**STUDY TITLE:** Return of eMERGE III Genomic Results

##### STUDY NUMBER: 2016-3361

##### FUNDING ORGANIZATION: National Human Genome Research Institute

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**INtroduction**

We are asking for your permission to be in a research study so that we can learn new information that may help others. If you decide not to be in this study, we will still give your child good health care at Cincinnati Children’s Hospital and Medical Center (CCHMC). If you do decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study.

**Why are we doing this research?**

CCHMC is working with 10 other health care organizations in the United States to learn how genetic changes impact human disease. DNA from your child will be studied and de-identified results will be shared with other researchers from the 10 sites. “De-identified” means personal identifying information, such as your name and other information that can be linked directly back to you, will not be given with the data. Some of the genetic information being studied is known to increase the risk of some diseases. Knowing the result could inform how doctors care for people. Experts from the 10 sites have agreed that participants should be offered the opportunity to learn results for the set of genes known to increase disease risk. As part of this research study, we want to give up to 250 adolescents and their parents the choice to learn results for some, all or none of the genes that increase disease risk. The genetic test we are using is called a “panel.” A panel looks at many genes at the same time. In this study, the panel we are using will examine your child’s DNA for about 100 genes for research purposes. Information from about half of the genes on the panel can tell you about disease risk for your child and you can choose to learn these results. The other genes on the panel are only useful for research and the results will not be offered as choices. We are doing this study to learn how parents and adolescents feel about their choices and the genetic results you both choose to learn.

**WHO IS IN CHARGE OF THE RESEARCH?**

Melanie Myers, PhD. is the researcher at Cincinnati Children’s Hospital Medical Center (CCHMC) that is in charge of this study.

##### CCHMC is being funded by the National Human Genome Research Institute, to do this study.

**WHO SHOULD NOT BE IN THE STUDY?**

You cannot be in this study if:

1. You are not the legal guardian of your child.
2. Your child is under the age of 13
3. Your child is 18 years or older when making the decision about what results to receive.
4. Your child has developmental disabilities that interfere with his/her ability to make independent decisions.
5. You and/or your child do not wish to sign up for MyChart. MyChart gives your child and you online access to parts of your child’s medical records. For example, it will allow you to see the genetic test results from this study.
6. You cannot speak English.

**What will happen in the STUDY?**

The research staff will explain the study to you and you will be able to ask questions to make sure that you understand what is involved in the study. You and your child can stop being in this study at any time.

If you and your child decide to be in this study, you will come to CCHMC for one study visit. Before you come to this visit, you and your child will each be asked to complete some forms which will include your contact information, family history and some basic information about you and your child (age, race, gender, ethnicity, health status, etc.). We will also give you a link to a brief video that explains the type of genetic test we will be using in our study (goo.gl/4siQXK).

The study visit will take place in the Schubert Research Clinic and may take up to 2 hours. During that visit the following will happen:

1. Your child will be registered for MyChart if your child is not already registered.
2. You will decide the type of results you want to learn about your child. Your child will decide the type of results they want to learn about themselves. Each of you will be asked about the decision making process.
3. Once you have both decided which results you would like to learn, we will ask you to complete a brief survey. We will then ask you and your child to share and discuss your choices with one another. A member of the study team will talk with you and your child about the reasons for your choices. We will audio record this information. We hope that after you talk with one another, you will both agree on a set of choices about the types of conditions on the panel that you want to learn about. If you both are not able to come to an agreement, we will consider your choices that overlap to be the final decision and you will only receive those results.
4. We will ask you to both sign and date a “joint” preference model that only shows the results that you and your child both agree on. This will serve as the official record of your decisions.
5. Once you and your child have signed the “joint” preference model we will ask you both to answer survey questions about the decision making process.
6. A blood sample will be collected from your child.
7. After the study visit is over you will have 2 weeks to change your decision. If you want to change your decision you may mail your request with both your signature and your child’s signature to the study team (Matt Veerkamp, 3333 Burnett Ave, Cincinnati, OH 45229 MLC15012), you may also scan and then email the request to ([Matthew.Veerkamp@cchmc.org](mailto:Matthew.Veerkamp@cchmc.org)) however it will still require both your signature and your child’s signature on the request.

It may take 4 to 9 months before the results are ready to share with you and your child. First, we need to wait until we have DNA samples from at least 96 children before we can ship them as a group to the laboratory. Once the laboratory receives the group of DNA samples, it will take them about 3 months to send us the results.

You and your child will be randomized to learn results by a scheduled phone appointment or through MyChart. Negative results mean that the test did not show any gene changes that can increase the risk for the types of diseases you and your child selected. A positive result means a change or “variation” in a gene was found that can increase the risk for a disease that was included in your choices. Neither you nor the study staff will know what group you are in until the results come back. At that time you will be asked to view the results in MyChart or to make an appointment to learn about the results by phone. Study staff who ask you to view the results in MyChart or ask you to make an appointment to learn about results by phone will not know if the results are positive or negative.

All results (negative or positive) that you choose to receive on the joint preference model will be placed in your child’s electronic medical record at CCHMC. We will also mail a copy of the same results to your child’s doctor.

About a week after you and your child learn the results, each of you will be e-mailed or sent a text message with a unique link to an online questionnaire. Your answers to the questions will help us understand what you think about the results and what you think about the way you learned the results. We will ask you to complete the online questionnaire a second time about 6 months later. Your answers will help us understand if opinions change over time. If completing an online questionnaire is difficult for you, we will mail paper questionnaires to you and your child and give you a pre-addressed, postage paid envelope to return the completed questionnaires.

Your participation and your child’s participation in the study will last about 2 years. Researchers may spend an additional 2 years analyzing data and publishing the results.

**What are the good things that can happen from this research?**

You and your child’s participation may help others in the future who are given choices to learn genetic test results. You may have good feelings about learning your child’s negative results. Learning your child has a positive result may help you and your child’s doctor prevent the related disease or catch it early so it can be treated.

**WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?**

* If blood is drawn from your child, your child may feel brief pain from the needle. Your child may have some bruising or swelling. Infection, light-headedness and fainting are also possible but unlikely.
* Travel and time required for the visits may be inconvenient for you.
* There is a risk of error in the results. Errors could be due to limitations with the test technology such as a false positive or false negative. Another error could occur if the result goes to the wrong person in the study.
* There may be false assurance if your child receives negative results because the test can’t find all the changes in genes that might lead to a disease.
* There may be psychological risk such as distress, anxiety or confusion for those who receive a positive result.
* A positive result could mean other biologic family members have the same gene change.
* What we understand about genetic test results may change as more studies are done. Learning that knowledge about genetic test results have changed may cause confusion, emotional distress, or possible clinical, behavioral, and economical consequences.
* Your child’s insurance company will have access to the genetic test results that are placed in your child’s medical record. Health insurance companies are not allowed to use genetic information to take away health insurance or to keep you from getting health insurance. We do not know if other types of insurance companies will use this information to decide about life, disability, or long-term care insurance.
* There may be unknown or unforeseen risks associated with participating in the study.

**WHAT OTHER Choices ARE THERE?**

Instead of being in this study, you can choose not to be in it.

**HOW WILL YOUR INFORMATION BE KEPT PRIVATE?**

Making sure that your information remains private is important to us. To protect your privacy in this research study we will:

* Use a study ID number unique for you and your child. The study ID number will be used for study forms and electronic data storage.
* Keep your study number secret so that only study staff will know it.
* Use a barcode for the DNA sample that is unique to your child when we store the DNA. We will also use a barcode when we send a portion of your child’s DNA to a laboratory outside of CCHMC for genetic testing that is needed for this study. The barcodes will be the only way to identify that the DNA samples came from your child. The barcode numbers linked to your child’s study number will be kept in an electronic file that requires a password.
* Use a study ID number to identify your and your child’s study data. This will also be kept in an electronic file that requires a password.
* Keep your and your child’s paper study records and data in a locked office or file within the Division of Human Genetics or the Center for Autoimmune Genomics and Etiology.

**WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?**

The study doctor will tell you if they find out new information from this or other studies that may affect your health, safety or your willingness for you to stay in this study.

**WILL IT COST YOU ANYTHING EXTRA FOR YOU TO BE IN THE RESEARCH STUDY?**

Your insurance company will be billed for usual costs of your medical care, but **will not** and **should not** be billed for participation in the study. Tests done specifically for the study will be paid for by the study. If you want to discuss your child’s result in person with a genetic counselor or genetics doctor during a clinic appointment, all fees associated with a clinical visit will be billed to you or your child’s insurance.

**WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?**

You will be reimbursed $30 through the Clincard payment system for your time and effort while you are in this research study. We are required by federal Internal Revenue Service (IRS) rules to collect and use your social security or tax ID number (SSN) in order to track the amount of money that we pay you. We will not use your SSN for any other reason or as any part of this research.

**WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?**

For questions, concerns, or complaints about this research study you can contact the study staff listed on page 1.

If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

**What else should you know about the research?**

Researchers from the 10 health care organizations will use results from all the genes tested on the panel to better understand human disease. However, you can only choose to learn about results for the genes that are known to be linked to disease and that have been approved by CCHMC’s Institutional Review Board.

**AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH**

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your “protected health information” (called PHI for short).

**What protected health information will be used and shared during this study?**

CCHMC will need to use and share your PHI as part of this study. This PHI will come from:

* Your CCHMC medical records
* Your research records

The types of information that will be used and shared from these records include:

* Laboratory test results, diagnosis, and medications
* Reports and notes from clinical and research observations
* Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
* If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

**Who will share, receive and/or use your protected health information in this study?**

* Staff at all the research study sites (including CCHMC)
* Personnel who provide services to you as part of this study
* Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
* The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

**How will you know that your PHI is not misused?**

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

**Can you change your mind?**

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

**Will this permission expire?**

Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository or biobank, this authorization will not expire.

**Will your other medical care be impacted?**

By signing this document you agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you decide not to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected

**SIGNATURES**

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your permission by signature below.

You will receive a copy of this signed document for your records.

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Printed Name of Research Participant

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Signature of Research Participant Date

Indicating Consent

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Signature of Individual Obtaining Consent Date