Program Announcement for the Department of Defense
Defense Health Program

Duchenne Muscular Dystrophy Research Program

Clinical/Translational Research Award

Funding Opportunity Number: HT942525DMDRPCTRA

Pre-Application Due: July 25, 2025

Application Due: August 8, 2025

This program announcement must be read in conjunction with the General Application Instructions, version CD25_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 the 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 the funding opportunity and that all parties meet eligibility requirements.

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 Contact 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 Alt + left arrow key (Windows) or command + left arrow key (Macintosh) on your keyboard.

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2025 (FY25) Duchenne Muscular Dystrophy Research Program (DMDRP) Clinical/Translational Research Award (CTRA) mechanism supports advanced translational research that will accelerate the movement of promising ideas in Duchenne muscular dystrophy (DMD) research into clinical applications. Research must address at least one of the FY25 CTRA focus areas. ***Research projects investigating therapies that will be efficacious across the life span, including infants, toddlers, and nonambulatory individuals, are strongly encouraged.***

Distinctive Features: Applications must include preliminary and/or published data relevant to DMD to support the proposed research project. Pilot, proof-of-principle clinical trials, and correlative studies to better inform development of drugs, devices, and other interventions are allowed. The CTRA offers two funding levels: **Funding Level 1** to support smaller, less complex preclinical and/or clinical research; and **Funding Level 2** to support larger, more complex preclinical and/or clinical research.

Early-Career Partnering PI Option (PPIO): The Partnering PI must be 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.

It is encouraged, but not required, that the partnering PI is an M.D. or M.D./Ph.D. to increase collaboration between clinical and nonclinical aspects of DMD research.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $8.46 million (M) to fund approximately 6 CTRA applications with total cost caps of $0.91M for Funding Level 1; $1.0M for Funding Level 1 with a PPIO; $1.75M for Funding Level 2; and $1.90M for Funding Level 2 with a 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 FY25 funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

Submission and Review Dates and Times

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern Time (ET), July 25, 2025
- **Application Submission Deadline:** 11:59 p.m. ET, August 8, 2025
- **End of Application Verification Period:** 5:00 p.m. ET, August 13, 2025
- **Peer Review:** October 2025
- **Programmatic Review:** February 2026

Announcement Type: Modified

Funding Opportunity Number: HT942525DMDRPCTRA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural organizations are eligible to apply***, including foreign and domestic organizations, for-profit and non-profit organizations, and public or private entities***.

Extramural Organization: An eligible non-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

2.1.2. Principal Investigator

Independent investigators at all career levels may be named as Principal Investigator (PI) or Initiating PI on the application. For titles outside of academia that may not be analogous to traditional hierarchies, investigators at or above an independent scientist level may be named by their organization as the PI on the application.

Early-Career Partnering PI Option: The Partnering PI must be 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.

It is encouraged, but not required, that the partnering PI is an M.D. or M.D./Ph.D. to increase collaboration between clinical and nonclinical aspects of DMD research.

Individuals affiliated with an eligible organization are eligible to be named as PI regardless of ethnicity, nationality, or citizenship status.

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, Appendix 1, for additional recipient qualification requirements.

3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP at the U.S. Army Medical Research and Development Command (USAMRDC) is the program office managing this FY25 funding opportunity as part of the DMDRP. Congress initiated the DMDRP in 2011 to provide support for research of exceptional scientific merit to promote the understanding, diagnosis, and treatment of DMD. Appropriations for the DMDRP from FY11 through FY24 totaled $79.6M. The FY25 appropriation is $12.5M.

The vision of the FY25 DMDRP is to preserve and improve the function and quality of life, and to extend the life span of all individuals with DMD. As such, the DMDRP seeks to support discovery, development, and delivery of 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 needs to improve treatments and reduce the disease burden for muscular dystrophy, including DMD.

3.1. Intent of the CTRA

The FY25 DMDRP 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.

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 across the life span, including infants, toddlers, and nonambulatory individuals, are strongly encouraged. Pilot, proof-of-principle clinical trials, and correlative 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, all applications for the FY25 DMDRP CTRA 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 delivery to target tissues.
    - Drug exposure.
    - Independent replication.
    - Comparative studies.

- Assay development, outcome measures, and/or biomarkers (e.g., pharmacodynamic, prognostic, or predictive biomarkers, including potential surrogate markers).

Clinical Research

- Clinical studies designed to improve care and quality of life.
- Prospective/real world data/post market studies for combination or sequential therapies, and/or long-term safety and efficacy studies.
- Assessment of clinical trial tools and outcome measures:
  - Studies in understudied systems (e.g., cognitive, cardiac, or gastrointestinal [GI]) or age ranges (e.g., infants, toddlers, and/or nonambulatory)
  - Discovery and qualification of pharmacodynamic, prognostic, and predictive biomarkers, including potential surrogate markers.
  - Novel clinical outcome assessments.
  - 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, cardiac, GI) or age ranges (e.g., infants, toddlers, nonambulatory adults) with an aim toward clinical trial readiness.

3.1.2. Key Elements for the CTRA

The FY25 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 **$910,000**, and with a PPIO, should not exceed **$1.0M**.
- **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**, and with a PPIO, should not exceed **$1.90M**.

Early-Career Partnering PI Option: The FY25 DMDRP encourages applications that include meaningful and productive collaborations between investigators. In an effort to promote enhanced research capacity within the DMD field, the FY25 CTRA includes an option for an Early-Career Partnering PI. 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 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

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Both pilot clinical trials and clinical research are permitted under this mechanism.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) 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. An ***intervention*** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease; (b) diagnostic or detection studies (e.g., biomarker or imaging); (c) health disparity studies; and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

Guidelines for Animal Research: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in SC Landis et al., “A Call for Transparent Reporting to Optimize the Predictive Value of Preclinical Research,” *Nature* 490 (2012): 187-191, https://doi.org/10.1038/nature11556. While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the Animal Research: Reporting *In Vivo* Experiments (ARRIVE) guidelines 2.0 to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported.

The DMDRP seeks to support research that is relevant to the health care needs of Service Members, Veterans, 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.

3.2. Funding Instrument

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

3.3. Funding Details

The requested funding level should be based on the scope of the research proposed. The government reserves the right to fund an application at a lower funding level.

CTRA Funding Level 1

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

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$910,000** for Funding Level 1 **or $1.0M** for Funding Level 1 – Partnering PI Option.

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.

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

CTRA Funding Level 2

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

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$1.75M** for Funding Level 2 or **$1.90M** for Funding Level 2 – Partnering PI Option.

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 **4** years.

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 FY25 DMDRP CTRA.

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 DOD 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. Step 1: Pre-Application Components

Pre-application submissions must include the following 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. Step 2: Full Application Components

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.

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.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(a), for detailed information.

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 listed in the General Application Instructions, Appendix 2.

- **Attachment 1: Project Narrative (15-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to

describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

Inclusion of preliminary data relevant to DMD and the proposed project is required. All applications must address at least one of the FY25 DMDRP CTRA Focus Areas.

- **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 are strongly encouraged to also 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 analysis. Clearly describe how data will be collected and analyzed in a manner that is consistent with the study objectives. If applicable, describe how collaborations support the research. Address potential problem areas and present alternative methods and approaches. 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 funds for a clinical trial are requested, details regarding the Clinical Trial Strategy must be described in Attachment 8.*** *Only those proposed studies measuring safety, effectiveness, and/or efficacy of an intervention are considered clinical trials and should submit a Clinical Trial Strategy.*
- **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.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

  - **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.
  - **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 government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
  - **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
  - **Letters of Support *(if applicable)*:** Provide a signed letter from each collaborating individual and/or organization 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 an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.
  - **Intellectual Property:** Information can be found in 2 CFR 200.315, "Intangible Property."
    - **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.
  - **Inclusion Enrollment Plan (if applicable): (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.

- **Data and Research Resources 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 how data and resources generated during the period of performance will be shared with the research community and other affected communities. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.

- **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.*** 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. 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.
  - **Specific Aims:** State the specific aims of the study.
  - **Study Design:** Describe the study design, including appropriate controls.
  - **Impact:** Briefly describe how the proposed project will have an impact on at least one of the FY25 CTRA Focus Areas and 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.
  - **Relevance to Military Health:** Briefly describe how the proposed research is relevant to the health care needs of Service Members, Veterans, their Families, and/or Family readiness of Service Members**.**

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard; spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

  Lay abstracts should address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine***. Avoid overuse of scientific jargon, acronyms, and abbreviations.

  - Describe the ultimate applicability of the research.
  - State the FY25 CTRA Focus Area(s) the project addresses.
  - What types of patients will it help, and how will it help them?

- What are the potential clinical applications, benefits, and risks?
- 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?
- How is the proposed research relevant to the health care needs of Service Members, Veterans, their Families, and/or Family readiness of Service Members?

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

  For the CTRA, 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 example is most appropriate for the proposed effort, for guidance on preparing the SOW.

  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 for lay persons.***
  - Describe how the proposed research is relevant to at least one of the FY25 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: Animal Research Plan (required if application includes research on animal models; five-page limit): Upload as "AnimalPlan.pdf."**

  If 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 Institutional Animal Care and Use Committee (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, sex, 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 the animal studies will be conducted in accordance with the ARRIVE guidelines 2.0.

○ **Attachment 8: Clinical Trial Strategy, 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 be submitted a Clinical Trial Strategy.***

- Describe the scientific rationale for the proposed clinical trial. State the product/intervention name. Demonstrate how the proposed clinical trial is supported by strong preliminary data and relevant literature citations. Provide a description of the intervention, and the endpoints to be measured.
- Provide detailed plans for initiating the clinical study within the first year, including **FDA IND/Investigational Device Exemption (IDE) application submission prior to the FY25 DMDRP CTRA application submission deadline**, 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.
- Define the study population and indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria; include a justification for the plans and alternative strategies if issues arise. Describe the informed consent process.
- 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. The suggested Inclusion Enrollment Report is a one-page fillable PDF form available on 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.
- 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. 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.

- State how many months into the award the anticipated clinical trial would be initiated, taking into account any clinical trial preparation (IRB and DOD 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.

- **Attachment 9: Partnership Statement (one-page limit): Upload as "Partnership.pdf".** ***(Attachment 9 is only applicable and required for applications submitted under the Early-Career Partnering PI Option.)***

  Describe the experience of the Initiating and Early-Career Partnering PIs, and indicate how the award will help to enhance research capacity within the DMD field. Describe the contribution and the 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 10: 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 11: Representations** ***(Grants.gov submissions only)*****: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the "Required Representations" document that is available on eBRAP. For more information, see the General Application Instructions, Appendix 8, Section B, Representations.

- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form** ***(if applicable)*****: Upload as "IGBudget.pdf".** If an intramural DOD 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 that is

available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.

(c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).

(d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and senior/key person's current/pending support information must be attached to the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.

- **Biographical Sketch:** Upload as "Biosketch_LastName.pdf".

  The CDMRP staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.

  Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a PDF form created in SciENcv for NIH or the U.S. National Science Foundation (NSF).

- **Current/Pending Support:** Upload as "Support_LastName.pdf".

  Current and pending (other) support information are used to assess the capacity or any conflicts of commitment that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.

  Current and pending support documentation must conform to the federal wide format. To prepare their Current and Pending Support form, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for NIH or NSF.

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

- **Budget Justification (no page limit):** For instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c), Section L; for eBRAP submissions, refer to General Application Instructions, Section V.B.(c), Budget Justification Instructions.

- ***Early-Career Partnering PI Option: 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 even if they are located within the same organization. Refer to Section 3.4, Funding Details, for detailed information.***

(f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov Submissions only)*: Refer to the General Application Instructions, Section IV.C.(e), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload it through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward. Combine them into a single document, then upload the file to Grants.gov as an attachment named "IGBudget.pdf".

4.3.2. Full Application Submission Components for the Partnering PI (If Applying Under the Early-Career 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)*: Refer to the General Application Instructions, Section IV.B.(a), for detailed information.

NOTE: Enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier Box

(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) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).

(d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and Senior/Key Person's current/pending support information must be attached to the individual's Profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

- **Budget Justification (no page limit):** Upload as "BudgetJustification.pdf".

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 should not

include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section 3.4, Funding Details, for detailed information.

(f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov Submissions Only)*: Refer to the General Application Instructions, Section IV.C.(e), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.
- **Intramural DOD Subaward:** Complete the "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled "IGBudget.pdf" to Grants.gov.

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 HT942525DMDRPCTRA from Grants.gov or eBRAP, depending on which submission portal will be used.

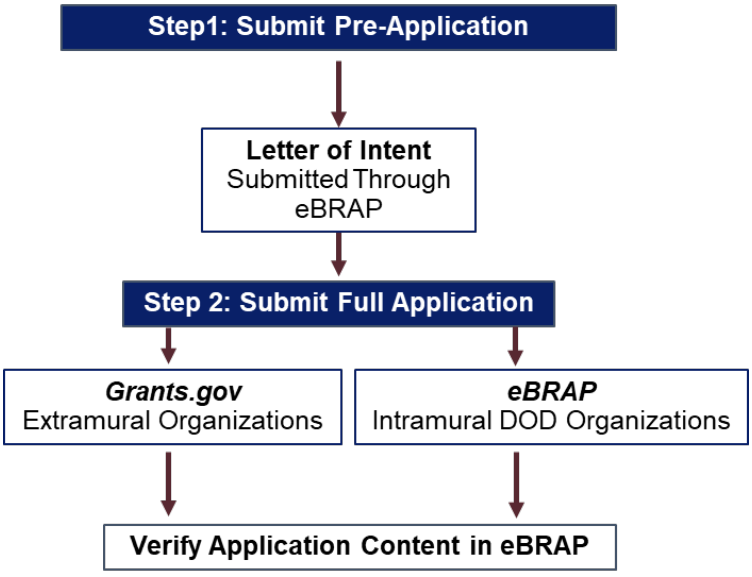
5.2. Unique Entity Identifier and System for Award Management

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. More information regarding SAM registration can be found in the General Application Instructions, Section IV.A.

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions.

Application Submission Workflow



5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI or Initiating PI through eBRAP (https://eBRAP.org/), including the submission of contact information for the Partnering PI if exercising the Early-Career 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. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

Early-Career Partnering PI Option: After the Initiating PI confirms submission of the pre-application, the Partnering PI will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI must follow the link in the notification email to associate the partnering pre-application with their eBRAP account.***

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:

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

When starting the pre-application, applicants will be asked to select a "Mechanism Option". Be sure to select the correct option appropriate to your 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

Refer to the General Application Instructions, Section III.A, for considerations and detailed instructions regarding pre-application submission.

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding Grants.gov submissions.

eBRAP Submissions: Only intramural DOD organizations may submit full applications through eBRAP. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding eBRAP submissions.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of 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 into eBRAP to review, modify and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure the proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted through the appropriate portal prior to the full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. 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 USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant.***

All submission dates and times are indicated in Section 1, Basic Information above.

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 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 full position 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. Refer to the General Application Instructions, Appendix 7, Section B.

Members of the FY25 DMDRP Programmatic Panel should 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 FY25 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 individually evaluated according to the following **scored criteria**, which are of equal importance***:***

- **Research Strategy and Feasibility**
    - 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 applicant provides sufficient evidence that the research is ready to move into the proposed stage of research.
    - How well the study aims, hypotheses or objectives, experimental design, methods, and analyses are developed.
    - How well the application acknowledges potential problems and addresses alternative approaches.

- If animal studies are included, how well they are designed in accordance with the ARRIVE guidelines 2.0 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.
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
- 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, quality control for all data and/or critical reagents, and/or cohorts, where relevant.

- **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 FY25 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. Whether the informed consent process is clearly articulated.
  - Whether the application describes the 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.

- **Impact**
  - How well the proposed research addresses at least one of the FY25 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.
  - To what degree the proposed study could make a significant impact on DMD research and/or patient care, including the goal of preserving and improving the function and quality of life, and extending the lifespan of all individuals with DMD.
- **Statistical Plan**
  - Whether the statistical plan, including sample size projections and power analysis, is adequate for the study (if applicable).
- **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.
  - **Early-Career 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**:

- **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.
  - If applicable, to what degree the intellectual and material property plan is appropriate
- **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 the peer reviewers.
- Relevance to the priorities of the FY25 DMDRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity.
  - Program portfolio composition.
  - Relative 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 made to the Commanding General, USAMRDC. ***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 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 SAM.

An applicant organization may review 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 and all associated laws, all fundamental research funded by the DoD 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 OUSD R&E 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 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.

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 USAMRAA 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).***

Intra-DOD 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 DOD 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 DOD 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. For additional information about pre-award costs for Grants.gov submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section; and for eBRAP submissions, refer to the General Application Instructions, Section 1.D, Pre-Award Costs section.

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.

Refer to the General Application Instructions, Appendix 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions for further information.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued 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 and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB, or Ethics Committee (EC) review. Refer to the General Application Instructions, Appendix 6, for additional information.

8.2. Reporting

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

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

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

Award Expiration Transition Plan: 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.

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 SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were

connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

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.

Refer to the General Application Instructions, Appendix 7, Section H, for general information on organization or PI changes.

9. Other Information

9.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code CD25_01d. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

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.
- Project Narrative is missing.
- Budget is missing.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to review for 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 FY25 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.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY25, 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.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization 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.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- An application proposing a clinical trial where Attachment 8: Clinical Trial Strategy 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 USAMRAA Grants Officer for a determination of the final disposition of the application.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded	
	PI/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"	☐	
Animal Research Plan – Attachment 7, upload as "AnimalPlan.pdf"	☐	
Clinical Trial Strategy – Attachment 8, upload as "Clinical.pdf"	☐	
Partnership Statement – Attachment 9, upload as "Partnership.pdf"	☐	
Transition Plan – Attachment 10, upload as "Transition.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"**	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach Biographical Sketch for PI and Senior/Key Persons ("Biosketch_LastName.pdf")	☐	☐
Attach Current/Pending Support for PI and Senior/Key Persons ("Support_LastName.pdf")	☐	☐
Research & Related Budget **Include Budget Justification**	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form (*if applicable*)	☐	☐

Appendix 2. Acronym List

ARRIVE	Animal Research: Reporting *In Vivo* Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CTRA	Clinical/Translational Research Award
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DMD	Duchenne Muscular Dystrophy
DMDRP	Duchenne Muscular Dystrophy Research Program
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
GI	Gastrointestinal
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
NSF	U.S. National Science Foundation
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
OUSD	Office of the Under Secretary of Defense
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PPIO	Partnering PI Option
QWERTY	First six letters of the second row of a standard English-language keyboard
R&D	Research and Development
RPPR	Research Performance Progress Report
SAM	System for Award Management

SciENcv	Science Experts Network Curriculum Vitae
SF424	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code