes of Health |
| OHRO | Office of Human Research Oversight (previously Human Research Protection Office) |
| ORRC | Office of Research and Regulatory Compliance |
| PDF | Portable Document Format |
| PHS | Public Health Service |
| PI | Principal Investigator |
| R&D | Research and Development |
| RPPR | Research Performance Progress Report |

| | |
|---|---|
| SAM | System for Award Management |
| SF424 R&R | Standard Form 424 (Application for Federal Assistance, Research & Related) |
| SOW | Statement of Work |
| SPIRIT | Standard Protocol Items: Recommendations for Interventional Trials |
| STROBE | STrengthening the Reporting of OBservational studies in Epidemiology |
| UEI | Unique Entity Identifier |
| URL | Uniform Resource Locator |
| USC | United States Code |
| VA | U.S. Department of Veterans Affairs |