Myotonic Dystrophy FOUNDATION

MDF Policy for Sharing Research Opportunities with the Myotonic Dystrophy (DM) Community

Purpose

To protect the welfare, privacy, and autonomy of individuals and families affected by myotonic dystrophy (DM), the Myotonic Dystrophy Foundation (MDF) has adopted the following policy governing the review and distribution of research opportunities, including but not limited to surveys, focus groups, clinical studies, and other data collection efforts.

Policy Overview

The MDF will share research opportunities with the DM community only when the following ethical, legal, and privacy standards are met:

1. Ethical Review and Oversight

All research opportunities, including market research, must undergo formal ethical review for any human subject research, including research related to subjects, tissues, materials, and/or animal testing. The Primary Investigator (PI) is required to provide documentation of compliance with all policies, rules, and regulations governing human subjects research and/or clinical trials including those of applicable federal or country regulatory agencies, the respective institution, and the MDF. Permitted documentation includes:

- A complete copy of the **research protocol approved** by the recipient organization's Human Subjects or Institutional Review Board (IRB), or national equivalent, and a copy of that Board's current approval notice, or
- An IRB-issued **waiver,**
- Or in the case of animal testing, IACUC (Institutional Animal Care and Use Committee) documentation, including Animal Use Protocols.

The MDF reserves the right to verify all protocols, IRB status, and documentation. Research opportunities lacking appropriate IRB and ethical oversight or waiver will not be shared under any circumstances.

Market research, brand or preference testing, or any research not subject to IRB review or oversight will **not** be considered for dissemination through MDF channels without IRB approval **or waiver**. We encourage IRB approval/waiver for ALL research related to the study of people living with or caring for people with myotonic dystrophy.

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2. **Informed Consent and Participant Protection**

Projects must include a **clear and appropriate informed consent process** that meets current ethical and regulatory standards. The MDF requires a **copy of the patient informed consent form(s) to be used.**

Participant privacy and data use practices must be disclosed as part of the consent process, including:

- What information will be collected
- How it will be used, stored, and shared
- Any potential risks or benefits of participation

The PI is responsible for having and keeping in place systems to deal with the prevention of fraud, administrative malfunction, and/or data protection.

The PI will ensure no study participants in relation to the research project are charged and that such participants will be made aware of their responsibility for any applicable ancillary costs such as travel, lodging, and food.

3. **Protection of Personal Health Information (PHI)**

Any research collecting PHI must comply with the **US Health Insurance Portability and Accountability Act (HIPAA)** standards, or relevant **national equivalent** in the country where the study is conducted, for privacy and security.

Researchers must detail how PHI will be securely stored, who will have access, and how data will be de-identified if applicable.

The MDF may request documentation outlining these protocols before agreeing to disseminate the opportunity.

4. **Transparency and Accountability**

If a research project claims affiliation or collaboration with a government agency or public health authority (e.g., CDC, NIH), **documentation verifying this relationship** must be submitted, such as a Letter of Support.

The MDF requires a clear statement of how data will be shared with that agency, including timelines and intended use.

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All funding sources, sponsors, or clients commissioning the research must be disclosed to MDF. If a third-party organization or company is conducting the research on behalf of another entity, the MDF must be informed of the identify and role of that partner or client, including who will "own" any collected data, and who is funding or requesting the research.

The MDF will not distribute research opportunities if project sponsors or investigators provide misleading or unverifiable information about their affiliations, funding, or oversight process.

5. **Restrictions on Outreach**

Under no circumstances should researchers contact MDF Support Group Facilitators, Peer leaders, or members directly without MDF authorization.

6. **Reconsideration Upon Compliance**

The MDF may reconsider sharing a research opportunity once all above requirements are met and verified.

Researchers are welcome to resubmit with appropriate documentation (e.g., IRB approval/waiver, HIPAA-Compliant protocols, confirmed agency affiliations).

Our Commitment

The MDF is committed to protecting our community's safety, dignity, and trust whenever possible. Any research opportunity shared through our channels must demonstrate the highest ethical standards and regulatory compliance. MDF reserves the right to deny or withdraw support for any project that does not align with this policy.

For questions or to submit a request for sharing research opportunities, please contact: research@myotonic.org and include "Research Outreach Request" in the subject line.

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