

**Program Announcement**  
for the  
**Department of Defense**  
**Defense Health Program**  
**Congressionally Directed Medical Research Programs**

**Duchenne Muscular Dystrophy Research Program**  
**Investigator-Initiated Research Award**

**Funding Opportunity Number: W81XWH-16-DMDRP-IIRA**  
**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical**  
**Research and Development**

**SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 19, 2016
- **Invitation to Submit an Application:** September 2016
- **Application Submission Deadline:** 11:59 p.m. ET, October 19, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, October 24, 2016
- **Peer Review:** January 2017
- **Programmatic Review:** March 2017

*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 2016 (FY16) 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 (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing 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 Duchenne. Appropriations for the DMDRP from FY11 through FY15 totaled \$16.8 million (M). The FY16 appropriation is \$3.2M.

The vision of the FY16 DMDRP is to preserve and improve the function and quality of life, and to extend the life span of all individuals with Duchenne. As such, the DMDRP is seeking to better support the discovery and development of therapeutics, devices, and other interventions, and to promote their effective clinical testing. Additionally, DMDRP supports the efforts of the National Institutes of Health Muscular Dystrophy Coordinating Committee (MDCC) and the [2015 MDCC Action Plan for the Muscular Dystrophies](#), which prioritizes the needs to improve treatments and reduce the disease burden for muscular dystrophy including Duchenne.

### B. FY16 DMDRP Focus Areas

All applications for the FY16 DMDRP funding opportunities *must* address at least one of the following Focus Areas:

- Cardiac studies including identifying mechanisms of pathology and therapeutic interventions
- Clinical studies and novel interventions that could improve clinical care and quality of life, in areas such as:
  - Comorbidities
  - Endocrinology
  - Orthopedics
  - Gastrointestinal issues
  - Psychosocial issues
  - Cognitive function
  - Respiratory issues (including sleep-focused studies)
- Assessment of clinical trial tools and outcome measures, such as:
  - Discovery and qualification of pharmacodynamic, prognostic, and predictive biomarkers

- 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 existing preclinical translational data in support of a specific therapeutic development path (including independent replication and comparative studies)

### C. Award Information

The DMDRP Investigator-Initiated Research Award (IIRA) supports translational research that will accelerate the movement of promising ideas in Duchenne research into clinical applications. Translational research may be defined as an integration of basic science and clinical observations with the specific goal of developing new therapies. The ultimate goal of translational research is to move a concept or observation forward into clinical application. However, Principal Investigators (PIs) should not view translational research as a one-way continuum from bench to bedside. The research plan should involve a reciprocal flow of ideas and information between basic and clinical science. Within this continuum, the IIRA supports later stage translational research projects, including early-phase, proof-of-principle clinical trials and correlative studies to better inform the development of drugs, devices, and other interventions. Research projects may also include preclinical studies utilizing animal models, human subjects, or human anatomical substances.

Studies proposed under this award *should not include*:

- Target discovery
- Drug screening
- Mechanism of action studies

### Biomarker Studies

For projects addressing “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.<sup>1</sup> 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.<sup>2</sup> Alternatively, **biomarker validation** refers to the process of ensuring that a biomarker or technology (e.g., imaging) will be accurately and reliably measured through the performance

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

<sup>2</sup> 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.

characteristics of a biomarker assay.<sup>3</sup> The DMDRP encourages the study of biomarkers that can be detected through minimally invasive procedures (e.g., blood, urine, tissue, imaging). Examples of biomarkers may include signatures of genetic or epigenetic changes, specifically expressed genes, proteins, or metabolites, and molecular, physiological, and/or imaging entities, among others.

**Candidate Biomarker(s) and Evaluation:** Applications proposing biomarker qualification and/or validation studies should include a clear description of the candidate biomarker(s) to be studied. Applications must include relevant preliminary data from pilot testing that demonstrate the suitability of the biomarker(s) for further testing toward clinical application. Sufficient detail must be provided to demonstrate how the biomarker(s) will be qualified or validated, including the approaches that will be applied to establish feasibility, reliability, and reproducibility, and the criteria that will provide the evidence for evaluating the biomarkers. These criteria may include, but are not limited to:

- Improved performance relative to current, clinically accepted biomarkers
- Biological association of the biomarker(s) with Duchenne (e.g., muscle damage/fibrosis, cardiomyopathy, etc.)
- Strength of association of changes in biomarker levels with pathological/clinical outcomes
- Availability of a robust analytical assay to reliably and reproducibly assess the validity of the biomarker's association with Duchenne or clinical outcomes
- Evidence that a biomarker is a reliable indicator of target engagement, to support the decision-making process in clinical trials

In addition, applications must be consistent with current U.S. Food and Drug Administration (FDA) guidance for biomarker qualification. Useful information can be found online at the following:

FDA Biomarker Qualification Process:

- <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm284076.htm>
- <http://www.c-path.org/pdf/FDADraftDDTools.pdf>

FDA Office of In Vitro Diagnostics and Radiological Health:

- <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOices/ucm115904.htm>

***All applications must include preliminary data that are relevant to Duchenne and the proposed project. Clinical trials are supported by this award mechanism and, if proposed, require the submission of Attachment 11, Human Subject Recruitment and Safety Procedures.***

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<sup>3</sup> Sistare FD, Dieterle F, Troth S, et al. 2010. Towards consensus practices to qualify safety biomarkers for use in early drug development. *Nature Biotechnology* 28:446-454.

The FY16 DMDRP strongly supports collaborative research between basic scientists and clinical researchers, and between academic scientists and biotechnology/pharmaceutical industry scientists. Collaborations that bring new perspectives from other disciplines, or bring new investigators into the Duchenne field, are also *strongly encouraged*.

**Optional Nested Resident or Medical Student Traineeship:** The IIRA mechanism allows for the inclusion of a Nested Resident or Medical Student Traineeship, which would allow the applicant to request additional funds as described in [Section I.E., Funding](#). The Government reserves the right to fund an application at a lower funding level if it does not meet the eligibility criteria or intent of the optional feature. The intent of the Nested Resident or Medical Student Traineeship is to provide mentored research opportunities in Duchenne. It is expected that the training will provide a valuable opportunity to develop the experience necessary to advance the trainee's research career in Duchenne. *Only one traineeship may be requested per application. Plans for training and mentorship must be well developed and clearly described by the PI in the Statement of Traineeship.*

**Guidelines for Animal Research:** All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S. C., et al., A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (<http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html>). Projects that include research on animal models are required to submit Attachment 10, Animal Research Plan, as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE (Animal Research: Reporting In Vivo Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported, to include such areas as randomization, blinding, sample-size estimation, and data handling. The ARRIVE guidelines can be found at [http://www.elsevier.com/\\_data/promis\\_misc/622936arrive\\_guidelines.pdf](http://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf).

**Research Involving Animals:** All Department of Defense (DoD)-funded research involving new and ongoing research with animals must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." *Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.* Refer to General Application Instructions, Appendix 6, for additional information.

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRMC ORP, Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional

Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC 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/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 6, 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.

***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 4, Section K.***

#### **D. Eligibility Information**

- The PI must be ***at or above*** the level of Assistant Professor (or equivalent).
- Optional Nested Resident or Medical Student Traineeship: By the time of the application submission deadline, the Resident Trainee must be enrolled in an accredited residency program, or the Medical Student Trainee must be enrolled in a nationally accredited (or equivalent) medical school. The trainee must be able to devote a minimum of 40% level of effort to this project for the 1-year period of performance of the traineeship.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- 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. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. ***If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.***
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

## **E. Funding**

### **IIRA Funding Level (without Nested Trainee)**

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$600,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$600,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.

### **IIRA with Optional Nested Resident Trainee Funding Level**

- The maximum period of performance is **3** years.
- The maximum period of performance for the Resident Trainee is **1** year, which may occur during any 1 year of the 3-year period of performance.
  - For the Optional Nested Resident Traineeship, the maximum allowable direct costs are \$50,000.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$650,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$650,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.

### **IIRA with Optional Nested Medical Student Trainee Funding Level**

- The maximum period of performance is **3** years.
- The maximum period of performance for the Medical Student Trainee is **1** year, which may occur during any 1 year of the 3-year period of performance.
  - For the Optional Nested Medical Student Traineeship, the maximum allowable direct costs are \$30,000.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$630,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$630,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.

### **For All Funding Levels**

- Only one traineeship may be requested per application.
- 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 **3** years.

- Any application that requests the higher level of funding and that does not include or meet requirements for an Optional Traineeship will have its budget reduced as appropriate.

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

- Salary
- Research supplies
- Equipment
- Clinical research costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for up to 2 investigators to travel to 1 scientific/technical meeting per year.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

***The CDMRP expects to allot approximately \$1.92M of the \$3.2M FY16 DMDRP appropriations to fund approximately 2 Investigator-Initiated Research Award applications, 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(s).***

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.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. 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 Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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.

***The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 prior to the application deadline.***

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.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the [application verification period](#). After the end of the application verification period, the full application cannot be modified.

#### **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-16-DMDRP-IIRA in Grants.gov (<http://www.grants.gov/>).

#### **B. Pre-Application Submission Content**

***The pre-application process should be started early to avoid missing deadlines. There are no grace periods. During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.***

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](mailto: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):

- **Tab 1 – Application Information**
- **Tab 2 – Application Contacts**
  - 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 SF424 (R&R) Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
  - Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on “Add Organizations to this Pre-application.” The organization(s) must either be selected from the eBRAP drop-down 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.
- **Tab 3 – Collaborators and Key Personnel**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
  - [FY16 DMDRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to Panel members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.
  - To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

- **Tab 4 – Conflicts of Interest (COIs)**

- 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). Refer to Appendix 1, Section C, of the General Application Instructions for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

**Note:** *Upload documents 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) 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:

- **Research Idea:** Clearly articulate the rationale for the project by presenting the ideas and reasoning behind the proposed research; include relevant literature citations.
- **Research Strategy:** State the hypothesis to be tested or the objective to be reached. State the project's specific aims and describe the experimental approach.
- **Impact:** State how the proposed work addresses at least one of the [FY16 DMDRP Focus Areas](#). Describe how the proposed research will have an impact on improving the function, quality of life, and/or extending the lifespan for all individuals with Duchenne.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* 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 per individual).** *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

- 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:

- **Research Idea:** How well the rationale for the research idea is supported by the reasoning and information presented as background.
- **Research Strategy:** To what degree the experimental approach for accomplishing the specific aims is feasible and addresses the hypothesis or objective.
- **Impact:** How well the research addresses at least one of the [FY16 DMDRP Focus Areas](#). If successful, how the study will impact the function, quality of life, and/or extend the lifespan for all individuals with Duchenne.

- **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. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

### **C. Full Application Submission Content**

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

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant's organization's Entity registration in the SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

*All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.*

*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 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 Investigator-Initiated Research 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. SF424 (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 (12-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.

Describe the proposed project in detail using the outline below. The Project Narrative must include preliminary data that are relevant to Duchenne and the proposed project.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations and preliminary data that led to the development of the proposed study. 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. If this project is part of a larger study, present only tasks that this award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate randomization, blinding, sample-size estimation, and controls, in sufficient detail for analysis. If applicable, describe how collaborations support the research. Address potential problem areas and present alternative methods and approaches. For projects involving biomarker evaluation, include appropriate preliminary data and sufficient detail on how the biomarker(s) will be qualified or validated, as described in [Section I.C., Award Information](#). If animal studies will be conducted, address statistical analyses, choice of models used, and study design in Attachment 10. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.

If proposing a clinical trial to be supported by this award, describe the intervention to be studied, how it will be applied, and the projected outcomes of the study. Define the study variables, describe how they will be measured, and include a description of appropriate controls and the endpoints to be tested. Document the availability and accessibility of the intervention. Include a detailed plan for the recruitment of subjects and safety procedures in Attachment 11.

- **Data and Statistical Analysis Plan:** Describe how data will be handled, collected, and analyzed in a manner that is consistent with the study objectives. If applicable, include a complete power analysis to demonstrate that the sample size is appropriate to meet the objective(s) of the study.
- **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 Patents: 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. **If the application indicates proprietary material(s) will be utilized for the proposed work, a letter of support confirming the PI will have access to the required material(s) is necessary.**
- Intellectual Property
  - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
    - Clearly identify all such property;
    - Identify the cost to the Federal government for use or license of such property, if applicable; or
    - Provide a statement that no property meeting this definition will be used on this project.
  - 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 4, Section K, 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.”** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or***

**confidential information.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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.
  - 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.
  - Impact: Briefly describe how the proposed project will have an impact on at least one of the [FY16 DMDRP Focus Areas](#) and on improving the function, quality of life, and/or extending the lifespan for all individuals with Duchenne.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. **Do not include proprietary or confidential information.** 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 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 [FY16 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 Duchenne 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 Investigator-Initiated Research 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.2., for detailed guidance on creating the SOW.
- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf.”**  
 Explain in detail why the proposed research project is important and the impact it will have on at least one of the [FY16 DMDRP Focus Areas](#).

*Describe the short-term impact:* Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research.

*Describe the long-term impact:* Explain the anticipated long-term gains from the proposed research, including how the new understanding may ultimately contribute to the goal of improving the function, quality of life, and/or extending the lifespan for all individuals with Duchenne.
- **Attachment 7: Transition Plan (one-page limit): Upload as “Transition.pdf.”**  
 Provide information on the methods and strategies proposed to move the outcome(s) of this project to the next level of research development or use after successful completion of the award. The transition plan should include the components listed below.

  - Details of the funding strategy that will be used to bring the outcome(s) to clinical studies, clinical trials, and/or regulatory approval and commercialization (e.g., specific potential commercial partners, specific funding opportunities to be applied for, etc.).
  - A description of collaborations and other resources that will be used to provide continuity of development.
  - Outline the regulatory pathway needed to advance development, if applicable.
  - A brief schedule and milestones for bringing the outcome(s) to clinical studies, clinical trials, and/or regulatory approval and commercialization.
- **Attachment 8: Statement of Traineeship (required if requesting an Optional Nested Resident or Medical Student Traineeship; two-page limit): Upload as “Traineeship.pdf.”**  
 Clearly describe the Duchenne research training program for the trainee, incorporating consideration of the candidate’s goals and prior experience. This should include a plan to obtain any background, in addition to the research experience and skills, necessary to support the trainee during the 1-year period of performance of the traineeship. Describe the availability of courses in relevant topics such as research design, biostatistics, and epidemiology at the institution and

how they will be integrated into the training plan. A timeline of key activities and planned attendance at conferences and seminars should be provided. Include information to describe the mentor's (i.e., the PI's) research support related to the candidate's research plan and the nature of the supervision that will occur during the proposed award period. The sponsoring institution must demonstrate a research and training program related to the candidate's area of interest, including a high-quality research environment with staff capable of productive collaboration with the trainee.

- **Attachment 9: Eligibility Statement (required if requesting Nested Resident or Medical Student Traineeship; one-page limit): Upload as "Eligibility.pdf."**

- Nested Resident Trainee: Provide a Statement of Eligibility form signed by the Program Director, Chair, or equivalent that verifies that the trainee is enrolled in an accredited residency training program and is able to participate at a minimum of 40% level of effort to this project for the 1-year period of performance of the traineeship.
- Nested Medical Student Trainee: Provide a Statement of Eligibility form signed by the Dean or equivalent that verifies that the trainee is enrolled in a nationally accredited (or equivalent) medical school program and is able to participate at a minimum of 40% level of effort to this project for the 1-year period of performance of the traineeship.

- **Attachment 10: Animal Research Plan (required if application includes research on animal models; five-page limit): Upload as "AnimalPlan.pdf."**

If the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, sex, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and

handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- **Attachment 11: Human Subject Recruitment and Safety Procedures (required if application includes a clinical trial; no page limit): Upload as “HumSubProc.pdf.”** Describe the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects and/or samples (i.e., convenience, simple random, stratified random). Address any potential barriers to accrual and plans for addressing potential delays. Describe how the subject-to-group assignments process will be conducted (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Include a discussion of the screening procedures and risk/benefit considerations. In addition, include a clear and detailed description of the potential ethical issues raised by the proposed study and provide a detailed plan for how the ethical issues will be addressed.
  - **Attachment 12: 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 with 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 (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information.
- **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. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.  
  
Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
  - **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.”
    - Include a biographical sketch for the Nested Resident or Medical Student Trainee (if applicable).

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

Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.Gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 12, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. 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 or 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.*** 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 submission rejection.

## F. Other Submission Requirements

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

All extramural 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 consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and DMDRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section III.B.2., Programmatic Review](#).* 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 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, which are of equal importance:

- **Research Strategy and Feasibility**

- How well the preliminary data and rationale support the research project.
- How well the hypotheses or objectives, aims, experimental design, methods, statistical plan, and analyses are developed and integrated into the project.
- How well the PI identifies potential problems and addresses alternative approaches.
- Whether the proposed research can be completed in the proposed period of performance.

For studies involving animal research:

- How well the animal study (or studies) is designed to achieve the objectives, including the relevance of model and endpoints/outcome measures to be used.
- How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

For applications proposing clinical trials:

- How well the PI addresses the availability, accessibility, and interest of human subjects for the clinical trial or how well the PI has justified the availability and accessibility of human samples for correlative studies.
- How well the inclusion, exclusion, and randomization criteria meet the needs of the proposed clinical trial and how well the level of risk to the human subjects is minimized.
- Whether there is evidence that a plan to address potential ethical issues raised by the proposed study has been appropriately considered and developed (if applicable).
- How well the recruitment processes for human subjects, or the collection processes for human samples, are designed to meet the needs of the proposed study.
- Whether there is evidence of an adequate contingency plan to resolve potential delays (e.g., slow accrual, attrition).

- **Impact**

- How well the proposed research addresses at least one of the [FY16 DMDRP Focus Areas](#).
- How the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) of the proposed research project will impact the Duchenne research field, patient care, and/or quality of life.
- Whether the proposed research project, if successful, will develop an outcome that is important and relevant to improving function, quality of life, and/or extending the lifespan of individuals with Duchenne.

- **Transition Plan**
  - Whether the funding strategy described to bring the anticipated outcome(s) to the next level of development and/or delivery to market is appropriate.
  - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
  - How the schedule and milestones for bringing the anticipated outcome(s) to the next level of development and/or delivery to market are appropriate.
- **Personnel**
  - How the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed work.
  - The degree of appropriateness of the levels of effort by the PI and other key personnel to ensure success of the project.
  - Optional Nested Resident or Medical Student (if applicable):
    - Whether the proposed Resident or Medical Student is an appropriate candidate for this traineeship and whether he/she is able to participate at a minimum of 40% level of effort over the 1-year period of performance.
    - Whether the PI and other scientific personnel are well qualified to conduct training for the trainee and whether a senior staff member has been identified who will be responsible for the trainee.
    - How well the research training is structured and balanced to ensure that the trainee will acquire the knowledge and necessary skills relevant to the area of Duchenne being studied.

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

- **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 (including collaborative arrangements).
  - To what degree the quality and extent of institutional 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 criteria are used by programmatic reviewers:
- a. Ratings and evaluations of the peer reviewers**
  - b. Relevance to the mission of the DHP and FY16 DMDRP, as evidenced by the following:**
    - Adherence to the intent of the award mechanism
    - Program portfolio composition
    - Relative impact

### **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:

- An FY16 DMDRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY16 DMDRP Programmatic Panel members can be found at <http://cdmrp.army.mil/dmdrp/panels/panels16>.*
- 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).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, 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.
- The invited application does not propose the same research project described in the pre-application.

- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.
- An application that does not address at least one of the [FY16 DMDRP Focus Areas](#) will be withdrawn.

#### **D. Withhold**

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

### **V. AWARD ADMINISTRATION INFORMATION**

#### **A. Award Notice**

Awards will be made no later than September 30, 2017. Refer to the General Application Instructions, Appendix 4, 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 4 for general information regarding administrative requirements.

#### **C. National Policy Requirements**

Refer to the General Application Instructions, Appendix 5 for general information regarding national policy requirements.

#### **D. Reporting**

Refer to the General Application Instructions, Appendix 4, Section H, for general information on reporting requirements.

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

## **E. Award Transfers**

Refer to the General Application, Appendix 4, Section L, for general information on organization or PI changes. 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 4, Section L, for general information on organization or PI changes.

## **VI. VERSION CODES AND AGENCY CONTACTS**

### **A. Program Announcement/Funding Opportunity and General Application Instructions Version**

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code [20160210i]. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code [20160210].

### **B. 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](mailto:help@eBRAP.org)

### **C. 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; International 1-606-545-5035

Email: [support@grants.gov](mailto: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
SF424 (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	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf."	
	8	Traineeship: Upload as Attachment 8 with file name "Traineeship.pdf," if applicable.	
	9	Eligibility Statement: Upload as Attachment 9 with file name "Eligibility.pdf," if applicable	
	10	Animal Research Plan: Upload as Attachment 10 with file name "AnimalPlan.pdf," if applicable.	
	11	Human Subject Recruitment and Safety Procedures: Upload as Attachment 11 with file name "HumSubProc.pdf," if applicable.	
	12	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 12 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.	