

Program Announcement for the Department of Defense Defense Health Program

Duchenne Muscular Dystrophy Research Program Idea Development Award

Funding Opportunity Number: HT942525DMDRPIDA

Pre-Application Due: July 25, 2025

Application Due: August 8, 2025

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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.

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1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2025 (FY25) Duchenne Muscular Dystrophy Research Program (DMDRP) Idea Development Award (IDA) promotes new ideas that are still in the early stages of development and have the potential to yield impactful data and new avenues of investigation. This award supports conceptually innovative, high-risk/high-reward research that could lead to critical discoveries or major advancements that will accelerate progress in improving outcomes for individuals with Duchenne muscular dystrophy (DMD). Applications should include a well-formulated, testable hypothesis based on strong scientific rationale.

Distinctive Features: The FY25 DMDRP IDA mechanism has a **New Investigator** category for applicants early in their careers (i.e., within 10 years of their first faculty appointment or equivalent) **or** for established investigators new to DMD research.

- The <u>New Investigator Early Stage</u> category is designed to allow applicants early in their faculty appointments to compete for funding separately from established investigators.
- The New Investigator Transitioning category is designed for investigators in an area other than muscular dystrophy, at or above the level of Assistant Professor, seeking to transition to a career in DMD, thereby bringing their expertise to the field.

Preliminary data relevant to DMD that supports the feasibility of the research hypotheses and research approaches are required.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$1.68 million (M) to fund approximately 3 Idea Development Award applications with direct cost caps of \$350,000. The maximum period of performance is 2 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: Initial

Funding Opportunity Number: HT942525DMDRPIDA

Assistance Listing Number: 12.420

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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

Although a Principal Investigator (PI) may be eligible for the New Investigator – Early Stage, New Investigator – Transitioning, and Established Investigator categories, only one category may be chosen; the choice of application category is at the PI's discretion, provided the eligibility criteria are met.

Established Investigator

The PI must be an independent investigator at or above the level of Assistant Professor (or equivalent).

New Investigator – Early Stage

By the application submission deadline date, the PI must:

- Not have previously received a DMDRP IDA.
- Be an independent investigator at or above the level of Assistant Professor (or equivalent) who is within 10 years of their first faculty appointment (or equivalent) by the time of the application submission deadline. Lapses in research time or appointments, as denoted in the biographical sketch, may be articulated in the application.

New Investigator – Transitioning

- Be an investigator in an area other than muscular dystrophy at or above the level of Assistant Professor seeking to transition to a career in DMD, thereby bringing their expertise to the field.
- Investigators must pursue an active line of research in DMD and commit at least 10% minimum effort during each budget year toward the proposed DMD research project.

Pls using the New Investigator categories are strongly encouraged to strengthen their applications by collaborating with investigators experienced in DMD research and/or possessing other relevant expertise. It is the responsibility of the applicant to describe how the included collaboration will augment the Pl's expertise to best address the research question.

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

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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.

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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 high potential impact and exceptional scientific merit. 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 dystrophies, including DMD.

3.1. Intent of the Idea Development Award

The FY25 DMDRP IDA promotes new ideas that are still in the early stages of development and have the potential to yield impactful data and new avenues of investigation. This award supports conceptually innovative, high-risk/high-reward research that could lead to critical discoveries or major advancements that will accelerate progress in improving outcomes for individuals with DMD. Applications should include a well-formulated, testable hypothesis based on strong scientific rationale.

Preliminary data relevant to DMD that supports the feasibility of the research hypotheses and research approaches are required. Preliminary data may include unpublished results from the laboratory of the PI, research team, or collaborators named on the application.

3.1.1. Focus Areas for the IDA

To meet the intent of the funding opportunity, applications *must address opportunities and challenges in the development of safe and effective therapies that focus on primary pathology of DMD*. Therapies that will be efficacious across the life span, including infants, toddlers, and non-ambulatory individuals, are strongly encouraged.

Studies proposed under this award mechanism may include:

- Preclinical testing of combination therapies with small molecules and/or biologics that have existing human clinical data in DMD or repurposed from other disorders.
- Optimized delivery to specific tissues or cell types, including targeting to skeletal muscle, heart, brain, and muscle stem cells (e.g., ligand-assisted delivery, tissue-specific promoters, nanoparticles, alternative vectors, identification of biological barriers to delivery).
- Strategies to overcome preexisting immunity and to facilitate repeat administration of biologic therapies (e.g., immune system modulation, vector modification).
- Repopulation of the muscle compartment using cell-based therapies, including, but not limited to, selection of novel cell types, expansion, cell delivery and homing, differentiation and integration.

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- Non-genomic therapies that are downstream from the genetic defect to address disease pathogenesis (e.g., mitochondrial dysfunction, inflammation, fibrosis, fatty infiltration, etc.).
- Research that will inform and improve therapy in individuals ineligible for currently approved therapies or in development therapeutics (e.g., age, type of mutations, seropositivity, rare exons).
- Discovery and validation of novel targets, including genetic modifiers and factors that determine the selective vulnerability/resistance of individual muscles, especially in humans.
- Validation of novel models to address human pathophysiologies in DMD beyond skeletal muscle (e.g., smooth muscle).
- Therapies that address muscle regeneration deficits.

Studies proposed under this award mechanism *may not* include:

- Testing the efficacy of candidate therapeutics without a strong mechanistic rationale.
- Evaluation of vectors or delivery technologies already prevalent in research studies (e.g., AAV9).

3.1.2. Key Elements for the IDA

New Investigators: The FY25 DMDRP IDA mechanism encourages applications from independent investigators in the early stages of their careers (i.e., within 10 years of their first faculty appointment or equivalent) **or** applications from established investigators new to DMD research.

- The New Investigator Early Stage category is designed to allow applicants early in their faculty appointments to compete for funding separately from established investigators.
- The <u>New Investigator Transitioning</u> category is designed to allow investigators in an area
 other than muscular dystrophy, at or above the level of Assistant Professor, seeking to
 transition to a career in DMD, thereby bringing their expertise to the field.

Applications from New Investigators and Established Investigators will be peer and programmatically reviewed separately. Pls using the New Investigator – Early Stage category or New Investigator – Transitioning category are strongly encouraged to strengthen their applications by collaborating with investigators experienced in DMD research and/or possessing other relevant expertise. It is the responsibility of the applicant to describe how the included collaboration will augment the Pl's expertise to best address the research question. All applicants for the New Investigator categories must meet the specific eligibility criteria described in Section 2, Eligibility Information.

In addition, other key elements of this award are:

- **Innovation:** Research deemed innovative may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities.
- **Impact:** Research that has high potential impact may lead to major advancements and significantly accelerate progress toward improving outcomes for individuals with DMD.

It is the responsibility of the PI to clearly and explicitly articulate the project's innovation and its potential impact on DMD. The project's impact to both DMD research and to individuals with DMD should be articulated, even if clinical impact is not an immediate

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outcome. Applications that demonstrate exceptional scientific merit but lack innovation and high potential impact do not meet the intent of the IDA.

3.1.3. Other Important Considerations for the IDA

Clinical trials are not allowed under this funding opportunity. Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity. Investigators wishing to apply for funding to support a clinical trial should consider submitting an application to the FY25 DMDRP Clinical/Translational Research Award (funding opportunity number HT942525DMDRPCTRA).

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.

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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

Period of Performance: The maximum period of performance is **2** years.

Cost Cap: The application's direct costs budgeted for the entire period of performance should not exceed **\$350,000**. 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 **2** 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 IDA.

Must not be requested for:

Clinical trial costs.

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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 (<u>eBRAP</u>) 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

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 (10-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.

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- Background: Explain how the novel idea is supported by sound logical reasoning and strong mechanistic rationale that is relevant to DMD. Cite relevant, published literature and any applicable preliminary data.
- Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.
- Specific Aims: Concisely explain the project's specific aims to be supported by this
 application. If the proposed research is part of a larger study, present only tasks that
 this award would fund.
- Research Strategy and Feasibility: Describe the experimental design, methods, and analyses including appropriate controls, in sufficient detail for evaluation. Clearly describe how data will be collected and analyzed in a manner that is consistent with the study objectives. Address potential limitations and present alternative methods and approaches. If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE <u>guidelines 2.0</u> 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. *This award cannot be used to conduct clinical trials*.
- Statistical Analysis Plan: Describe the statistical analysis plan for the resulting outcomes. If applicable, include a complete power analysis to demonstrate 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

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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: Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI meets eligibility criteria, and for the New Investigator Transitioning category, that the PI has support for 10% effort during each budget year toward the proposed DMD research project.
- 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.
 - 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.
- Inclusion Enrollment Plan (only required if clinical research 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. State whether the proposed plan for data sharing includes databases most relevant to DMD and whether the plan describes organizational and technical capabilities sufficient to share project data in a timely manner. Refer to CDMRP's Policy on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available. Include plans for making raw data publicly available in appropriate databases (e.g., database of Genotypes and Phenotypes, Gene Expression Omnibus) at the time of publication or at the time of conclusion of the funding. The government reserves the right to identify repositories for submission of data for archive. Any costs associated with submission will be addressed during award negotiations.
- 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

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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. Provide evidence or scientific rationale that supports the hypothesis/objective(s).
- **Specific Aims:** State the specific aims of the study.
- Study Design: Describe the study design, including appropriate controls.
- Innovation: Briefly describe how the proposed project is innovative.
- Impact: Summarize the potential impact of the proposed project toward the development of safe and effective macromolecular and cellular therapies 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.
 - What types of patients will it help and how will it help them?
 - What are the potential clinical applications, benefits, and risks? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field.
 - 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?
 - 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 IDA, refer to the <u>"Example: Assembling a Generic Statement of Work"</u> for guidance on preparing the SOW.

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- 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 project is expected to make an important and original contribution to addressing opportunities and challenges in the development of safe and effective macromolecular and cellular therapies that address primary pathology of DMD. The relevance of all research, including basic, should relate to patient outcomes and how it benefits those affected by DMD.
 - Explain how the proposed research will significantly accelerate progress towards improving outcomes for individuals with DMD.
 - Explain briefly 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 7: Innovation Statement (one-page limit): Upload as "Innovation.pdf". Describe how the proposed work is innovative. Research deemed innovative may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities (i.e., concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways). Describe how the proposed research represents more than an incremental advance beyond ongoing research and published data.
- Attachment 8: 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 9: 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 <u>SciENcv</u> for NIH or the U.S. National Science Foundation (NSF).

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- Current/Pending Support: Upload as "Support LastName.pdf".
 - Current and pending (other) support information are used to assess the capacity or any <u>conflicts of commitment</u> 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.
- (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 "<u>Suggested</u>
 <u>Intragovernmental/Intramural Budget Form</u>" for each intramural DOD subaward. Combine
 them into a single document, then upload the file to Grants.gov as an attachment named
 "IGBudget.pdf".

4.4. Other Application Elements

- If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, <u>DoD Instructions 3200.12</u> will be requested.
- The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

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5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942525DMDRPIDA from <u>Grants.gov</u> or <u>eBRAP</u>, 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), <u>SAM.gov</u>, 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.

Step1: Submit Pre-Application Letter of Intent Submitted Through eBRAP Step 2: Submit Full Application Grants.gov Extramural Organizations Verify Application Content in eBRAP

Application Submission Workflow

5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI through eBRAP.

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-

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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.

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:
Established Investigator: An independent investigator at or above the level of Assistant Professor (or equivalent).	Idea Development Award – Established Investigator
New Investigator – Early Stage: An independent investigator at or above the level of Assistant Professor (or equivalent) and within 10 years of their first faculty appointment (or equivalent).	Idea Development Award – New Investigator – Early Stage
New Investigator – Transitioning: An investigator in an area other than muscular dystrophy at or above the level of Assistant Professor seeking to transition to a career in DMD.	Idea Development Award – New Investigator – Transitioning

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

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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 <u>Section 1, Basic Information</u> above.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

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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 <u>CDMRP's full position on research duplication</u>.

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 preapplication 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 <u>letters</u> to confirm <u>PI eligibility</u> 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* <u>FY25 DMDRP Programmatic Panel members</u> can be found on the CDMRP website.

Additional restrictions and associated administrative responses are outlined in <u>Section 9.2</u>, <u>Administrative Actions</u>.

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:

Innovation

- o To what degree the proposed research is innovative.
- How well the research proposes a new paradigm, challenges existing paradigms, looks at existing problems from new perspectives, or is otherwise creative in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
- Whether the proposed research represents more than an incremental advance upon published data.

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Impact

- How well the proposed research addresses opportunities and challenges in the development of safe and effective therapies that address primary pathology of DMD.
- The degree to which the proposed study could make a significant impact on accelerating progress toward improving outcomes for individuals with DMD.

Research Strategy and Feasibility

- How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, relevant preliminary data, and logical reasoning.
- How well the hypotheses or objectives, aims, experimental design, methods, analyses, data collection, statistical analysis plan, rationale for the statistical methodology, and power analysis (if applicable) are developed.
- If animal studies are included, how well they are designed in accordance with the ARRIVE <u>guidelines 2.0</u> to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured.
- If human subjects or human biological samples will be used, how well the plan for the recruitment of subjects or the acquisition of samples is justified and appropriate to accomplish the proposed work.
- If clinical research is proposed, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
- How well the application acknowledges potential limitations and addresses alternative methods and approaches.
- Whether the proposed plan for data sharing includes databases most relevant to DMD (if applicable), and whether the plan describes organizational and technical capabilities sufficient to share project data in a timely manner.
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

Personnel

- The degree to which the levels of effort by the applicant (minimum of 10% for New Investigators – Transitioning per budget year) and other key personnel are appropriate to ensure the success of this research effort.
- Based on the biosketch, how well the applicant's record of accomplishment demonstrates their ability to accomplish the proposed work.
- For New Investigators Transitioning, to what extent the PI will bring their expertise to the field of DMD and pursue an active line of research in DMD.

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.

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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.
- o 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 with consideration of New and Established Investigators.
 - o Relative impact, innovation, 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 <u>Section 6.2.3</u>, <u>Programmatic Review</u>. 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

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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 abovementioned laws and guidance prior to award.

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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.

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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 <u>DoD R&D Terms and Conditions</u> and the <u>USAMRAA Research</u> 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 Institutional Animal Care and Use Committee (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.

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

PHS Inclusion Enrollment Reporting (*Required for research proposing clinical research studies*): 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).

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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 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.

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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_01c. 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 <u>FY25 DMDRP Programmatic Panel</u> is named as being involved in the development or execution of the research proposed or is found to have assisted in the preapplication 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 <u>CDMRP website</u>.
- 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.

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- 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.
- A clinical trial is proposed.

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.

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Appendix 1. Full Application Submission Checklist

Full Application Components	
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"	
<u>Lay Abstract</u> – Attachment 4, upload as "LayAbs.pdf"	
Statement of Work - Attachment 5, upload as "SOW.pdf"	
Impact Statement – Attachment 6, upload as "Impact.pdf"	
Innovation Statement – Attachment 7, upload as "Innovation.pdf"	
Representations (Grants.gov submissions only) –	
Attachment 8, upload as "RequiredReps.pdf"	
<u>Suggested Intragovernmental/Intramural Budget Form</u> (<i>if applicable</i>) – Attachment 9, upload as "IGBudget.pdf"	
Research & Related Personal Data	
Research & Related Senior/Key Person Profile (Expanded)	
Attach <u>Biographical Sketch</u> 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	П
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Research & Related Subaward Budget Attachment(s) Form (if applicable)	

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Appendix 2. Acronym List

ARRIVE Animal Research: Reporting In Vivo Experiments

CDMRP Congressionally Directed Medical Research Programs

CFR Code of Federal Regulations
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

IACUC Institutional Animal Care and Use Committee

IDA Idea Development Award
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)

OUSD Office of the Under Secretary of Defense

PDF Portable Document Format

PHS Public Health Service
PI Principal Investigator

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

SF424 Standard Form 424 (Application for Federal Assistance, Research & Related)

SciENcv Science Experts Network Curriculum Vitae

SOW Statement of Work
UEI Unique Entity Identifier

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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