

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

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Duchenne Muscular Dystrophy Research Program**

**Clinical/Translational Research Award**

**Announcement Type: Initial**

**Funding Opportunity Number: HT942524DMDRPCTRA**

**Assistance Listing Number: 12.420 Military Medical  
Research and Development**

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

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), August 1, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, August 22, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, August 27, 2024
- **Peer Review:** November 2024
- **Programmatic Review:** February 2025

*This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”*

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## II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

### II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Duchenne Muscular Dystrophy Research Program (DMDRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the DMDRP in 2011 to provide support for research of exceptional scientific merit to promote the understanding, diagnosis, and treatment of Duchenne muscular dystrophy (DMD). Appropriations for the DMDRP from FY11 through FY23 totaled \$69.6 million (M). The FY24 appropriation is \$10.0M.

*The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.*

The vision of the FY24 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 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.

#### II.A.1. FY24 DMDRP Focus Areas

To meet the intent of the funding opportunity, all applications for the FY24 DMDRP Clinical/Translational Research Award (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, and predictive biomarkers, including potential surrogate markers)

### Clinical Research

- Clinical studies designed to improve care and quality of life
- Prospective real-world data collection for combination or sequential therapies, and/or follow-up safety and efficacy studies
- Assessment of clinical trial tools and outcome measures
  - In understudied systems (e.g., cognitive, cardiac, and/or gastrointestinal [GI]) or age ranges (e.g., infants, toddlers, and/or non-ambulatory).
  - Discovery and qualification of pharmacodynamic, prognostic, and predictive biomarkers, including potential surrogate markers
  - 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, cardiac, and/or GI) or age ranges (e.g., infants, toddlers, and/or non-ambulatory) with an aim toward clinical trial readiness

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

The DMDRP Translational Research Award (TRA) mechanism was first offered in FY21. Since then, 42 TRA applications have been received, and eight have been recommended for funding. The name of this award was updated to the Clinical/Translational Research Award (CTRA).

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

The FY24 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 non-ambulatory 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.

**Early-Career Partnering PI Option:** The FY24 DMDRP encourages applications that include meaningful and productive collaborations between investigators. In an effort to promote enhanced research capacity within the DMD field, the FY24 CTRA includes an option for an Early-Career Partnering Principal Investigator (PI). The Partnering PI Option 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, refer to [Section II.D.2, Content and Form of the Application Submission](#).

The FY24 DMDRP CTRA offers two funding levels (refer to [Section II.D.5 Funding Restrictions](#)). 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:** Funding Level 1 is intended to support smaller, less complex preclinical and/or clinical research. Pilot clinical trials are allowed. The proposal/application's *direct costs* budgeted for the entire period of performance should not exceed **\$650,000**.
- **Funding Level 2:** Funding Level 2 is intended to support larger, more complex preclinical and/or clinical research. Pilot clinical trials are allowed. The proposal/application's *direct costs* budgeted for the entire period of performance should not exceed **\$1.35M**.

Additionally, both funding levels will support an Early-Career Partnering PI Option at the same maximum direct costs and periods of performance, respectively.

***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.

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

*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](#).

All investigators applying to FY24 DMDRP funding opportunities and conducting clinical research are encouraged to consult the [Strategies to Promote Diversity in Muscular Dystrophy Research Participation](#) developed by the MDCC.

**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 Landis SC, et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature*, 490:187-191 (<http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html>). 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 ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>.

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

The anticipated direct costs budgeted for the entire period of performance for an FY24 Clinical/Translational Research Award should not exceed **\$650,000 for Research Funding Level 1 and \$1,350,000 for Research Funding Level 2**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

***The CDMRP expects to allot approximately \$4.24M to fund approximately three Clinical/Translational Research Award applications. 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. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.*

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

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

**II.C.1.a. Organization:** Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

**Extramural Organization:** An eligible non- 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.

Awards are made to eligible *organizations*, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

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

Independent investigators at all career levels may be named as 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.

### **II.C.1.c. 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 non-clinical aspects of DMD research.

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

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

Cost sharing/matching is not an eligibility requirement.

### II.C.3. Other

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

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

## II.D. Application and Submission Information

### II.D.1. Location of Application Package

Submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a *full application* (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

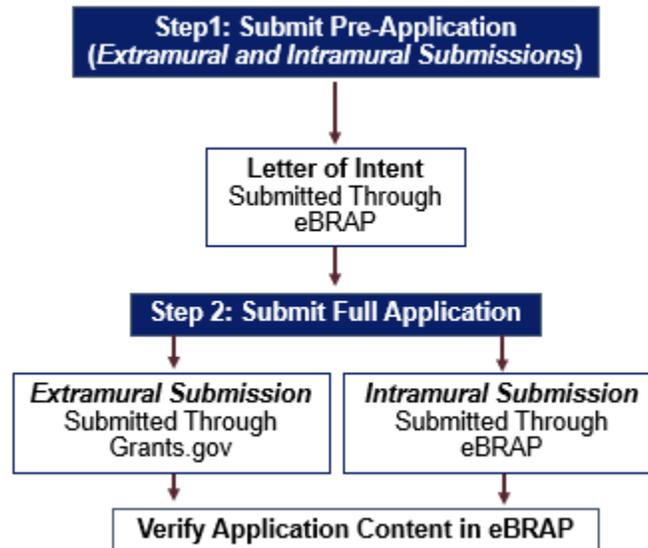
The CDMRP uses two portal systems to accept pre- and full application submissions.

**eBRAP** (<https://ebrap.org>) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

**Grants.gov** (<https://grants.gov>) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

## Pre-Application Module

### *Application Submission Workflow*



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

#### ***Extramural Submission:***

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

#### ***Intramural DOD Submission:***

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org.

***Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.***

**Extramural Submission:** An application submitted by an [extramural organization](#) for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524DMDRPCTRA from Grants.gov (<https://grants.gov>). Full applications from extramural organizations **must** be submitted through Grants.gov.

**Intramural Submission:** An application submitted by an [intramural DOD organization](#) for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524DMDRPCTRA from the anticipated submission portal eBRAP (<https://ebrap.org>) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of 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 organization using system-to-system interfaces with Grants.gov.***

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

***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).***

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at <https://cdmrp.health.mil/funding/researchDup>.

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.

FY24 DMDRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

### **II.D.2.a. Step 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 each PI, the Business Official(s), performing organization(s), and contracting organization(s) 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](mailto: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.* If not previously registered, the Partnering PIs must register in eBRAP.

After associating the pre-application with their eBRAP account, the Partnering PI should email the eBRAP Help Desk ([help@ebrap.org](mailto:help@ebrap.org)) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the Business Official, the name of the Performing/Contracting Organization, and the submission-type for the pre-application (extramural or intramural).

**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 complete these steps as soon as possible. If they are not completed:

- 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”. Please be sure to select the correct option appropriate to your pre-application:

<b>Application Includes:</b>	<b>Select Option:</b>
Funding Level 1 and Single PI and NO Clinical Trial	CTRA, Funding Level 1 Option
Funding Level 1 and Single PI and Clinical Trial	CTRA – Clinical Trial, Funding Level 1 Option
Funding Level 1 and Partnering PI Option but NO Clinical Trial	CTRA with Partnering PI Option, Funding Level 1 Option
Funding Level 1 and Partnering PI Option and Clinical Trial	CTRA with Partnering PI Option – Clinical Trial, Funding Level 1 Option
Funding Level 2 and Single PI and NO Clinical Trial	CTRA, Funding Level 2 Option
Funding Level 2 and Single PI and Clinical Trial	CTRA – Clinical Trial, Funding Level 2 Option
Funding Level 2 and Partnering PI Option but NO Clinical Trial	CTRA with Partnering PI Option, Funding Level 2 Option
Funding Level 2 and Partnering PI Option and Clinical Trial	CTRA with Partnering PI Option – Clinical Trial, Funding Level 2 Option

### II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for detailed instructions regarding pre-application submission):

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the Focus Area under which the application will be submitted.

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.*

### II.D.2.b. Step 2: Full Application Submission

#### II.D.2.b.i. Full Application Submission Type

**Extramural Submissions:** Full applications from extramural organizations *must* be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

**Intramural Submissions:** Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

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

Each application submission must include the completed full application package for this program announcement. See [Section II.H.3](#) of this program announcement for a checklist of the required application components.

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

**(b) Attachments:**

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 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 FY24 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 (<https://arriveguidelines.org/arrive-guidelines>) 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/gender, 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 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 Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of

support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

- **Letters of Collaboration (if applicable):** 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. 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 the 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.
  - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instructions 3200.12](#). **Do not duplicate the Data and Research Resources Sharing Plan.** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project 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 & Resource Sharing located on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm> for more information about CDMRP’s expectations for making data and research resources publicly available.

- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.
- **Use of U.S. Department of Veterans Affairs (VA) Resources (if applicable):** Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Inclusion Enrollment Plan (if applicable):** Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement. The Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. ***Abstracts of all funded research projects will be posted publicly.*** 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.

Of particular importance, programmatic reviewers typically do not have access to the full application, and therefore rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important. Technical abstracts should be written using the outline below.

- **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 FY24 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.
- **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 [FY24 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?
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** Refer to the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for the suggested SOW format and recommended strategies for assembling 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.*

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. Use the “Suggested SOW Format” to develop the SOW for the proposed research. Submit as a PDF.

- **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 [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.

- **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 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 (<https://arriveguidelines.org/arrive-guidelines>).
- **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 submit 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 FY24 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 9 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 alternatives 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/gender, 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/gender, race, and ethnicity. The suggested Inclusion Enrollment Report is a one-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
  - 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 [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 (*Extramural Submissions Only*): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 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 performance of the project, complete a separate budget using the “Suggested Intragovernmental/Intramural Budget Form”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The **total** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs.

Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

- (c) Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.
- (d) Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.
- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch\_LastName.pdf”.
  - **PI Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
  - **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch\_LastName.pdf”.
  - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
- (e) Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), 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 II.D.5, Funding Restrictions](#), for detailed information.*
- (f) Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only):** Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 12.

### **II.D.2.b.iii. Full Application Submission Components for the Partnering PI (if applying under the Early-Career Partnering PI Option)**

**Early Career Partnering PI Option:** The CDMRP requires separate full application package submissions for the Initiating PI and the Partnering PI, even if the PIs are located within the same organization. Each full application package must be submitted using the unique eBRAP log number received by the Initiating and Partnering PI during pre-application submission. *All associated applications (the Initiating PI’s and the Partnering PI’s) must be submitted by the full application submission deadline.*

The application submission process for the Partnering PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

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

**(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 (*Extramural submissions only*):** Upload as “RequiredReps.pdf”.
- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form:** Upload as “IGBudget.pdf”.

**(c) Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed information.

**(d) Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed information.

- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch\_LastName.pdf”.

- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
- **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch\_LastName.pdf”.
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.

**(e) Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed information.

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

*The initiating and Partnering PI must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.*

**(f) Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to General Application Instructions, Section V.A.(f), for detailed information.

**(g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only):** Refer to the General Application Instructions, Section IV.B.(g), 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 as [Attachment 12](#).

### **II.D.2.c. Applicant Verification of Full Application Submission in eBRAP**

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. 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 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 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.

### **II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)**

The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/content/home>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

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

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

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

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

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.

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

The maximum period of performance is 3 years.

The applications direct costs budgeted for the entire period of performance should not exceed **\$650,000**. 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 of 3 years.

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

The maximum period of performance is 4 years.

The application’s direct costs budgeted for the entire period of performance should not exceed **\$1.35M**. 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.

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 FY24 DMDRP Clinical/Translational Research Award.

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

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

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

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

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

To determine technical merit, all applications will be 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 (<https://arriveguidelines.org/arrive-guidelines>) 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 FY24 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/gender, 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/gender, 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 [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 **direct** costs exceed the allowable direct costs as published in the program announcement.
- Whether the budget is appropriate for the proposed research **and** the **selected funding level**.

- **Environment**

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

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

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the Defense Health Program (DHP) and FY24 DMDRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Relative impact

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

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, 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 II.E.1.b, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.health.mil/about/2tierRevProcess>.

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

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

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, 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.

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

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

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. 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 funding recommendation 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 extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to

the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

***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.***

## **II.F.2. PI Changes and Award Transfers**

Unless otherwise restricted, changes in 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 F, for general information on organization or PI changes.

## **II.F.3. 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.

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 OHARO, prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

## II.F.4. 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.

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

PHS Inclusion Enrollment Reporting Requirement (*only required for clinical research studies and clinical trials*): Enrollment reporting on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in 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).

## II.G. Federal Awarding Agency Contacts

### II.G.1. eBRAP Help Desk

*Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission*

Phone: 301-682-5507

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

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

*Questions regarding Grants.gov registration and Workspace*

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

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

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

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

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

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

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

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

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

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

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

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

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

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

- An FY24 DMDRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation.

*A list of the FY24 DMDRP Programmatic Panel members can be found at <https://cdmrp.health.mil/dmdrp/panels/panels24>.*

- 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.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>).
- 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) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- 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 application does not address at least one of the [CTRA Focus Areas](#).
- 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.

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

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

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

Full Application Components	Uploaded	
	Single or Initiating PI	Partnering PI
<b>SF424 Research &amp; Related Application for Federal Assistance</b> <i>(Extramural submissions only)</i>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Summary (Tab 1) and Application Contacts (Tab 2)</b> <i>(Intramural submissions only)</i>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Attachments</b>		
Project Narrative – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>	
Supporting Documentation – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>	
Technical Abstract – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>	
Lay Abstract – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>	
Statement of Work – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Impact Statement – Attachment 6, upload as “Impact.pdf”	<input type="checkbox"/>	
Animal Research Plan – Attachment 7, upload as “AnimalPlan.pdf”	<input type="checkbox"/>	
Clinical Trial Strategy – Attachment 8, upload as “Clinical.pdf” if applicable	<input type="checkbox"/>	
Partnership Statement – Attachment 9, upload as “Partnership.pdf” if applicable	<input type="checkbox"/>	
Transition Plan – Attachment 10, upload as “Transition.pdf”	<input type="checkbox"/>	
Representations <i>(Extramural submissions only)</i> – Attachment 11, upload as “RequiredReps.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form <i>(if applicable)</i> – Attachment 12, upload as “IGBudget.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Personal Data</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Senior/Key Person Profile (Expanded)</b>	<input type="checkbox"/>	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>	<input type="checkbox"/>

Full Application Components	Uploaded	
	Single or Initiating PI	Partnering PI
<b>Research &amp; Related Budget</b> ( <i>Extramural submissions only</i> ) Include budget justification	<input type="checkbox"/>	<input type="checkbox"/>
<b>Budget</b> ( <i>Intramural submissions only</i> ) Include budget justification	<input type="checkbox"/>	<input type="checkbox"/>
<b>Project/Performance Site Location(s) Form</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Subaward Budget Attachment(s) Form</b> ( <i>if applicable</i> )	<input type="checkbox"/>	<input type="checkbox"/>

## APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
ARRIVE	Animal Research: Reporting In Vivo Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CTRA	Clinical/Translational Research Award
DMD	Duchenne Muscular Dystrophy
DMDRP	Duchenne Muscular Dystrophy Research Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	Food and Drug Administration
FY	Fiscal Year
GI	Gastrointestinal
IACUC	Institutional Animal Care and Use Committee
IND	Investigational New Drug
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MDCC	Muscular Dystrophy Coordinating Committee
MIPR	Military Interdepartmental Purchase Request
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
SAM	System for Award Management
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
VA	U.S. Department of Veterans Affairs