INFORMED CONSENT DOCUMENT

Research Sample

Project Title: **Muscle Tissue and Cell Repository**

Principal Investigator: **Steven Moore, M.D., Ph.D.**

Research Team Contacts: **Steven Moore, M.D., Ph.D. (319) 384-9084**
Carrie Stephan, R.N., M.A. (319) 356-2673

- If you are the parent/guardian of a child under 18 years old who is being invited to be in this study, the word "you" in this document refers to your child. You will be asked to read and sign this document to give permission for your child to participate.
- If you are an adult or a teenager reading this document because you are being invited to be in this study, the word "you" in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not sign this form unless the study research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you have a neuromuscular disease or because you are an unaffected blood relative (parent, sibling, grandparent, aunt, uncle, or cousin) of someone with a neuromuscular disease. You may also be invited to participate if you are undergoing an elective or orthopedic surgical procedure. This is so we can compare tissue of affected vs. non-affected persons.

The purpose of this research study is to gather and store a large number of tissue samples (for example pieces of muscle), blood and urine samples that can be used now and in the future to study diseases of muscle. This is called a Muscle Tissue and Cell Repository. Other researchers may apply to the repository to obtain tissue and/or blood and/or urine samples for use in their research studies.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 1800 people will take part in this study at the University of Iowa. Nationwide, approximately 100 additional people per year will participate. This is an ongoing study with no determined end date.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will consist of a one-time visit for muscle biopsies and/or skin biopsies and/or buccal swabs. A muscle biopsy takes approximately one hour. A skin biopsy or buccal swab would take approximately 10-15 minutes

If you are taking part in the study to provide blood and/or urine samples, your involvement today will take approximately 10-15 minutes. You may be asked to provide blood and/or urine samples every year, for example if you are participating in biomarker sample collection.

WHAT WILL HAPPEN DURING THIS STUDY?

You will come to the clinic to provide a biologic sample. The sample may be muscle tissue, skin, blood, urine and/or buccal swab. If you provide muscle or skin tissue, we will use local anesthetic before taking the sample. For blood samples, we will draw 3-4 tablespoons of blood. For a buccal swab, the inside of the cheek is scraped with a swab to obtain cells from the mouth. Urine samples are collected in a sterile cup. All of these methods are routinely used for obtaining tissue samples. If a skin biopsy is obtained, it may be used to start a fibroblast cell culture.

Or you may be undergoing an elective surgical procedure unrelated to this study. During this elective procedure, your surgeon will obtain a muscle or skin sample for research purposes. If a skin biopsy is obtained, it may be used to start a fibroblast cell culture.

We may also collect information from your medical record to be placed in our database. Examples of the types of things we may collect include your age, gender, address, clinical diagnosis, pathology reports and results of genetic testing. On an annual basis, we may review your medical record to obtain the latest diagnostic information. We may ask you about the health of your family members. For example, we may ask the ages of your siblings, parents, and grandparents, and whether any of them have neuromuscular conditions.

Tissue Storage for Future Use

As part of this study, we are obtaining blood and/or urine and/or skin and/or muscle tissue from you. We would like to study your blood and/or urine and/or skin and/or muscle tissue in the future, after this study is over. The tests we might want to use to study your blood and/or urine and/or skin and/or muscle tissue may not even exist at this time. Therefore, we will store your blood and/or urine and/or skin and/or muscle tissue so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding neuromuscular diseases, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your blood and/or urine and/or skin and/or muscle tissue might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your blood and/or urine and/or skin and/or muscle tissue but decide in the future that you would like to have it removed from future research, you should contact Steve Moore, M.D. at (319) 384-9084. However, if some research with your blood and/or urine and/or skin and/or muscle tissue has already been completed, the information from that research may still be used.

Genetic Research

One purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for the body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a sample of blood and/or skin and/or muscle or heart tissue for genetic research. What we learn about you from this sample will not be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.

A new federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more persons to discriminate against you based on your genetic information. Based on this new law, health insurance companies and group health plans are prohibited from requesting your genetic information that we get from this research. This means that they may not use your genetic information when making decisions regarding your eligibility for insurance coverage or the amount of your insurance premiums. Be aware that this new federal law will not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. The law also does not prohibit discrimination if you already have a manifest genetic disease or disorder.

Your sample, information, and/or data may be stripped of identifiers (such as name, date of birth, address, etc) and placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. Other qualified researchers who obtain proper permission may gain access to your sample and/or data for use in approved research studies that may or may not be related to in the purpose of this study.

We will keep your name and contact information on file so that we can contact you about future studies on neuromuscular disease. Participation in this study does not obligate you to participate in any future studies. You would be asked to review and sign a separate Consent Document for any future studies.

WHAT ARE THE RISKS OF THIS STUDY?

There may be some risks from being in this study as outlined below.

Potential risks from the muscle or skin biopsy include infection, bleeding, pain or scarring at the biopsy site. Risks from the blood draw include bruising, pain, swelling or infection at the site of the needle puncture, lightheadedness, or fainting. Risks from the buccal swab include irritation on the inside of the cheek.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a computer with a password. Only **Steven A. Moore, M.D., Ph.D.** will have access to your name.

Are there any Unforeseen Risks?

In addition to the risks described above, there may be unknown risks, or risks that we did not anticipate, associated with being in this study.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study as researchers learn more about muscle diseases.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study. The costs of obtaining a research sample will be borne by your treating physician and/or the Muscle Tissue and Cell Repository. You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that the University of Iowa is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- No compensation for treatment of research-related illness or injury is available from the University of Iowa unless it is proven to be the direct result of negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, federal government regulatory agencies, the NIH, auditing departments of the University of Iowa, and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

To help protect your confidentiality, we will use coded names and identification numbers to identify study participants. All study material will be stored in a locked file in a locked office, and all access to study data is password protected. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The Informed Consent Document will not be placed in your medical record.

The University of Iowa Hospitals and Clinics generally requires that we document in your medical record chart that you are participating in this study. The information included in the chart will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, and the NIH.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Steven A. Moore, M.D., Ph.D. University of Iowa Department of Pathology, 200 Hawkins Drive, Iowa City, Iowa 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Steven A. Moore, M.D., Ph.D. via email at steven-moore@uiowa.edu or by phone at (319) 384-9084.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for Health Sciences, 600 Newton Road, The University of Iowa, Iowa City, Iowa, 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://research.uiowa.edu/hso.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 08/04/20.

_____ _____

(Signature of Subject) (Date)

Two Parents/Guardians Names and Relationship to Subject:

_____ _____
(Name - printed) (Relationship to Subject - printed)

Do not sign this form if today's date is on or after **EXPIRATION DATE: 08/04/20.**

_____ _____
Signature of Parent/Guardian (Date)

Parent/Guardian Name and Relationship to Subject:

_____ _____
(Name - printed) (Relationship to Subject - printed)

Do not sign this form if today's date is on or after **EXPIRATION DATE: 08/04/20.**

_____ _____
Signature of Parent/Guardian (Date)

Check the method by which consent is being obtained:

□ Consent is being obtained by mail without a discussion between a research team member and the subject. (Research team member does not sign this document)

□ Consent is being obtained in person or by mail after a discussion between a research team member and the subject. (Research team member signs below.)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)