

# National Registry of Myotonic Dystrophy and Facioscapulohumeral Muscular Dystrophy Patients and Family Members



## National Registry for Myotonic Dystrophy and Facioscapulohumeral Muscular Dystrophy Patients and Family Members

### Consent Form – Affected Adult

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Study Coordinator: James Hilbert, MS  
Study Coordinator: Elizabeth Luebbe

### INTRODUCTION

You are being asked to participate in a National Registry for research in myotonic dystrophy (DM) and facioscapulohumeral muscular dystrophy (FSHD) and related diseases (whose symptoms are identical to those of DM or FSHD) because you are affected with either myotonic dystrophy or FSHD. The Registry has been established at the University of Rochester with the support of The National Institutes of Health (NIH). Please read this consent form carefully and ask any questions you may have before making a decision whether or not to participate. This form contains important information that might be helpful in the future.

### PURPOSE

The purpose of the Registry is to:

- Encourage more research on these diseases.
- Facilitate research by collecting names of individuals who are either affected or related to affected individuals.
- Use the information provided by participants to understand how these diseases can affect people.
- Establish contact between researchers and Registry participants.

### IMPORTANT FACTS ABOUT THE REGISTRY

- Participation is totally voluntary.
- You may ask that your name be removed at any time.
- No personally identifiable information about you will be given to anyone.
- No one, including your own family members, can find out if you are listed in the Registry.

- No information will be given to insurance companies.
- You will remain under the care of your primary physician.
- Some research projects will only need general information about your condition. Other research projects may involve collection of blood or tissue samples, tests of your muscles or testing new treatments. Each research project will require additional consent before tests or interviews.

## DESCRIPTION OF THE REGISTRY

- The forms you have received will take about 20 minutes to read and complete. The following information will be requested:
  1. A consent form for you to read and sign prior to participation.
  2. Your name, address and phone number.
  3. Information about your muscle strength, general health, and how your disease has affected your daily life.
  4. A Request for Medical Information form for you to complete and return to us. Please provide the complete name, address, and phone number of your doctors on this form. This form gives us permission to contact your doctors requesting information about your disease and how it was diagnosed. This form permits your physician to send test results such as: the results of muscle biopsy, genetic testing, heart tracing, electromyography (recording of electrical activity in your muscles), as well as records that pertain to your muscular dystrophy. You will not be able to participate in the Registry if your medical records are not sent to the Registry.
- You will be asked to mail all completed forms to us in the enclosed pre-addressed postage paid envelope.
- Once you are entered into the Registry we will review your forms and may call you to make sure that information is correct.
- Once you are entered into the Registry, we may contact you by mail about opportunities to participate in research studies. We will send you information about researchers, their phone numbers, and about the projects for which you may be eligible.
- If you are interested, you can contact the researcher for more information about the study. Only then will the researcher contact you directly. **The Registry will not provide your name or medical records to the investigator.** All research projects will have been reviewed and approved by the researcher's human subjects institutional review board and the Scientific Advisory Committee of this Registry.

- Once a year, Registry Staff will contact you to update your address, phone number, and information about your health and problems caused by your muscle disease. The staff will also ask you about any studies in which you have participated. Investigators will be requested to provide any new results about your diagnosis to the Registry to expand the information in the Registry. It should take about 15 minutes to review the “annual update” information and to make any necessary changes.

This mailing is confidential. If the post office is unable to deliver the letter to the address we have on file, the letter will be returned to the National Registry. We are unable to forward the letter to a new address. Therefore, we ask that you contact us if you move so that we are able to update your address.

- Participation of family members is strongly encouraged. However, while family relationships may be recorded in the Registry, none of their names or identifying information will be collected. No information about you will be shared with members of your family. Each family member is encouraged to enter the Registry and to complete the forms themselves.

### **BENEFITS OF PARTICIPATION**

Joining the Registry may give you the opportunity to participate in research studies. You will receive a newsletter at least once a year about Registry activities and research advances in myotonic dystrophy, FSHD, and related diseases.

### **RISKS OF PARTICIPATION**

The only risk of participation is the possible loss of confidentiality due to unauthorized release of medical information.

### **CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION**

While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use related information from your medical records, results of laboratory tests, and both clinical and

research observations made while you take part in the research.

We will use your health information to conduct the study, to determine research results, and possibly to develop new tests, procedures, and commercial products. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; The National Institutes of Health.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others. For example, by Federal law, we must send study information to the FDA for drug and device studies it regulates. Information that may need to be reported to FDA cannot be removed from your research records.

As stated in the section on Voluntary Participation in the Consent Form, you can also refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above.

The information for this Registry is collected under the authority of Sections 435-442 of the PHS Act (285d-285d-7 of Title 42, USC). The data will be maintained in accordance with the Privacy Act 42 United States Code 241.

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## **CONTACT PERSONS**

For more information about this research study please contact:

James Hilbert, MS  
University of Rochester, Department of Neurology  
601 Elmwood Ave, Box 673  
Rochester, NY 14642

Telephone: (888) 925-4302 or (585) 506-0004.

If you have any questions about your rights as a research subject, you may contact:

Human Subjects Protection Specialist  
University of Rochester Research Subjects Review Board  
601 Elmwood Avenue, Box 315  
Rochester, NY 14642-8315

Telephone: (585) 276-0005 or Toll Free: (877) 449-4441

**VOLUNTARY PARTICIPATION**

Participation in this study is voluntary. You are free not to participate or to withdraw at anytime, for whatever reason, without risking loss of present or future care you would otherwise receive. In the event you decide to withdraw from the Registry, all information you have provided will be destroyed.

**SIGNATURE/DATES**

I have received two identical copies of this consent form (one to keep and one to return) and have read the contents. If I had any questions, I have called one of the Study Coordinators listed below and have received the answers to my questions. I agree to participate in this study. **After signing one copy** of this consent form, I will **mail the entire form** to:

Health Project Coordinator  
National Registry of DM and FSHD  
University of Rochester, Department of Neurology  
601 Elmwood Ave, Box 673  
Rochester, NY 14642

**REGISTRY PARTICIPANT PRINTED NAME:** \_\_\_\_\_

**REGISTRY PARTICIPANT SIGNATURE:** \_\_\_\_\_

**DATE:** \_\_\_\_\_

GUARDIAN (Person legally responsible for applicant, if applicable) - Guardian must sign when applicant is mentally incapable of understanding the consent form.

**GUARDIAN'S PRINTED NAME:** \_\_\_\_\_

**GUARDIAN'S SIGNATURE:** \_\_\_\_\_

**DATE:** \_\_\_\_\_

**For Registry Staff Use Only:**

**REGISTRY COORDINATOR PRINTED NAME:** \_\_\_\_\_

**REGISTRY COORDINATOR'S SIGNATURE:** \_\_\_\_\_

**DATE:** \_\_\_\_\_

