

# **Program Announcement**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Duchenne Muscular Dystrophy Research Program**

### **Investigator-Initiated Research Award**

**Funding Opportunity Number: W81XWH-11-DMDRP-IIRA**

**Catalog of Federal Domestic Assistance Number: 12.420**

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

- **Pre-application Submission Deadline:** 5:00 p.m. Eastern time (ET), October 11, 2011
- **Invitation to Submit an Application:** November 2011
- **Application Submission Deadline:** 11:59 p.m. ET, January 10, 2012
- **Scientific Peer Review:** February 2012
- **Programmatic Review:** April 2012

*New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.*

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## **I. FUNDING OPPORTUNITY DESCRIPTION**

### **A. Program Description**

Applications for the Duchenne Muscular Dystrophy Research Program (DMDRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The DMDRP was established in fiscal year 2011 (FY11) to promote the understanding, diagnosis, and treatment of DMD. The FY11 appropriation is \$4 million (M).

The vision of the FY11 DMDRP is to extend and improve the function, quality of life, and life span for all individuals diagnosed with DMD. As such, the DMDRP is seeking to fund research to accelerate the development and clinical testing of new therapeutics and increase our understanding of successes and failures of therapeutics in clinical trials.

Applications involving multidisciplinary collaborations among academia, industry, the military, and other government agencies are highly encouraged. Although the program supports groundbreaking research, all projects must demonstrate solid judgment and rationale.

**Research Focus Areas:** All applications for the FY11 DMDRP funding opportunity are highly encouraged to address at least one of the following focus areas:

- Developing new biomarkers to improve evaluation of diagnosis, disease severity, disease progression, and/or response to treatment
- Assessment of clinical trial outcomes, such as:
  - Molecular, functional, imaging, etc.
  - Testing and validating surrogate markers
  - Evaluating potential composite scores for outcomes assessment
  - Patient outcomes, e.g., quality of life, activities of daily living, etc.
- Ancillary studies conducted in conjunction with clinical trials or observational studies
- Characterization of animal models and development of greater access to them
- Extension or expansion of pre-clinical data in support of the therapeutic development path. This could include preparation for Investigational New Drug (IND) and clinical trials.

### **B. Award Information**

The DMDRP Investigator-Initiated Research Award (IIRA) mechanism supports studies that will make an important contribution toward understanding mechanisms of initiation or progression, and/or improving patient care for DMD.

Research projects should focus on translational research that will accelerate the movement of promising ideas in DMD into clinical applications. Translational research may be defined as an integration of basic science and clinical observations. Observations that drive a research idea

may be derived from a laboratory discovery, population-based studies, or a clinician's firsthand knowledge of patients and anecdotal data.

The DMDRP Investigator-Initiated Research Award does not support clinical trials, but may support correlative studies that are associated with an existing clinical trial, and projects that develop endpoints for clinical trials. Research projects may also include preclinical studies in animal models and human subjects, and human anatomical substances.

Translational research can also include the advancement of promising preclinical findings into products for clinical applications in DMD. The product(s) to be developed may be pharmacologic agents (drugs or biologicals) and/or devices. For research projects focused on an outcome(s) that will move into subsequent clinical trials and/or regulatory approval(s) and commercialization, the Principal Investigator (PI) must provide a transition plan (including timelines, milestones, potential funding and resources) showing how the product(s) of the research will progress to clinical trials and/or delivery to market after the completion of the DMDRP award.

Examples of the types of research that may be supported include, but are not limited to:

- Developing and/or evaluating biomarkers that are diagnostic or prognostic
- Developing and/or evaluating outcomes assessments and endpoints for preclinical and clinical trials (e.g., laboratory, imaging, functional, etc.)
- Developing and/or evaluating patient outcomes such as quality of life, activities of daily living, etc.
- Testing new therapeutic modalities (agents, delivery systems, and chemical modification of lead compounds) using established or validated novel preclinical systems
- Designing and implementing pilot or full-scale, Good Manufacturing Practice (GMP) production of therapeutics and/or delivery systems for use in advanced preclinical and initial clinical trials
- Developing pharmacologic agents through adsorption, distribution, metabolism, excretion, and toxicity (ADMET) phase
- Developing pharmacologic agents to IND stage for initiation of Phase I clinical trials
- Developing prototype devices for diagnosis or treatment to Investigational Device Exemption (IDE) stage for initiation of Phase I clinical trials

***Applications must include preliminary data that is relevant to DMD and the proposed project.***

**Optional Qualified Collaborator:** The FY11 DMDRP strongly supports collaborative research between basic scientists and clinical researchers, and between academic scientists and biotechnology/pharmaceutical industry scientists. Collaborations that bring new perspectives from other disciplines, or bring new investigators into the DMD field are also strongly encouraged.

Collaborations that meet the criteria below will qualify for a higher level of funding as described in Section I.D below. The PI must submit a Statement of Collaboration that clearly identifies the collaborating investigator and addresses how each of the criteria are met. Additionally, the collaborator must provide a letter of collaboration describing his/her involvement in the proposed work. It should be clear that the success of the project depends on the unique skills and contributions of each partner.

- The collaborator must significantly contribute to the project such that the proposed work could not be accomplished without his/her involvement.
  - A proposed project in which the collaborator 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 collaborator. Contribution of the collaborator should be reflected in the application's budget.
- The collaborator must be at or above the level of Assistant Professor (or equivalent).

**Optional Nested Resident and Medical Student Traineeships:** Nested Resident and Medical Student Traineeships are being offered as an optional part of the IIRA. The intent of the Nested Resident and Medical Student Traineeship is to provide mentored research opportunities in DMD. It is expected that the training will provide a valuable opportunity to develop experience necessary to advance the trainee's research career in DMD.

Funding for Nested Resident and Medical Student Traineeship(s) can be requested for an additional maximum of \$75,000 for a resident, and \$55,000 for a medical student (M.D. or M.D./Ph.D.), inclusive of direct and indirect costs over a 1-year period of performance. Only one traineeship of each type may be requested per application.

The DMDRP can decide to fund a submission for an IIRA with a Nested Resident and Medical Student Traineeship but **not fund** the traineeship.

***Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity.*** A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction.

**Use of Human Subjects and Human Anatomical Substances:** All Department of Defense (DOD)-funded research involving new and ongoing research with human subjects and human anatomical substances must be reviewed and approved by the US Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is NOT required. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DOD. These laws and directives are rigorous and detailed, and will require

information in addition to that supplied to the local IRB. Allow a minimum of 4 months for HRPO regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

### **C. Eligibility Information**

- PIs must be *at or above* the level of Assistant Professor (or equivalent).
- Optional Collaborator must be *at or above* the level of Assistant Professor (or equivalent).
- Optional Nested Resident and Medical Student Traineeships: Resident trainee must be enrolled in an accredited residency program, and 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 for the 1-year period of performance of the traineeship.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

### **D. Funding**

- The maximum period of performance is **3** years.
- The maximum allowable direct total costs for the entire period of performance is **\$525,000**, plus indirect costs.
- If requesting an Optional Qualified Collaborator, the maximum allowable direct total costs for the entire period of performance is **\$675,000**, plus indirect costs.
- Additional funds may be requested for optional traineeships:
  - If requesting an Optional Nested Resident Traineeship, the maximum allowable total costs (direct and indirect) are \$75,000 for a 1-year period of performance, or
  - If requesting an Optional Nested Medical Student Traineeship, the maximum allowable total costs (direct and indirect) are \$55,000 for a 1-year period of performance.
  - Only one traineeship of each type may be requested per application.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 3 years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

- Applications requesting the higher level of funding that do not include an Optional Qualified Collaborator or optional traineeships will have their budgets reduced as appropriate.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget form. In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs (No clinical trials allowed)
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

*The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$3.4M of the \$4M FY11 DMDRP appropriation to fund approximately 3 Investigator-Initiated Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.*

## **II. SUBMISSION INFORMATION**

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt system (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The government reserves the right to reject duplicative applications.

### **A. Where to Obtain the Application Package**

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-11-DMDRP-IIRA.

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

All pre-application components must be submitted by the PI through the CDMRP eReceipt system (<https://cdmrp.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 application should be the same as those identified in the pre-application. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

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

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**
- **Required Files – Tab 4**

**Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

The Preproposal Narrative should include the following:

- **Research Idea:** Describe the ideas and reasoning on which the proposed work is based; include relevant literature citations.
- **Research Strategy:** Concisely state the project's objectives and specific aims.
- **Impact:** Describe how the proposed research will have an impact on improving the function, quality of life, and life span for all individuals diagnosed with DMD.
- **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research project. If an optional collaborator is included, describe how the project depends on the unique skills of the collaborator. If an optional traineeship(s) is included, briefly describe the training plan and how the trainee(s) will be included in the research project.

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

- **References Cited: (one-page limit):** List relevant references 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). The inclusion of Internet URLs to references is encouraged.
  - **Key Personnel Biographical Sketches (four-page limit per individual):** Include biographical sketches for the PI and other key collaborators.
- **Submit Pre-application – Tab 5**
  - **Other Documents Tab**

No additional documents are required.

## Pre-Application Screening

- **Pre-Application Screening Criteria**

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

- **Research Ideas:** How well the research demonstrates sound scientific rationale.
- **Research Strategy:** How well the specific aims support the research hypothesis and objectives.
- **Impact:** If successful, how the study will impact the function, quality of life and life span for all individuals diagnosed with DMD.
- **Personnel:** How the personnel's background and expertise are appropriate to accomplish the proposed research. If an optional collaborator is included, how the collaborator's background and expertise is necessary to accomplish the proposed project. If an optional traineeship(s) is included, how the training plan will facilitate the trainee in acquiring the knowledge and necessary skills relevant to the area of DMD being studied.

- **Notification of Pre-Application Screening Results**

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

### C. Application Submission Content and Form

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

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

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

1. **SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
2. **Attachments Form**
  - **Attachment 1: Project Narrative (15-page limit):** Upload as "ProjectNarrative.pdf."

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

- **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to this project.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project's specific aims to be funded by this application. 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 controls, in sufficient detail. If applicable, describe how collaborations support the research. Address potential problem areas and present alternative methods and approaches. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Describe the statistical plan if appropriate for the research proposed. *This award may not be used to conduct clinical trials.*
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *Each component has no page limit unless otherwise noted.*
  - **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 if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information.
  - **Publications and/or Patent Abstracts (five-document limit):** Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then they must be included. 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, reflecting the laboratory space, equipment, and other resources available for the project.
  - **Letter of Eligibility (required if requesting Nested Resident and Medical Student Traineeship):**

- Nested Resident Trainee: Provide a Statement of Eligibility form signed by the Program Director, Chair, or equivalent that verifies the trainee is enrolled in an accredited residency training program and is able to participate at a minimum of 40% level of effort for the 1-year period of performance of the traineeship.
- Medical Student Trainee: Provide a Statement of Eligibility form signed by the Dean or equivalent that verifies 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 for the 1-year period of performance of the traineeship.
- 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 (if applicable): Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP’s expectations for making data and research resources publically available.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”  
Technical abstracts should be written using the outline below.
  - Background: Present the ideas and reasoning behind the proposed work.
  - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design including appropriate controls.
  - Impact: Briefly describe how the proposed project will have an impact on improving the function, quality of life, and life span for all individuals diagnosed with DMD.
- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”  
Public abstracts should be written using the outline below.
  - Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed work.
    - Do not duplicate the technical abstract.
  - 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?
    - What is the projected time it may take to achieve a patient-related outcome?

- What are the likely contributions of this study to advancing the field of DMD research or patient care?
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information.
- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.”  
 Explain in detail why the proposed research project is important.  
*Describe the short-term impact:* Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research.  
*Describe the long-term impact:* Explain the anticipated long-term gains from the proposed research, including how the new understanding may ultimately contribute to the goal of improving the function, quality of life, and life span for all individuals diagnosed with DMD.
- **Attachment 7: Transition Plan (if applicable), (one-page limit):** Upload as “Transition.pdf.”  
 Provide information on the methods and strategies proposed to move the outcome(s) to clinical trial and/or delivery to market upon successful completion of the award, including, if applicable, information regarding transfer to a commercial partner(s) for further clinical development, manufacturing development, and regulatory management. 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 trial and/or regulatory approval and commercialization (e.g., specific potential industry partners, specific funding opportunities to be applied for, etc.).
  - A description of collaborations and other resources that will be used to provide continuity of development.
  - A brief schedule and milestones for bringing the outcome(s) to clinical trial and/or regulatory approval and commercialization.
  - A risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 8: Statement of Collaboration (required if requesting an Optional Qualified Collaborator, two-page limit).** Upload as “Collaboration.pdf.” The following components should be addressed:
  - The PI must identify the Optional Qualified Collaborator and address all criteria described above in Section I.B, Award Information.
  - In addition, the Optional Qualified Collaborator must describe how he/she will significantly contribute to the project such that the proposed work could not be accomplished without his/her involvement.
  - It should be clear that the success of the project depends on the unique skills and contributions of each partner.

- **Attachment 9: Statement of Traineeship (required if requesting an Optional Nested Resident and Medical Student Traineeship; two-page limit).** Upload as “Traineeship.pdf.”

Clearly describe the DMD research training program for the trainee, incorporating consideration of the candidate's goals and prior experience. This should include a plan to obtain any necessary 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 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 research support related to the candidate's research plan, and nature of the supervision that will occur during the proposed award period. The sponsoring institution must demonstrate a research and training program related to the candidate's area of interest, including a high-quality research environment with staff capable of productive collaboration with the trainee.

3. **Research & Related Senior/Key Person Profile (Expanded) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
  - PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
  - PI Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - Key Personnel Biographical sketches (four-page limit each): Upload as “Biosketch\_LastName.pdf.”
    - Include biosketch for optional collaborator (if applicable).
    - Include biosketch(-es) for resident and medical student trainee applicants (if applicable).
  - Key Personnel Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
  - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

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

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

## **E. Other Submission Requirements**

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

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

## **III. APPLICATION REVIEW INFORMATION**

### **A. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on scientific merit, the overall goals of the program, and specific intent of the award mechanism. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

### **B. Application Review Criteria**

- 1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

- **Research Strategy and Feasibility**
  - How well the preliminary data and rationale support the research project.
  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
  - How well the PI identifies potential problems and addresses alternative approaches.
  - If the application includes an Optional Qualified Collaborator, how well the nature and extent of the collaboration supports the research project.
  - Whether the proposed research can be completed in the proposed period of performance.
- **Impact**
  - How the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) of the proposed research project will impact the research field, patient care, and/or quality of life.
  - Whether the proposed research project, if successful, will develop an outcome that is important and relevant to improving function, quality of life, and/or life span of individuals diagnosed with DMD.
- **Transition Plan (if applicable)**
  - Whether the funding strategy described to bring the outcome(s) to clinical trials 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 outcome(s) to clinical trial and/or delivery to market are appropriate.
  - How well the potential risk analysis for cost, schedule, manufacturability, and sustainability is developed.
- **Personnel**
  - How well the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed work.
  - The appropriateness of the levels of effort by the PI and other key personnel to ensure success of the project.
  - Optional Qualified Collaborator (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 Optional Qualified Collaborator as verified by the Statement of Collaboration (i.e., the

collaborator is at or above the level of Assistant Professor [or equivalent]; the collaborator is contributing at least 10% level of effort).

- Optional Nested Resident and Medical Student (if applicable):
  - Whether the resident and/or medical student is an appropriate candidate for this traineeship, and whether he/she is able to participate at a minimum of 40% level of effort over the 1-year period of performance.
  - Whether the PI and other scientific personnel are well qualified to conduct training for the trainee, and whether there is a senior staff member who is identified and 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 DMD being studied.

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

- **Environment**
  - How the scientific environment is appropriate for the proposed research.
  - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - How the quality and extent of institutional support are appropriate for the proposed research.
  - If multi-organizational, the quality and completeness of the Intellectual and Material Property Plan.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of the Program Announcement/Funding Opportunity.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influenced the review.

**2. Programmatic Review:** To determine the application's relevance to the mission of the DOD and CDMRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Programmatic relevance
- Ratings and evaluations of the peer reviewers
- Relative impact on DMD

### **C. Recipient Qualification**

Refer to the General Application Instructions, Appendix 1, for additional information on organization and government agency requirements.

### **D. Application Review Dates**

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

### **E. Notification of Application Review Results**

Each PI and organization will receive notification of the funding recommendation. PIs will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

## **IV. ADMINISTRATIVE ACTIONS**

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

### **A. Rejection**

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

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

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.

### **B. Modification**

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

## **C. Withdrawal**

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

- FY11 DMDRP Integration Panel (IP) member is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY11 DMDRP IP members may be found at <http://cdmrp.army.mil/newprogs11/dmdrp/panels/panels11.shtml>
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- The proposed research is, or request funding for a clinical trial.
- The PI does not meet the eligibility criteria.

## **D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

## **V. AWARD ADMINISTRATION INFORMATION**

### **A. Award Notice**

Awards will be made no later than September 30, 2012. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

### **B. Administrative and National Policy Requirements**

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

### **C. Reporting**

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

## **D. Award Transfers**

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

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements and questions related to the submission of the pre-application through the CDMRP eReceipt system 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 inquires.

Phone: 1-301-682-5507

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

### **B. Grants.gov Contact Center**

Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, 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: 1-800-518-4726

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

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

## VII. APPLICATION SUBMISSION CHECKLIST

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Completed</b>
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Transition Plan (Transition.pdf) as Attachment 7 (if applicable).	
	Upload Statement of Collaboration (Collaboration.pdf) as Attachment 8 (if applicable).	
	Upload Statement of Traineeship (Traineeship.pdf) as Attachment 9 (if applicable).	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Bioskeetch_LastName.pdf) to the appropriate field.	
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Bioskeetch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete form as instructed. Attachment Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form	Complete form as instructed.	