

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

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Duchenne Muscular Dystrophy Research Program**

**Investigator-Initiated Research Award**

**Announcement Type: Initial**

**Funding Opportunity Number: W81XWH-18-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), August 29, 2018
- **Invitation to Submit an Application:** October, 2018
- **Application Submission Deadline:** 11:59 p.m. ET, December 5, 2018
- **End of Application Verification Period:** 5:00 p.m. ET, December 10, 2018
- **Peer Review:** February 2019
- **Programmatic Review:** April 2019

*This Program Announcement must be read in conjunction with the General Application Instructions, version 20180329. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”*

**TABLE OF CONTENTS**

- I. OVERVIEW OF THE FUNDING OPPORTUNITY..... 1**
- II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY ..... 3**
  - II.A. Program Description..... 3
    - II.A.1. FY18 DMDRP Focus Areas ..... 3
  - II.B. Award Information ..... 4
  - II.C. Eligibility Information..... 10
    - II.C.1. Eligible Applicants ..... 10
    - II.C.2. Cost Sharing..... 11
    - II.C.3. Other ..... 11
  - II.D. Application and Submission Information..... 11
    - II.D.1. Address to Request Application Package ..... 11
    - II.D.2. Content and Form of the Application Submission ..... 12
    - II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM) ..... 29
    - II.D.4. Submission Dates and Times..... 30
    - II.D.5. Funding Restrictions..... 30
    - II.D.6. Other Submission Requirements ..... 32
  - II.E. Application Review Information ..... 32
    - II.E.1. Criteria ..... 32
    - II.E.2. Application Review and Selection Process..... 35
    - II.E.3. Integrity and Performance Information..... 36
    - II.E.4. Anticipated Announcement and Federal Award Dates..... 36
  - II.F. Federal Award Administration Information ..... 37
    - II.F.1. Federal Award Notices..... 37
    - II.F.2. Administrative and National Policy Requirements..... 37
    - II.F.3. Reporting..... 38
  - II.G. Federal Awarding Agency Contacts..... 39
    - II.G.1. CDMRP Help Desk ..... 39
    - II.G.2. Grants.gov Contact Center ..... 39
  - II.H. Other Information..... 39
    - II.H.1. Program Announcement and General Application Instructions Versions..... 39
    - II.H.2. Administrative Actions..... 39
    - II.H.3. Application Submission Checklist ..... 42
- APPENDIX 1: ACRONYM LIST ..... 44**

## II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

***New for 2018:*** Application submission by extramural organizations through Grants.gov requires use of the Workspace interface, which separates the application package into individual forms. Applicants must create a Workspace in Grants.gov, complete the required forms, and submit their application Workspace package.

### II.A. Program Description

Applications to the Fiscal Year 2018 (FY18) Duchenne Muscular Dystrophy Research Program (DMDRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement 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 FY17 totaled \$23.2 million (M). The FY18 appropriation is \$3.2M.

The goal of the FY18 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 discovery and development of therapeutics, devices, and other interventions and to promote their rigorous clinical testing. Additionally, DMDRP supports the efforts of the National Institutes of Health (NIH) Muscular Dystrophy Coordinating Committee (MDCC) and the [2015 MDCC Action Plan for the Muscular Dystrophies](#), which prioritizes the needs to improve treatments and reduce the disease burden for muscular dystrophy including Duchenne.

#### II.A.1. FY18 DMDRP Focus Areas

All applications for the FY18 DMDRP funding opportunities ***must*** address at least one of the following Focus Areas:

- Bone, cardiac, central nervous system (CNS), and/or gastrointestinal tract studies, including identifying mechanisms of pathology and therapeutic interventions
- Translational and clinical studies, novel interventions, and drug and biologic delivery technologies designed to improve care and quality of life in areas such as:
  - Cognitive function
  - Endocrinology
  - Gastrointestinal issues

- Immunology
- Orthopaedics
- Psychosocial issues
- Pulmonology (including sleep-focused studies)
- Skeletal muscle
- Assessment of clinical trial tools and outcome measures, such as:
  - Discovery and qualification of pharmacodynamic, prognostic, and predictive biomarkers
  - Novel clinical outcome assessment
  - Patient-centered outcomes (e.g., quality of life, activities of daily living)
  - Potential surrogate markers
  - Secondary data analysis that helps to address clinical research tool validation and/or to understand natural history
- Extension or expansion of existing preclinical translational data in support of a specific therapeutic development path (such as optimizing delivery to target tissues, including drug exposure, independent replication, and comparative studies)

## **II.B. 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 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 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)
- 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

---

<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.

<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.

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:

- <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/BiomarkerQualificationProgram/ucm20086360.htm>
- <https://www.c-path.org/pdf/FDADraftDDTools.pdf>

FDA Office of In Vitro Diagnostics and Radiological Health:

- <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/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 12: Human Subject Recruitment and Safety Procedures](#).*

**Optional Features:** The IIRA mechanism allows for the inclusion of the following options, which would allow the applicant to request additional funds as described in [Section II.D.5, Funding Restrictions](#). 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(s).

**Optional Interdisciplinary Collaborator (OIC):** The FY18 DMDRP strongly encourages interdisciplinary collaborations between diverse groups of academic scientists, clinicians, industry scientists, the military Services, the Department of Veterans Affairs (VA), and other Federal Government agencies. The goal of the OIC is to bring new perspectives from other disciplines and/or bring new investigators into the Duchenne field that through their collaboration the team can undertake conceptually and technically novel approaches that would be less likely to succeed if undertaken by a more narrowly focused group of investigators. Some examples would include projects that establish interdisciplinary collaborations between, but not limited to, experimental biologists and immunologists, orthopaedists, or engineers.

The PI must declare any intent to include an OIC in the pre-application [Preproposal Narrative](#). Applications must include a Statement of Collaboration ([Section II.D.2.b.ii, Attachment 8: Statement of Collaboration](#)) that clearly identifies the OIC, describes the collaboration, and addresses how each of the criteria below are met. In addition, the OIC must provide a letter of collaboration ([Section II.D.2.b.ii, Letters of Collaboration](#)) and a biographical sketch ([Section II.D.2.b.ii, Research & Related Senior/Key Person Profile](#)) describing his/her involvement in the proposed research project.

- An interdisciplinary collaboration must involve independent investigators whose primary training, research, and experience are in different fields.

- The interdisciplinary collaboration must involve a new collaboration between independent investigators who have not coauthored primary research publications within the past 3 years and who have not had research funding together from any source within the past 5 years.
- It should be clear that the success of the proposed research project depends on the unique skills and contributions of both the PI and the OIC. A proposed project in which the OIC merely supplies tissue samples or access to patients will *not* meet the intent and will *not* be qualified for the higher level of funding.
- At least a 10% level of effort is required of the OIC, and this should be reflected in the budget.
- Only one OIC may be requested per application.

**Optional Nested Resident or Medical Student Traineeship:** The intent of the Optional 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 [Attachment 9: Statement of Traineeship](#).

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

The anticipated direct costs budgeted for the entire period of performance for an FY18 DMDRP IIRA will not exceed **\$600,000** or **\$750,000** if applying for the IIRA with an OIC. Additional funding can be requested above the maximums specified for the IIRA or the IIRA with an OIC to specifically support the Optional Nested Resident or Medical Student Trainee. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of the Department of Defense (DoD) during project performance is the key factor in determining whether to award a grant or cooperative agreement.

***Extramural Organizations:*** An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305) and the award will identify the specific substantial involvement. Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

**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 U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (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.*** Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

A clinical trial is defined as a prospective accrual of patients (human subjects) in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction.

**Use of DoD or VA Resources:** If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the PI is responsible for demonstrating such access at the time of application submission and should develop a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information.

**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 11, 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 [https://www.elsevier.com/\\_data/promis\\_misc/622936arrive\\_guidelines.pdf](https://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf).

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC 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 the General Application Instructions, Appendix 1, for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement 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 2, Section K.

Awards will be made no later than September 30, 2019. For additional information refer to [Section II.F.1, Federal Award Notices](#).

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

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

**II.C.1.a. Organization:** All organizations, including international organizations, are eligible to apply.

**Government Agencies Within the United States:** Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this Program Announcement may be submitted by extramural and intramural organizations, these terms are defined below.

**Extramural Organization:** An eligible non-DoD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, Government, and research institutes.

**Intramural DoD Organization:** A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center.

**Note:** Applications from an intramural DoD organization or from an extramural Federal organization may be submitted through a research foundation.

The USAMRAA makes awards to eligible organizations, not to individuals.

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

- The PI must be *at or above* the level of Assistant Professor (or equivalent).
- The OIC must be at or above the level of Assistant Professor (or equivalent). The OIC is required to devote a minimum of 10% level of effort to this project.
- The PI and OIC must be independent investigators whose primary training, research, and experience are in different fields.
- 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.

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

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <http://orcid.org/>.

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

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

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

There are no limitations on the number of applications for which an investigator may be named as a PI.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

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

## **II.D. Application and 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).*

*Extramural Submission* is defined as an application submitted by an organization to Grants.gov.

*Intramural DoD Submission* is defined as an application submitted by a DoD organization to eBRAP.

### **II.D.1. Address to Request Application Package**

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.

*Extramural Submissions:* Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://eBRAP.org). Full application packages must be accessed and submitted at Grants.gov.

*Intramural DoD Submissions:* Pre-application content and forms and full application packages must be accessed and submitted at [eBRAP.org](http://eBRAP.org).

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

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

Submission is a two-step process requiring both *pre-application* and *full application* as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

**Pre-Application Submission:** All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (<https://eBRAP.org/>).

**Full Application Submission:** Full applications must be submitted through the online portals as described below.

**Submitting Extramural Organizations:** Full applications from extramural organizations must be submitted through a Grants.gov Workspace. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in [Section II.C.1, Eligible Applicants](#).

**Submitting Intramural DoD Organizations:** Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP.

**For Both Extramural and Intramural Applicants:** A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement 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.

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

## II.D.2.a. Step 1: Pre-Application Submission Content

**During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number is required during the full application submission process.**

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 to request a change in designation.

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. A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

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**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://ebrap.org/eBRAP/public/Program.htm>. Note that the codes have recently been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **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 be either 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 be either 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.

[FY18 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 II.H.2.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 pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY18, 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>). Pre-applications or 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 Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

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 the General Application Instructions, Appendix 3, Section C, 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 [FY18 DMDRP Focus Areas](#). Describe how the proposed research will have an impact on preserving and improving the function and quality of life, and extending the life span of all individuals with Duchenne.
- **OIC:** If proposing to include an OIC, describe the new collaboration and the different disciplines that are coming together that will lead to new scientific advances beyond the progress attainable in the absence of the collaboration.
- **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 the following:
  - 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, reference title, and reference source, including 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 [FY18 DMDRP Focus Areas](#). If successful, how the study will impact the function and quality of life, and extend the life span of all individuals with Duchenne.
- **OIC:** If proposing to include an OIC, how well the OIC contributes to the overall success of the proposed project and the proposed research strategy. Whether the addition of the OIC brings a different discipline and perspective to the project that will enable scientific advances that could not be achievable in the absence of the collaboration.

Upon reviewing a pre-application that includes an OIC, if the FY18 DMDRP Programmatic Panel deems that the proposed collaboration does not meet the intent of the OIC, the Programmatic Panel may recommend inviting the PI to submit a full application without the OIC option (i.e., without the request for additional funding to support an OIC).

- **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 in [Section I, Overview of the Funding Opportunity](#). Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

## **II.D.2.b. Step 2: 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 full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<http://www.grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

### **II.D.2.b.i. Full Application Guidelines**

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in the Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person

is entering text into an application package, the *same version* of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

**Table 1. Full Application Submission Guidelines**

Extramural Submissions	Intramural DoD Submissions
<b>Application Package Location</b>	
Download application package components for W81XWH-18-DMDRP-IIRA from Grants.gov ( <a href="http://www.grants.gov">http://www.grants.gov</a> ) and create a Grants.gov Workspace. The Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-18-DMDRP-IIRA from eBRAP ( <a href="https://ebrap.org">https://ebrap.org</a> ).
<b>Full Application Package Components</b>	
<b>SF424 (R&amp;R) Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.	<b>Tab 1 – Summary:</b> Provide a summary of the application information. <b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">R&amp;R Subaward Budget Attachment(s) Form</a> (if applicable)</li> </ul>	<b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.

Extramural Submissions	Intramural DoD Submissions
<b>Application Package Submission</b>	
<p><b>Create a Grants.gov Workspace.</b> Add participants (investigators and Business Officials) to the Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b> An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p>Note: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget 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.</p>	<p><b>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</b></p> <p><b>Tab 5 – Submit/Request Approval Full Application:</b> After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email.</p>

Extramural Submissions	Intramural DoD Submissions
<b><u>Application Verification Period</u></b>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, <b><i>with the exception of the Project Narrative and Budget Form</i></b>, may be modified.</p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, <b><i>with the exception of the Project Narrative and Budget Form</i></b>, may be modified. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>
<b>Further Information</b>	
<p><b>Tracking a Grants.gov Workspace Package.</b> After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

Application viewing, modification, and verification in eBRAP are 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. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

***Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.***

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

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

- **Extramural Applications Only**

**SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

**Attachments:**

*Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.*

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full 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) 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 evaluation. 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 II.B, Award Information](#). If animal studies will be conducted, address statistical analyses, choice of models used, and study design in [Attachment 11](#). 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 12](#).

- **Data and Statistical Analysis Plan:** Describe how data will be handled, collected, and analyzed in a manner that is consistent with the study objectives. Detail a statistical analysis plan for the resulting outcomes. If applicable, include a complete power analysis to demonstrate that the sample size is appropriate to meet the objective(s) of the study. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Attachment 2: Supporting Documentation:** Combine and upload as a single file named “Support.pdf.” Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format 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, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (required for applications including an OIC): 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 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.

Letters should describe:

- Availability of and access to research resources (to include proprietary material for the purpose/duration of the proposed research), and/or
- Availability of and access to appropriate populations (and/or access to available samples/data or databases), if applicable.

***For applications that include an OIC, a signed letter from the OIC must be provided.***

- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), “Intangible Property.”
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- 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 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Use of DoD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military patient populations and/or DoD resources or databases.

- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **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 to be reached/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 [FY18 DMDRP Focus Areas](#) and on preserving and improving the function and quality of life, and extending the life span of 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 [FY18 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 IIRA mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

Include the name(s) of the key personnel and contact information for each study site/subaward site.

Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

Identify cell line(s) and commercial or organizational source(s) to be used.

If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the U.S. FDA or other Government agency.

- **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 [FY18 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 preserving and improving the function and quality of life, and extending the life span of 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 anticipated 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).
- A description of collaborations and other resources that will be used to provide continuity of development.
- Outline the regulatory pathway needed to advance the outcome(s) 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 Collaboration (only required if requesting an OIC; two-page limit):** Upload as “Collaboration.pdf.”

The following components should be addressed:

- The PI must identify the OIC and address all criteria described above in [Section II.B, Award Information](#).
- Describe how the OIC will contribute significantly to the project such that the proposed work could not be accomplished without his/her involvement.
- Describe the different disciplines, unique skills, and contributions of the PI and the OIC and how they will contribute to the success of the project.

- **Attachment 9: Statement of Traineeship (only 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 (e.g., senior staff member who will supervise the trainee). The sponsoring institution must demonstrate availability of 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 10: Trainee Eligibility Statement (only required if requesting Nested Resident or Medical Student Traineeship; one-page limit):** Upload as "TraineeEligibility.pdf." Use the Trainee Eligibility Statement template (available for download on the Full Announcement page in Grants.gov).
  - Nested Resident Trainee: Provide the Eligibility Statement 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 the Eligibility Statement 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 11: Animal Research Plan (required if application includes research on animal models; five-page limit):** Upload as "AnimalPlan.pdf."

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

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, sex, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal

- treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
  - Describe how the animal studies will be conducted in accordance with the ARRIVE guidelines ([https://www.elsevier.com/data/promis\\_misc/622936arrive\\_guidelines.pdf](https://www.elsevier.com/data/promis_misc/622936arrive_guidelines.pdf)).
- **Attachment 12: 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 13: Representations, if applicable (extramural submissions only):** Upload as “MandatoryReps.pdf.” All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information see the General Application Instructions, Appendix 5, Section B, Representations.
  - **Attachment 14: DoD Military Budget Form(s), if applicable:** Upload as “MFBudget.pdf.” If a military facility (Military Health System facility, research laboratory, medical 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 DoD Military 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 III.A.7, for detailed information.
- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in

science, technology, engineering, or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

**Research & Related Personal Data:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

**Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, 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 NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.
- 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 biographical sketches for the OIC, Nested Resident Trainee, or Medical Student Trainee (if applicable).
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - Include OIC previous/current/pending support (if applicable).

**Research & Related Budget:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, 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.

**Project/Performance Site Location(s) Form:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only**

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

**Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 14. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

### **II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)**

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. Verify the status of the applicant’s organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

**New Requirement:** In March 2018, the General Services Administration (GSA) implemented fraud prevention security measures in the SAM that require every *new* contractor registrant to provide a written (hard copy), notarized letter confirming the entity’s Administrator authorized to register the entity in the SAM database or to make changes to its registration. Effective April 29, 2018, the notarized letter process is now mandatory on all *current* registrants at SAM who have a requirement to update data on their SAM record. The notarized letter is mandatory and is required before the GSA Federal Service Desk (FSD) will activate the entity’s registration. The Office of the Secretary of Defense and GSA realize the length of time needed to transmit, receive, process, and approve the notarized letters presents a significant impact on the ability of the contracting activity to make timely awards, but these steps must be taken to mitigate fraud concern. ***Notarized letters are required for all new and existing SAM-registered entities.*** The notarized letters must be postal service mailed (not emailed or faxed) to the “Federal Service Desk” and must contain the information outlined in the SAM-posted Frequently Asked Questions (FAQs) at <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update>. Instructions for domestic entities and instructions for international entities with embedded

templates for use are also provided within the SAM Update notice with frequently asked questions at <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update>.

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

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

#### **Applicant Verification of Full Application Submission in eBRAP**

Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement 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. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

***Extramural Submission:*** The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

***Intramural DoD Submission:*** After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.

***For All Submissions:*** Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

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

The maximum period of performance is **3** years.

### **IIRA Funding Level**

- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$600,000**. If indirect cost rates have been negotiated, 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 cost rate exceeding the organization's negotiated rate.

### **IIRA with OIC Funding Level**

- If requesting an OIC, the anticipated direct costs budgeted for the entire period of performance will not exceed **\$750,000**. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. No budget will be approved by the Government exceeding **\$750,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

### **Optional Nested Resident or Medical Student Trainee Funding Level**

- The maximum period of performance for the Resident or Medical Student Trainee is **1** year, which may occur during any 1 year of the 3-year period of performance.
- Additional funding can be requested above the maximums specified for the IIRA or the IIRA with an OIC. The anticipated direct costs budgeted for the entire period of performance to specifically support this option will not exceed **\$30,000** for a Medical Student Trainee or **\$50,000** for a Resident Trainee plus indirect costs in accordance with the organization's negotiated rate.

### **For All Funding Levels**

- Only one OIC and one Optional Traineeship may be requested per application.
- 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 the requirements and intent for an OIC and/or Optional Traineeship will have its budget reduced as appropriate.

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

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

- Salary
- Research supplies
- Clinical research costs

- Support for multidisciplinary collaborations, including travel
- Travel costs for one investigator to travel to one scientific/technical meeting per year to present project outcomes or disseminate project results of the FY18 DMDRP IIRA.

Awards made to extramural organizations will consist solely of assistance agreements (grants and cooperative agreements). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.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 the General Application Instructions, Section III.A.4.*

*The CDMRP expects to allot approximately \$1.92M of the \$3.2M FY18 DMDRP appropriation to fund approximately two IIRA applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.*

Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this funding opportunity will be funded with FY18 funds, which will expire for use on September 30, 2024.

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

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

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

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

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

To determine technical merit, all applications will be 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, 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:

- To what degree the intervention addresses the clinical need(s) described.
  - How well the application addresses the availability, accessibility, and interest of human subjects for the clinical trial or how well the application 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).
- **Statistical Analysis Plan**
    - Whether an appropriate statistical analysis plan is provided, including power analysis.
    - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
  - **Impact**
    - How well the proposed research addresses at least one of the [FY18 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 preserving and improving the function and quality of life, and extending the life span 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.
  - OIC (if applicable):
    - Whether the collaborator’s experience, expertise, and involvement in the study significantly contribute to the project such that the proposed work could not be accomplished without his/her involvement.
    - Whether the collaborator meets the criteria for an OIC as verified by the Statement of Collaboration ([Attachment 8](#)).
  - Optional Nested Resident or Medical Student Traineeship (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 provide 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:

- **Budget**
  - Whether the **direct** maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement.
  - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.
- **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.

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

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY18 DMDRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relative impact

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

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review 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 Commanding General, USAMRMC, on behalf of the DHA 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.

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 II.E.1.b, 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 and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

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

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold (currently \$150,000) over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

### **II.E.4. Anticipated Announcement and Federal Award Dates**

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

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.

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

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

Awards will be made no later than September 30, 2019. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from the USAMRAA will contact the business official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing document.

***Federal Organizations:*** Awards to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

After email notification of application review results through eBRAP, and if selected for funding, a representative from the CDMRP will contact the business official authorized to negotiate on behalf of the PI's organization.

#### **II.F.1.a. PI Changes and Award Transfers**

Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA Grants Officer, provided that the intent of the award mechanism is met. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

### **II.F.2. Administrative and National Policy Requirements**

Applicable requirements in the DoDGARs found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

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

Refer to full text of the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations](#): Addendum to the DoD R&D Terms and Conditions and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

### **II.F.3. Reporting**

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. *If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.*

Annual progress reports as well as a final progress report will be required.

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

Award Chart: An Award Chart will be required within 20 business days after award. For the IIRA mechanism, use the format example titled, “Award Charts,” available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>).

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

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions (see General Application Instructions, Section III.A.4).

## **II.G. Federal Awarding Agency Contacts**

### **II.G.1. CDMRP Help Desk**

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission 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)

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

Questions related to extramural 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 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.

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

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

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20180329g. The Program Announcement numeric version code will match the General Applications Instructions version code 20180329.

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

After receipt of pre-applications or applications, the following administrative actions may occur:

#### **II.H.2.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.

#### **II.H.2.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.

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

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

- An FY18 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 FY18 DMDRP Programmatic Panel members can be found at <http://cdmrp.army.mil/DMDRP/panels/panels18>.*
- The application fails to conform to this Program Announcement 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 FY18, 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 Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The invited application does not propose the same research project described in the pre-application.
- An application for which the PI does not meet the eligibility criteria will be withdrawn.
- An application that does not address at least one of the [FY18 DMDRP Focus Areas](#) will be withdrawn.

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

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

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

Application Components	Action	Completed
SF424 (R&R) Application for Federal Assistance <b>(Extramural submissions only)</b>	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) <b>(Intramural submissions only)</b>	Complete these tabs as instructed.	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf."	
	Statement of Collaboration: Upload as Attachment 8 with file name "Collaboration.pdf," if applicable.	
	Statement of Traineeship: Upload as Attachment 9 with file name "Traineeship.pdf," if applicable.	
	Trainee Eligibility Statement: Upload as Attachment 10 with file name "TraineeEligibility.pdf," if applicable.	
	Animal Research Plan: Upload as Attachment 11 with file name "AnimalPlan.pdf," if applicable.	
	Human Subject Recruitment and Safety Procedures: Upload as Attachment 12 with file name "HumSubProc.pdf," if applicable.	
Representations (extramural submissions only): Upload as Attachment 13 with file name "MandatoryReps.pdf," if applicable.		

Application Components	Action	Completed
	DoD Military Budget Form(s): Upload as Attachment 14 with file name “MFBudget.pdf,” if applicable.	
Research & Related Personal Data	Complete form as instructed.	
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 ( <b>Extramural submissions only</b> )	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Budget ( <b>Intramural submissions only</b> )	Complete the DoD Military Budget Form and justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

## APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
ARRIVE	Animal Research: Reporting In Vivo Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CNS	Central Nervous System
COI	Conflict of Interest
DHA	Defense Health Agency
DHP	Defense Health Program
DMDRP	Duchenne Muscular Dystrophy Research Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FAQs	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
FSD	Federal Service Desk
FY	Fiscal Year
GSA	General Services Administration
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IIRA	Investigator-Initiated Research Award
IRB	Institutional Review Board
M	Million
MDCC	Muscular Dystrophy Coordinating Committee
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NPC	Non-Profit Corporation
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OIC	Optional Interdisciplinary Collaborator
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections

PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, Mathematics
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs