Emory University Research Subject HIPAA Authorization to Use or Disclose Health Information that Identifies You for a Research Study

Title: Characterization of 3q29 Deletion Syndrome and 3q29 Duplication Syndrome

Principal Investigator: Jennifer Mulle, MHS, PhD, Assistant Professor, Department of Epidemiology, Rollins School of Public Health

If you are the legal guardian of a child who we are requesting medical records on, the term "you" used in this document refers to you and your child.

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA). We refer to all of these laws in this form as the Privacy Rules. This form explains how we will use your PHI for this study.

Please read this form carefully and if you agree with it, sign it at the end.

This authorization describes how we may use or disclose your PHI for the main research study. This authorization also describes how we may use or disclose your PHI for the optional studies in which you may choose to participate.

You do not have to sign this form. If you do not sign, you may not be able to participate in the main research study.

Description of Research Study

The purpose of this study is to understand the medical and behavioral consequences of 3q29 deletion syndrome and 3q29 duplication syndrome. In this study, we are looking for people who have been diagnosed with 3q39 deletion syndrome or 3q29 duplication syndrome. We will use a set of questionnaires to ask about the behaviors of individuals with 3q29 deletion syndrome or 3q29 duplication syndrome. We want to understand how these people grow and develop. We will also ask for a copy of your child's clinical genetics report, with details about how they were diagnosed with 3q29 deletion syndrome or 3q29 duplication syndrome. We will also survey a set of people without 3q29 deletion syndrome or 3q29 duplication syndrome, as a comparison group.

PHI That Will Be Used/Disclosed

We will ask for a copy of your child's clinical genetics report (the report you received from your doctor) when your child was diagnosed with 3q29 deletion syndrome or 3q29 duplication syndrome. You will be able to scan and upload the report directly to the study website, or you can make a copy and mail it to Emory. This report will give us information about how your child was initially diagnosed with 3q29 deletion syndrome

or 3q29 duplication syndrome. If you do not have your child's clinical report, then we will contact your child's medical provider to obtain a copy of the report.

Purposes for Which Your PHI Will Be Used
If you sign this form, you give us your permission to use your and your child's PHI for the conduct and oversight of this research study.

People That Will Use or Disclose Your PHI and Purpose of Use/Disclosure
Different people and groups will use and disclose your PHI for the research study in which you agree to participate. They will do this only in connection with the research study. The following persons or groups may use and/or disclose your PHI:

- The Principal Investigator and the research staff.
- The Principal Investigator may use other people and groups to help conduct the study. These people and groups will use your PHI to do this work.
- The following groups may also use and disclose your PHI. They will do this to make sure the research is done correctly and safely. The groups are:
    - Emory offices who are part of the Human Research Participant Protection Program and those that are involved in study-related administration and billing

We will use or disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or elder abuse. We also will comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Expiration of Your Authorization
As this is a research study, your authorization will not expire. You may, however, revoke your authorization later.

Revoking Your Authorization
You do not have to sign this form. Even if you do, at any time later on you may revoke (take back) your permission. If you want to do this, you must write to:
Jennifer Mulle, MHS, PhD
Assistant Professor
Department of Epidemiology
Rollins School of Public Health
Mailstop 1518-002-3BB
1518 Clifton Road
Atlanta, GA 30322

After that point, the researchers would not collect any more of your PHI. But they may use or pass along the information you already gave them so they can follow the law, protect your safety, or make sure the research was done properly. If you have any questions about this, please ask.

Other Items You Should Know

If we disclose information to people who do not have to follow the Privacy Rules, your information will no longer be protected by the Privacy Rules. People who do not have to follow the Privacy Rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. Let us know if you have questions about this. During the study you will generally not have access to records related to the research study. This is to preserve the integrity of the research. If identifiers are removed from your PHI, then the remaining information will not be subject to the Privacy Rules. It may be used or disclosed with other people or organizations, and/or for other purposes.

Contacts

If you have any questions regarding the study, you may call Dr. Jennifer Mulle at 404-727-3042. If you have any questions about the study, or your rights as a study subject, you may contact the Emory University Institutional Review Board at 404-712-0720 or 1-877-503-9797, by email at irb@emory.edu.

Authorization

Review the HIPPA Patient Authorization [“HIPPA Patient Authorization” linked to HIPPA form], and choose the authorization option that applies to you.

By checking the box below, you certify that you have read and understand the HIPPA authorization form. You may print a copy of this authorization form to keep.

[box here] I am the parent or guardian of a child under 18 with 3q29 deletion syndrome or 3q29 duplication syndrome, and I give my authorization.

[box here] I am a Legal Guardian or Legally Authorized Representative with authority for research decisions of a person with 3q29 deletion syndrome or 3q29 duplication syndrome who is 18 years or older and cannot provide their own authorization. I give my authorization.

[box here] I am an adult participant with 3q29 deletion syndrome or 3q29 duplication syndrome, and I give my authorization.