

## Research Study Assent: Ages 7-12

IRB# NCR234775

**Principal Investigator:** Henry Kaminski, MD

**Study Title:** Genome Wide Association Study of Patients with Muscle-Specific Kinase Myasthenia Gravis

### **These are some things we want you to know about research studies:**

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things.

Whether or not to be in this research is your choice. You can say Yes or No. Whatever you decide is OK. Even if your parents say you can do it, the choice is still yours. Nobody will be upset if you say no.

### **Why am I being asked to be in this research study?**

You are being asked to be in the study because you have a disease called muscle specific kinase (MuSK) myasthenia gravis, a condition that affects your muscles and nerves.

### **What is the study about?**

We are trying to learn more about and identify differences in genes or genetic trait associated with patients. We plan to collect saliva samples from 1,000 subjects with MuSK myasthenia to do genetic testing in collaboration with the National Institutes of Health. The expectation for this study is a one-time saliva sample.

### **What will happen during this study?**

If you agree to be in this study, you will:

- need to contact the study team to learn more about the study.
- provide confirmation of your MuSK myasthenia gravis diagnosis (lab report)
- undergo assent process to sign assent form prior to sample collection provide saliva sample within 5 days of receipt of sample package in person or through mail to be returned back to George Washington University.

➤ **How to collect saliva:**

**Step 1:** Remove the collection funnel and tube from the pack. Next, close the collection funnel on to the tube lightly.

**Step 2:** Spit saliva into funnel until saliva liquid (not foam) reaches fill line.

**Step 3:** Untwist the collection funnel and replace with the tube cap tightly. Throw away the funnel.

**Step 4:** Shake tube a few times to mix the saliva with the solution.

## **Will the study hurt me?**

This study will not hurt you physically. However, some information can be lost. Research staff will make sure to keep your personal information private. The limited information (name, DOB, sex at birth, race, ethnicity) and clinical information (medical history and family history), will be collected by the George Washington University research team under supervision of Henry Kaminski, MD. This limited information will be stored in a primary research system at the Cincinnati Children's Hospital managed by the National Institutes of Health. The saliva sample without your private information from this study will be shared and stored forever at Dr. Traynor's lab at the NIH. Your sample will not be associated with you and you will not be named in presentations. There is also a law called Genetic Information Nondiscrimination Act to protect people against unfairness in health coverage or employment based on genetic information. You will be assigned an ID as part of the study and a code number called a Global Unique Identifier (GUID) using an NIH GUID system. The GUID is a unique code made up of letters and numbers that allows researchers to share data from other studies in which you have participated without letting others know who you are. A GUID does not contain personal information, and you cannot be identified using only the GUID. We will ask you for your name and full date of birth (day, month, year), city of birth, country of birth to create your GUID.

Also, to protect your privacy, we will not share your information to others. We have obtained a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers can use this Certificate to not give information about you.

## **What else should I know about the study?**

If you are afraid that something is wrong, tell an adult at once. You do not have to answer any questions that are asked of you.

### **What are the good things that might happen?**

People may have good things happen to them because they are in a research study. These are called “benefits. There is no benefit for providing one-time saliva sample but this will help to better learn what causes the disease and to treat it well.

### **Who should I ask if I have any questions?**

If you have any questions about this study, you or your parents can contact study team below.	Study Doctor	Study Coordinator
Name:	Henry Kaminski, MD	Helen Girma
Address:	2150 Pennsylvania Ave NW 7 <sup>th</sup> Floor Washington DC 20037	2150 Pennsylvania Ave NW 7 <sup>th</sup> Floor Washington DC 20037
Telephone number:	202-741-2710	202-677-6205
Email address:	<a href="mailto:hkaminski@mfa.gwu.edu">hkaminski@mfa.gwu.edu</a>	<a href="mailto:hgirma@mfa.gwu.edu">hgirma@mfa.gwu.edu</a>

### **Do I have to be in the study?**

No, you do not have to be in the study. Even if you say yes now, you can change your mind later. It is up to you. No one will be mad at you if you don't want to do this.

## **Signatures**

Before deciding if you want to be in the study, ask any questions you have. You can also ask questions during the time you are in the study.

If you sign your name below, it means that you agree to take part in this research study.

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Your Name (Printed)	Age
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Your Signature	Date
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Signature of Person Obtaining Consent	Date
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