INSTRUCTIONS FOR COMPLETION OF THE CLINICAL RESEARCH NETWORK GRANT APPLICATION

1. **Introduction**
   In preparing your grant application, please read and follow these instructions **carefully. Incomplete** or **improperly** prepared applications **will not be reviewed.** An application will be considered incomplete if: (1) it is not prepared and submitted according to instructions; or (2) the information it contains is not sufficient to permit an adequate review.

   To facilitate proper review of your application please remain succinct and limit the sections of your application describing your "Background", "Clinic Resources" and "Proposed Activities" to a **maximum total** of twelve (12) pages**. Applications must be submitted using Arial 11pt font only.**

2. **Deadline for Receipt of Completed Application**
   The application must be **RECEIVED on or before** the deadline date given at the time of Invitation.

3. **Submission Guidelines**
   Application **MUST** be submitted in English.
   Request support in **U.S. dollars ($) only.**
   Avoid abbreviations except for those in common use such as DNA, ATP, CK, and so forth.
   Appendix material is limited to preprints and manuscripts **accepted** for press but not yet published.**. DO NOT ATTACH MANUSCRIPTS, ABSTRACTS, OR REPRINTS ALREADY PUBLISHED.**

4. **Applicant/Principal Investigator**
   The Principal Investigator is the one person responsible for the scientific and technical direction of the project. For Clinical Research Network Grants, the PI must be a member of the MDA clinic team at the institution. If the PI is **not** a named MDA clinic director, a letter of support from the MDA clinic director(s) is required. If C**o-investigators** are involved with the proposed network, a letter of support and a curriculum vitae for each **MUST** be attached to the application.

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CONFLICT OF INTEREST DISCLOSURE

Any potential conflict of interest the Principal Investigator(s) or collaborator(s) may have relating to the project must be revealed. Such conflict would include, but may not be limited to, having a proprietary interest that may be affected by the outcome of a research project. It is expected that MDA grantees will observe the highest ethical standards in the conduct of research. Please attach a one-page explanation if a conflict of interest exists.

5. **Project Title**
   Whenever possible, the title should include the name of the neuromuscular disease or class of

neuromuscular disease to which the research network is most related. (MDA reserves the right to edit grant titles for clarity.)

6. **Institution & Contacts**
   Please be certain that the information on this page is complete.

NOTE: CHECKS MAY NOT BE MADE PAYABLE TO INDIVIDUALS

7. **Organization Assurances**
   If your application requests support for research involving human subjects, tissues or materials, experimental drugs or devices, this section **MUST** be completed. Instructions are self-explanatory. If your IRB or FDA approvals are pending, please indicate this in the space provided. A copy of the IRB/FDA approval **MUST** be attached to your application upon approval. MDA requires a copy of a current approval on file at all times.

   MDA-funded projects **MUST** be in compliance with all policies, rules, and regulations governing clinical trials, including those of the federal regulatory agencies, the respective university and institution, and MDA. MDA must be advised about any amendments to the original research protocol (including the patient consent form) occurring prior to the commencement of or during the course of the research project.

8. **Brief Lay Summary**
   Please provide a summary of your proposed research in layman's terms.

9. **Abstract Page**
   Please submit a succinct and non-technical description of your proposal. **DO NOT summarize past accomplishments or cite literature in this section.**

10. **Budget**
    Clinical Research Network Grant funds are intended to cover **infrastructure costs**, including full or partial salaries for personnel, such as clinical coordinators and/or clinical evaluators. Partial support for a PI's salary is permissible (see below). Funds may also be budgeted for other infrastructure necessary to support network activities. (**N.B.** Funding for individual research projects conducted through the MDA Clinical Research Network is expected to come from other sources, such as MDA research grants, grants from other agencies or support from pharmaceutical companies.)

    Personnel must be listed by name, title, and percentage effort devoted to project. Each site Principal Investigator's salary is permitted, equivalent to the ratio of effort up to $10,000 including fringe benefits. Requested salaries are **NOT** to be used to replace salaries or partial salaries that are already assured by institutional or other funds. The Principle Investigator's specific role(s) in the proposed research must be described under "Proposed Budget Justification."

    The "Institutional Base Salary" should be the Principle Investigator's **total** base salary and "Fringe Benefits" listed should be the proportionate percentage of the Principle Investigator's benefit cost.

Equipment, whether capital or not, must be listed in this section. Along with a full justification, identify the manufacturer and model number under budget justification section. Computer equipment is limited to $5,000 per grant.

Supplies must be listed by sub-category: glassware, chemicals, radioisotopes, animals, and so forth. If animals are to be used in your research, state how many are to be used, their unit purchase price and their unit care cost.

Travel expenses for network outreach and training is permitted. Also, funds for travel required in conducting the specific aims of the research project may be requested. All travel must be fully justified in the proposed budget justification and is restricted to personnel listed in the network proposed budget.

Other expenses may include items such as publication costs, computer charges, equipment maintenance and office supplies. Office supplies may **NOT** exceed **$600 per site** in any given year. The need for each item must be justified in the budget justification section.

Subcontract budgets for each sub site are required. Each site is bound by the above restrictions and budgetary maximums.

Indirect costs *are* ***only*** *permitted for the Principal Investigator's institution at a maximum of 10% of the direct costs ($6,000).*

Unauthorized Expenses - The following expenses are not permitted under MDA's research program:

- Salary or fringe benefits for collaborating investigators, or co-investigators.
- Salaries, travel and/or housing related to sabbatical leaves.
- Purchase or rental of office equipment, for example, typewriters, word processors, furniture, filing cabinets and copy machines.
- Expenses normally covered by the indirect costs of the Principal Investigator's institution including General Liability Insurance, General Auto Insurance and other insurance costs.
- Fees for tuition or other academic fees.
- Membership dues, subscriptions, books or journals.
- Expenses for or related to moving from one institution to another.
- Indirect costs with the exception of the Principal Investigator's institution.

11. Other Support

ALL sources of current and pending research support - including other MDA projects - must be identified in this section.

12. Network Plan

THE NETWORK PLAN SHOULD NOT EXCEED 12 PAGES

Regional clinical research centers, geographically distributed throughout the United States, will form the core of the MDA Clinical Research Network. These centers will be expected to collaborate on projects such as patient registries, establishment of standards of care, development of common data elements for use in natural history studies and clinical trials, and

performance of natural history studies and clinical trials. The goals of the MDA Clinical Research Network are:

Integration with global clinical research efforts in neuromuscular diseases:
The activities of the network are intended to complement those of existing and developing networks. When testing new therapies, it is important to ensure compatibility with other clinical research networks and to be able to compare data between clinical trials. Therefore, a core set of common data elements for disease registries, natural history studies and clinical trials is necessary for comparison of data between clinical studies and trials. Collaborative activities with existing and developing networks, worldwide, are encouraged. Data captured through the MDA Clinical Research Network will be compatible with that obtained by other national and international networks, such as TREAT NMD.

Background, Clinic Resources and Proposed Activities

Background:
In this section of the Network plan, please provide background information regarding the PI and MDA clinic's experience in medical management and clinical research of DMD, ALS, or DM. Indicate, clearly, whether the center seeks designation as a MDA DMD Clinical Research Center, as a MDA ALS Clinical Research Center or as a MDA DM Clinical Research Center. This section should clearly provide the reader with information about past experience in conducting clinical studies and trials, evidence for leadership within the DMD, ALS or DM community, and willingness to share information and act as part of a larger team. Be sure to include a list of studies or trials that the clinic has participated in over the past five years, particularly those related to DMD, ALS or DM.

Clinic Resources:
Please provide detailed information about institutional and clinic resources available for network activities. Such information should include, but not be limited to:

- Patient availability, at your MDA clinic site as well as regionally (it is expected that clinic sites should see, or have access to through regional collaboration, a minimum of 100 individuals with DMD, ALS or DM).
- Personnel available to participate in network activities.
- Physical facilities available for clinical research activities.
- Database and statistical support.
- Access to outside advice or collaboration.
- Personnel with experience in regulatory compliance.
- Institutional support.

Proposed Activities:
In this section please provide detailed information about a proposed research project to conduct through the network. Indicate the advantages of conducting this project through the network, as well as how this research will benefit the DMD, ALS or DM community.

Also provide a detailed plan to engage regional MDA clinics in collaborative activities, and how these activities will achieve the goals of the network. (Letters of support from or naming of regional clinics is **not** required as part of this application.) If applicable, include information about proposed collaborative activities with other networks, nationally or internationally.

13. Facilities to Conduct Research

List all facilities available for conducting the proposed project for each site. Include laboratory space, clinical facilities, computer facilities, office space, clerical staff, and major equipment available. Identify by name and address any facilities that are not part of the sponsoring institution and describe the arrangements made for using those off-site facilities.

14. References for Literature Cited

Make every attempt to be judicious in compiling a relevant reference list. It need not be exhaustive.

15. Personnel Curriculum Vitae

Attach a curriculum vitae or biosketch for the Principal Investigator. You will also need to attach a curriculum vitae/biosketch for each co-investigator, collaborator and/or other personnel who will be responsible for the execution of this project.

Each curriculum vita should clearly identify all papers in all fields published during the past five (5) years. Please list all grants held within the past five years, specifying funding source. Please identify films, tape recordings and monographs on which you may have collaborated.

IMPORTANT NOTE

One copy of your completed application should be filed with the business office of the sponsoring institution to alert them to your pending request for MDA support.