

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Duchenne Muscular Dystrophy Research Program

Therapeutic Idea Award

Funding Opportunity Number: W81XWH-15-DMDRP-TIA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), July 22, 2015
- **Invitation to Submit an Application:** September, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, October 21, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, October 26, 2015
- **Peer Review:** January 2016
- **Programmatic Review:** March 2016

The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2015 (FY15) Duchenne Muscular Dystrophy Research Program (DMDRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The DMDRP was initiated in 2011 to provide support for research of exceptional scientific merit and to promote the understanding, diagnosis, and treatment of DMD. Appropriations for the DMDRP from FY11 through FY14 totaled \$13.6 million (M). The FY15 appropriation is \$3.2M.

The vision of the FY15 DMDRP is to extend and improve the function, quality of life, and lifespan for all individuals diagnosed with DMD. As such, the DMDRP is seeking to better support the development of drugs, devices, and other interventions and promote their effective clinical testing. Additionally, DMDRP supports the efforts of the National Institutes of Health Muscular Dystrophy Coordinating Committee (MDCC) and the [Action Plan for the Muscular Dystrophies](#), which prioritizes the needs to improve treatments and reduce the disease burden for muscular dystrophy including Duchenne.

B. FY15 DMDRP Focus Areas

All applications to the FY15 DMDRP Funding Opportunities *must* address at least one of the following Focus Areas:

- Cardiopulmonary studies
- Clinical studies and novel interventions that could improve clinical care and quality of life in the near term, such as:
 - Comorbidity studies
 - Endocrine and bone issues
 - Gastrointestinal issues
 - Cognitive function
- Discovery and qualification of pharmacodynamic, prognostic, and predictive biomarkers, e.g., as drug development tools, indicators of disease progression, response to treatment, or clinical trial outcomes (see [Section I.C., Biomarker Studies](#) for further description).
- Assessment of clinical trial outcomes (invasive and noninvasive methods), such as:
 - Molecular, functional, imaging, etc.
 - Evaluating surrogate markers

- Evaluating potential composite scores for outcomes assessment
- Patient-centered outcomes, e.g., quality of life, activities of daily living
- Extension or expansion of preclinical translational data in support of the therapeutic development path (including independent replication and comparative studies)

C. Award Information

The DMDRP Therapeutic Idea Award mechanism was offered in FY12 and FY14, and is being offered again in FY15. It is designed to promote new ideas that are still in the early stages of development with the potential to yield high-impact data and new avenues of investigation for novel therapeutics for DMD treatment. This award mechanism supports conceptually innovative, high-risk/high-reward research that could ultimately lead to critical discoveries or major advancement in DMD therapeutics. Research projects should include a well-formulated, testable hypothesis based on strong scientific rationale.

Presentation of preliminary data is not consistent with the intent of the Therapeutic Idea Award mechanism. While the inclusion of preliminary data is not prohibited, the strength of the application should not rely on preliminary data.

Innovation and Impact are the most important aspects of the Therapeutic Idea Award.

Innovation: Research deemed innovative may introduce a new paradigm, challenge current paradigms, introduce novel concepts or agents, or exhibit other uniquely creative qualities that may lead to potential therapies for DMD (e.g., drug repurposing studies). Innovative research may include high-risk approaches to DMD research. Research that is investigating the next logical step or is an incremental advance upon published data is not considered innovative.

Impact: Research that has high potential to significantly impact development of therapeutics for DMD.

Biomarker Studies

For projects addressing the FY15 DMDRP Focus Area of “discovery and qualification of pharmacodynamic, prognostic, and predictive biomarkers,” a *biological marker*, or *biomarker*, is defined as a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or biological responses to a therapeutic intervention.¹ For the purpose of this award, **biomarker qualification** is defined as the evidentiary fit-for-purpose process of correlating a biomarker with the effects of an agent on biological processes and clinical endpoints.² The DMDRP encourages the discovery and study of biomarkers that can be detected through minimally invasive procedures (e.g., blood, urine, tissue, imaging, etc.). Examples of biomarkers may include signatures of genetic or epigenetic changes, specifically

¹ Biomarkers Definitions Working Group. 2001. Biomarkers and surrogate endpoints: Preferred definitions and conceptual framework. *Clinical Pharmacology and Therapeutics* 69:89-95.

² Wagner JA, Williams SA, and Webster CJ. 2007. Biomarkers and surrogate end points for fit-for-purpose development and regulatory evaluation of new drugs. *Clinical Pharmacology and Therapeutics* 81:104-107.

expressed genes, proteins, or metabolites, and molecular, physiological, and/or imaging entities, among others.

Research Involving Human Anatomical Substances, Human Subjects, or Human

Cadavers: All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 5, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity. A clinical trial is defined as a prospective accrual of patients where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. The term “human subjects” is used in this Program Announcement/Funding Opportunity to refer to individuals who will be recruited for or who will participate in the proposed clinical trial. For more information, a Human Subject Resource Document is provided at https://cdmnp.org/Program_Announcements_and_Forms/.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 3, Section L.

D. Eligibility Information

- Investigators at all academic levels (or equivalent).
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **2** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$300,000**. Associated indirect costs can be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$300,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total 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.

Refer to the General Application Instructions, Section II.C.5., for budget regulations and instructions for the Research & Related Budget. ***For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.5. of the General Application Instructions.***

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Research supplies
- Clinical research costs (No clinical trials allowed)
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Section II.A. of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The CDMRP expects to allot approximately \$0.48M of the \$3.2M FY15 appropriation to fund approximately one Therapeutic Idea Award application, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission of applications that are essentially identical or 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.

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-DMDRP-TIA in Grants.gov (<http://www.grants.gov/>).

B. Pre-Application Submission Content

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
 - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF-424 Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
 - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Collaborators and Key Personnel – Tab 3**
 - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
 - FY15 DMDRP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.
- **Conflicts of Interest (COIs) – Tab 4**
 - List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Pre-Application Files – Tab 5**

Note: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

Preproposal Narrative (two-page limit): The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Innovation:** Describe how the project may introduce a new paradigm, challenge current paradigms, introduce novel concepts or agents, or exhibit other uniquely creative qualities that may lead to potential therapeutics for DMD.
- **Impact:** Describe how the proposed research will have an impact on the development of therapeutics for DMD and on at least one FY15 DMDRP Focus Area.
- **Research:** State the project's hypothesis/objective, rationale, specific aims, and study design.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application *must be uploaded as individual documents* and are limited to:

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- **Key Personnel Biographical Sketches (five-page limit):** Include a biographical sketch for the PI only.

- **Submit Pre-Application – Tab 6**

This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the DMDRP, pre-applications will be screened based on the following criteria:

- **Innovation:** How the project may introduce a new paradigm, challenge current paradigms, introduce novel concepts or agents, or exhibit other uniquely creative qualities that may lead to potential therapeutics for DMD.
- **Impact:** How the proposed work will have an impact on the development of therapeutics for DMD and on at least one FY15 DMDRP Focus Area.
- **Research:** To what degree the experimental approach for accomplishing the specific aims is feasible and addresses the hypothesis or objective.
- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

C. Full Application Submission Content

Applications will not be accepted unless the PI has received notification of invitation.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed Grants.gov application package provided in Grants.gov for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID *prior to the application submission deadline*.

Grants.gov application package components: For the Therapeutic Idea Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. SF-424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section II.C., for detailed information.

2. Attachments Form

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition,

Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (eight-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, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Throughout the Project Narrative, describe how the proposed research is innovative and the potential impact it may have on the development of DMD therapeutics. Presentation of preliminary data is not required. However, PIs must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the application to be competitive. Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to this project.
 - **Hypothesis or Objective:** State the hypothesis to be tested or the objective(s) to be reached.
 - **Specific Aims:** Concisely explain the project’s specific aims and their relevance to the study objective(s).
 - **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, if applicable. Address potential problem areas and present alternative methods and approaches. If animals are to be used, explain why the animal model(s) being used can address the scientific objectives. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested 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 that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- 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 or not 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 Patent Abstracts: Include a list of relevant publication URLs and/or patent abstracts. If publications 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/Funding Opportunity, 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 or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual Property
 - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 3, Section L for more information about the CDMRP expectations for making data and research resources publicly available.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The technical abstract is used by all reviewers. 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 ideas and reasoning behind the proposed work and describe the FY15 Focus Area(s) the project addresses.
 - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
 - Specific Aims: State the specific aims of the study.
 - Study Design: Briefly describe the study design including appropriate controls.
 - Innovation: Briefly describe how the proposed project is innovative.
 - Impact: Briefly describe how the proposed project will have an impact on the development of therapeutics for DMD.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** 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. Minimize the use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community. Lay abstracts should be written using the outline below.

- Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine.*** Identify the FY15 DMDRP Focus Area(s) the proposed project addresses.
 - 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 it may take to achieve a patient-related outcome?
 - What are the likely contributions of this study to advancing the field of DMD research or patient care?
- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.”** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Therapeutic Idea

Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf.”**

State how the proposed work addresses at least one FY15 Focus Area. Describe how the proposed work, if successful, will impact the development of therapeutics for DMD. Outline the potential short-term or long-term impact of the proposed research on DMD therapeutics.

- **Attachment 7: Innovation Statement (one-page limit): Upload as “Innovation.pdf.”**

Summarize how the proposed study is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative. The following examples of ways in which proposed studies may be innovative, *although not all-inclusive*, are intended to help PIs frame the innovative features of their applications:

- Study concept: Investigation of a novel idea and/or research question.
- Research method or technology: Use of novel research methods or new technologies, including technology development, to address a research question.
- Clinical interventions: Use of a novel method or technology for preventing, detecting, diagnosing, or treatment.
- Existing methods or technologies: Application or adaption of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

- **Attachment 8: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded within a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP “Funding Opportunities & Forms” web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.

3. Research & Related Senior/Key Person Profile (Expanded): Refer to the General Application Instructions, Section II.C.4., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.

- PI Biographical Sketch (five-page limit): Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>)

in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used.

- 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.”

4. Research & Related Budget: Refer to the General Application Instructions, Section II.C.5., for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

5. Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.C.6., for detailed information.

6. R & R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section II.C.7., for detailed information.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. 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/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

E. Submission Dates and Times

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in application rejection.

F. Other Submission Requirements

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

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP and DMDRP, and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a nondisclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving 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 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 process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Process

- 1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria. Of these criteria, Innovation and Impact are weighted equally as the most important, with the remaining criteria listed in decreasing order of importance.

- **Innovation**

- How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research

methods or technologies, or adaptations of existing methods or technologies that will lead to new therapies for DMD.

- How well the application describes a new research idea and not the next logical step or continuation of a previous research project.
- To what degree the proposed research presents more than an incremental advance upon published data.
- How the proposed research introduces a novel concept or agent for treatment of DMD.
- **Impact**
 - How well the research project addresses at least one FY15 DMDRP Focus Area.
 - How well the research, if successful, might make a significant contribution toward the development of therapeutics for DMD.
 - To what extent the anticipated short-term outcome(s) or long-term gains from the proposed research will impact DMD therapeutics.
- **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 and/or by logical reasoning.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses (and if applicable, the statistical plan, rationale for the statistical methodology, and power analysis) have been developed and integrated into the project.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - If the study proposes using animals, how well the proposed model is appropriate to accomplish the proposed work.
 - 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.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **Personnel**
 - How the background and expertise of the PI, the research team, and any collaborators' demonstrate their ability to perform the proposed work.
 - How the levels of effort are appropriate for successful conduct of the proposed work.

- **Environment**
 - To what degree the scientific environment is appropriate for the proposed research.
 - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
 - To what degree the quality and extent of organizational support are appropriate for the proposed research.
 - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.

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

- a. **Ratings and evaluations of the peer reviewers**
- b. **Relevance to the mission of the DHP and FY15 DMDRP, as evidenced by the following:**
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Programmatic relevance
 - Relative impact and innovation

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

B. Modification

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

C. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- A FY15 DMDRP IP 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. A list of the FY15 DMDRP IP members can be found at <http://cdmrp.army.mil/dmdrp/panels/panels15>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- An application that does not address at least one of the FY15 DMDRP Focus Areas will be withdrawn.
- If a clinical trial is proposed, the application will be withdrawn.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution 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.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2016. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 3 for general information regarding administrative requirements.

C. National Policy Requirements

Refer to the General Application Instructions, Appendix 4 for general information regarding national policy requirements.

D. Reporting

Refer to the General Application Instructions, Appendix 3, Section I, for general information on reporting requirements.

E. Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 3, Section M, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

B. Grants.gov Contact Center

Questions related to application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

| Grants.gov Application Components | Upload Order | Action | Completed |
|---|--------------|---|-----------|
| SF-424 (R&R) Application for Federal Assistance | | Complete form as instructed. | |
| Attachments Form | 1 | Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf." | |
| | 2 | Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf." | |
| | 3 | Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf." | |
| | 4 | Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf." | |
| | 5 | Statement of Work: Upload as Attachment 5 with file name "SOW.pdf." | |
| | 6 | Impact Statement: Upload as Attachment 6 with file name "Impact.pdf." | |
| | 7 | Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf." | |
| | 8 | Collaborating DoD Military Facility Budget Form(s): Upload Attachment 8 with file name "MFBudget.pdf," if applicable. | |
| Research & Related Senior/Key Person Profile (Expanded) | | Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field. | |
| | | Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field. | |
| | | Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field. | |
| | | Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field. | |
| Research & Related Budget | | Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field. | |
| Project/Performance Site Location(s) Form | | Complete form as instructed. | |
| R & R Subaward Budget Attachment(s) Form | | Complete form as instructed. | |