

Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Duchenne Muscular Dystrophy Research Program

Investigator-Initiated Research Award

Funding Opportunity Number: W81XWH-13-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), July 31, 2013
- **Invitation to Submit an Application:** September 2013
- **Application Submission Deadline:** 11:59 p.m. ET, November 6, 2013
- **Peer Review:** January 2014
- **Programmatic Review:** February 2014

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

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) Duchenne Muscular Dystrophy Research Program (DMDRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The DMDRP was initiated in 2011 to provide support for research of exceptional scientific merit and to promote the understanding, diagnosis, and treatment of DMD. Appropriations for the DMDRP from FY11 through FY12 totaled \$7.2 million (M). The FY13 appropriation is \$3.2M.

The vision of the FY13 DMDRP is to extend and improve the function, quality of life, and lifespan for all individuals diagnosed with DMD. As such, the DMDRP is seeking to better inform the development of drugs, devices, and other interventions and promote their effective clinical testing.

B. FY13 DMDRP Focus Areas

All applications for the FY13 DMDRP funding opportunities *must* address at least one of the following focus areas:

- Extension or expansion of preclinical translational data in support of the therapeutic development path (including independent replication and comparative studies)
- Developing clinical biomarkers to improve evaluation of diagnosis, disease severity, disease progression, and/or response to treatment
- Assessment of clinical trial outcomes (invasive and non-invasive), such as:
 - Molecular, functional, imaging, etc.
 - Evaluating surrogate markers
 - Evaluating potential composite scores for outcomes assessment
 - Patient outcomes, e.g., quality of life, activities of daily living, etc.
- Novel interventions that could improve clinical care and quality of life in the near term

C. Award Information

The DMDRP Investigator-Initiated Research Award (IIRA) mechanism was first offered in FY11. Since then, 40 IIRA applications have been received, and 7 have been recommended for funding.

The DMDRP IIRA supports 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 with the specific goal of developing new therapies. While the ultimate goal of translational research is to move an observation forward into clinical application, translational research is most effective as a two-way continuum between the bench and the bedside. Within this continuum, the IIRA supports mid-stage or later translational research projects, including early-phase, proof-of-principle clinical trials and

correlative studies to better inform the development of drugs, devices, and other DMD interventions. Research projects may also include preclinical studies in animal models, human subjects, and human anatomical substances.

All projects should adhere to a core set of reporting standards for rigorous study design. The standards are described fully in www.nature.com/nature/journal/v490/n7419/full/nature11556 While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies and should be applied to those projects as well.

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

- Target discovery
- Drug screening
- Mechanism of action studies
- Hypothesis-driven pathophysiology studies

Applications must include preliminary data that are relevant to DMD and the proposed project. Clinical trials are supported by this award mechanism.

Optional Qualified Collaborator: The FY13 DMDRP strongly supports collaborative research between laboratory 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.E., Funding, below. The Principal Investigator (PI) must submit a Statement of Collaboration that clearly identifies the proposed collaborator, describes the collaboration, and addresses how each of the criteria below are met. In addition, the collaborator must provide a letter of collaboration describing his/her involvement in the proposed work. It should be clear from both documents that the success of the project depends on the unique skills and contributions of both the PI and the qualified collaborator.

- The collaborator must significantly contribute to the project such that the proposed work could not be accomplished without his/her involvement. This is expected to include both intellectual input and research resources.
 - 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. Contributions 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 or Medical Student Traineeship: A Nested Resident or Medical Student Traineeship is being offered as an optional part of the IIRA. The intent of the Nested Resident or Medical Student Traineeship is to provide mentored research opportunities in DMD. It is expected that the training will provide a valuable opportunity to develop the experience necessary to advance the trainee's research career in DMD.

Funding for a Nested Resident or Medical Student Traineeship can be requested for an additional maximum of \$75,000 for a resident or \$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 may be requested per application. Plans for training and mentorship must be well developed and clearly described by the PI for the IIRA.***

The DMDRP reserves the right to fund a submission for an IIRA that includes a Nested Resident or Medical Student Traineeship but ***not fund*** the traineeship.

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 U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is NOT required. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DoD. These laws and directives will require information in addition to that supplied to the IRB. Allow a minimum of 2-3 months for HRPO regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

D. Eligibility Information

- The PI must be ***at or above*** the level of Assistant Professor (or equivalent)
- An Optional Qualified Collaborator must be ***at or above*** the level of Assistant Professor (or equivalent).
- Optional Nested Resident or Medical Student Traineeship: By the time of the application submission deadline, the resident trainee must be enrolled in an accredited residency program, or the medical student trainee must be enrolled in a nationally accredited (or equivalent) medical school. The trainee must be able to devote a minimum of 40% level of effort to this project for the 1-year period of performance of the traineeship.
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.

- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **\$525,000** plus indirect costs. If requesting an Optional Qualified Collaborator, the maximum allowable direct costs for the entire period of performance are **\$675,000** plus indirect costs.
- Additional funds may be requested for an optional traineeship:
 - 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 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 Traineeship will have their budgets reduced as appropriate.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

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

- Salary
- Research supplies
- Equipment
- Clinical research costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

The CDMRP expects to allot approximately \$2.02M of the \$3.2M FY13 DMDRP appropriation to fund approximately two 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 two-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 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.

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-13-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 pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the preapplication, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

A change in PI or organization after submission of the pre-application will be allowed only at the discretion of the USAMRAA Contracting/Grants Officer.

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**

FY13 DMDRP Integration Panel (IP) members (<http://cdmrp.army.mil/dmdrp/panels/panels13>) should not be involved in any pre-application or application. For questions related to IP members and preapplications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

- **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. 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 application.

Note: *At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.*

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 and describe what focus area(s) the project addresses.
- **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 lifespan 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 Qualified Collaborator is included, describe how the project depends on the unique skills and resources of the collaborator.

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 the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **Key Personnel Biographical Sketches (two-page limit per individual):** Include biographical sketches for the PI and other key collaborators.

- **Submit Pre-Application – Tab 5**

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

- **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 DHP and the DMDRP, pre-applications will be screened based on the following criteria:

- **Research Ideas:** How well the research demonstrates sound scientific rationale and to what extent the research project addresses at least one of the focus areas.

- **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 lifespan for all individuals diagnosed with DMD.
- **Personnel:** How the personnel’s background and expertise are appropriate to accomplish the proposed research. If an Optional Qualified Collaborator is included, how the collaborator’s background and expertise is necessary to accomplish the proposed project.
- **Notification of Pre-Application Screening Results**

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

C. Application Submission Content and Form

Applications will not be accepted unless the PI has received notification 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 through the Grants.gov portal (<http://www.grants.gov/>).

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

1. **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 (12-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will 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 DMD 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 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. Identify what focus area(s) the proposed project addresses.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate randomization, blinding, sample-size estimation, and controls, in sufficient detail for analysis. If applicable, describe how collaborations support the research. Address potential problem areas and present alternative methods and approaches. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.
- **Data and Statistical Analysis Plan:** Describe how data will be handled, collected, and analyzed in a manner that is consistent with the study objectives. If applicable, include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.***
 - **References Cited:** List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
 - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
 - **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
 - **Publications and/or Patent Abstracts (five-document limit):** Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must 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 Collaboration (if applicable, **required for Optional Qualified Collaborator**): 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.
- Letter of Eligibility (required if requesting Nested Resident or 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 to this project 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 to this project for the 1-year period of performance of the traineeship.
- Intellectual Property
 - Background and Proprietary Information (if applicable): All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project. Identify any proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the federal purpose license.
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
 The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects.
 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 and identify the focus area(s) the proposed project addresses.
- 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 lifespan for all individuals diagnosed with DMD.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”

Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.*** Minimize the use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

- 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 focus area(s) the proposed project addresses.
- Describe the ultimate applicability of the research.
 - What types of patients will it help, and how will it help them?
 - What are the potential clinical applications, benefits, and risks? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field.
 - What is the projected time it may take to achieve a patient-related outcome?
- What are the likely contributions of this study to advancing the field of DMD research or patient care?
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.
- **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 lifespan for all individuals diagnosed with DMD.

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

Provide information on the methods and strategies proposed to move the outcome(s) of this project to the next level of clinical research or use after

successful completion of the award. The transition plan may include the components listed below.

- Details of the funding strategy that will be used to bring the outcome(s) to clinical studies, clinical trials, and/or regulatory approval and commercialization (e.g., specific potential commercial partners, specific funding opportunities to be applied for, etc.).
- A description of collaborations and other resources that will be used to provide continuity of development.
- 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 (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.C., 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 or 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.

- **Attachment 10: 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.

- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information. *Note: Some of the items in this attachment may be made available for programmatic review.*
 - PI Biographical Sketch (four-page limit): Upload as “Biosketch_LastName.pdf.”
 - PI Previous/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 a biographical sketch for the Optional Qualified Collaborator (if applicable).
 - Include a biographical sketch for the Nested Resident or Medical Student Trainee applicant (if applicable).
 - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., 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 will 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. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the

Entity Management functional area of the System for Award Management (SAM) with an “Active” status 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 peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DHP and DMDRP and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review 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 non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization’s application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review 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, statistical plan and analyses are developed and integrated into the project. Whether the research project addresses at least one of the focus areas.
 - 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.

- ***For applications proposing clinical trials:***
 - How well the PI addresses the availability, accessibility, and interest of human subjects for the clinical trial, or how well the PI has justified the availability and accessibility of human samples for correlative studies.
 - How well the inclusion, exclusion, and randomization criteria meet the needs of the proposed clinical trial, and how well the level of risk to the human subjects is minimized.
 - Whether there is evidence that a plan to address potential ethical issues raised by the proposed study has been appropriately considered and developed (if applicable).
 - How well the recruitment processes for human subjects, or the collection processes for human samples, are designed to meet the needs of the proposed study.
 - Whether there is evidence of an adequate contingency plan to resolve potential delays (e.g., slow accrual, attrition).
- **Impact**
 - How 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 lifespan of individuals diagnosed with DMD.
- **Transition Plan**
 - Whether the funding strategy described to bring the outcome(s) to clinical studies, 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 studies, clinical trials and/or delivery to market are appropriate.
- **Personnel**
 - How well the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed work.
 - The degree of appropriateness of the levels of effort by the PI and other key personnel to ensure success of the project.
 - Optional 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 or Medical Student (if applicable):
 - Whether the resident or medical student is an appropriate candidate for this traineeship and whether he/she is able to participate at a minimum of 40% level of effort over the 1-year period of performance.
 - Whether the PI and other scientific personnel are well qualified to conduct training for the trainee and whether 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 this 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 make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

- a. **Ratings and evaluations of the peer reviewers**

- b. **Relevance to the mission of the DHP and FY13 DMDRP, as evidenced by the following:**

- Adherence to the intent of the award mechanism
- Program portfolio balance or composition
- Programmatic relevance
- Relative impact on DMD

C. Recipient Qualification

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

D. Application Review Dates

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

E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

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

The following will result in administrative rejection of the application:

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

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Preproposal Narrative and the Project 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:

- A FY13 DMDRP IP member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY13 DMDRP IP members can be found at <http://cdmrp.army.mil/dmdrp/panels/panels13>.
- 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 & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The PI does not meet the eligibility criteria.
- The application does not address at least one of the focus areas.

D. Withhold

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

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2014. 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 D, for general information regarding administrative and national policy requirements.

C. Reporting

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

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

D. Award Transfers

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

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

The institutional 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.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through 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 inquiries.

Phone: 301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

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

Phone: 800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the application package. 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

Grants.gov Application Components	Action	Completed
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 Lay Abstract (LayAbs.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.	
	Upload Statement of Collaboration (Collaboration.pdf) as Attachment 8 (if applicable).	
	Upload Statement of Traineeship (Traineeship.pdf) as Attachment 9 (if applicable).	
	Upload Human Subject Recruitment and Safety Procedures (HumSubProc.pdf) as Attachment 10 (if applicable)	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	