STUDY TITLE: Return of eMERGE III Genomic Results

STUDY NUMBER: 2016-3361

FUNDING ORGANIZATION: National Human Genome Research Institute

Melanie F. Myers, PhD.
Division of Human Genetics, CCHMC
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INTRODUCTION

Since giving your assent to participate in the Return of eMERGE III Genomic Results study, you have turned 18 and are now considered a legal adult. We are contacting you to ask whether you are willing to continue in this study as an adult. If you do decide to continue in this study, you can stop at any time for any reason. If you decide to no longer be in this study, you will still get good health care at Cincinnati Children's Hospital Medical Center (CCHMC).

STUDY INFORMATION

We are attaching a copy of the assent form you signed when you originally agreed to be part of this study. Please review it before you decide whether or not to continue in this study. If you have any questions, please call or email Larragem Parsley at (513) 803-7985 or Larragem.Parsley@cchmc.org. You can also contact Dr. Melanie Myers, the person in charge of this study.

If you agree to continue in this study, you receive your study results by phone or through MyChart. However, we will ask you to complete new forms to give you and your parent access to MyChart.

SIGNATURES

Once you have had enough time to consider whether you should continue in this study, please sign below to document your permission by signature below. You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent — Date

_____ _____
Signature of Individual Obtaining Consent — Date

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INTRODUCTION

We are asking you 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, you will still get good health care at Cincinnati Children's Hospital Medical Center (CCHMC). If you do decide to be in this study, you can stop at any time, for any reason. Take all the time you need to make up your mind. 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 genes impact health. We will look at your DNA for this study. We may also share what we learn about your DNA with the other health care organizations involved in this study. If we share information about your DNA we won't share any personal information, such as your name, that can be linked directly back to you. Your DNA could tell us that you have a higher chance to get a disease. Knowing the result could inform how doctors care for you and other family members. The researchers for this study have agreed that you should be able to learn about your test results. You will be able to choose which results you want to learn about. The genetic test we are using to look at your DNA 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 DNA for about 100 genes for research purposes. Information from about half of the genes on the panel can tell you about disease risk 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 you and your parent feel about the 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 you:

1. Are under the age of 13.
2. Are 18 years or older when making the decision about what results to receive.
3. Have developmental disabilities that will impact your choice.
4. Do not want to sign up for MyChart. MyChart gives you online access to parts of your medical records. For example, it will allow you to see the genetic test results from this study.
5. You are pregnant.
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 can stop being in this study at any time.

If you decide to be in this study, you will come to CCHMC for one study visit with one of your parents. Before you come to this visit, you will each be asked to fill out a form which will ask for your contact information and some basic information (age, race, gender, ethnicity, health status, etc.). Your parent will fill out a similar form. We will also give you a link to a brief video that explains the type of genetic test we will be using (goo.gl/4siQXK).

The study visit will be in the Schubert Research Clinic at CCHMC. It could take up to 2 hours. This is what will happen during the study:

1. You will sign up for MyChart if you do not already have MyChart.
2. You will decide the type of results you want to learn. Your parent will also pick what results they want to learn about you. We will then ask you some questions about making your choices.
3. Once you and your parent have decided which results you would like to learn, we will ask you to complete a brief survey. We will then ask you to talk about your choices with your parent. A member of the study team will talk with you and your parent about why each of you made your choices. We will audio record this information. We hope that after you talk with your parent you will both agree on your choices. If you do not agree with each other, we will tell the laboratory to only give you and your parent the results that you both agree on.
4. We will ask you to both sign and date a “joint” preference model that only shows the results that you and your parents both agree on. This will be the official record of your decisions.
5. Once you and your parent have signed the “joint” preference model we will ask you some more questions about the decision making process
6. A blood sample will be collected from you.
7. After the study visit is over you will have 2 weeks to change your choices. If you

want to change your choices you may mail your new choices with both your signature and your parent'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) however it will still need both your signature and your parent's signature on the request.

It may take 4 to 9 months before the results are ready. First, we need to wait until we have DNA samples from at least 96 other people 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.

Most adolescents in this study will have negative results. A negative result means that the test did not show an increased risk for the types of diseases you and your parent chose. We expect no more than 10% (10 out of 100) adolescents will have positive results. A positive result means a change or "variation" in a gene was found that can increase the risk for one of the diseases you chose. When you get results we will put you in one of two groups at random. One group will get results by phone. The other group will get results through MyChart. Neither you nor the study staff will know what group you are in until the results come back. Study staff who contact you when results are ready will not know if the results are negative or positive. When the results come back we will ask you to look at them in MyChart or set up a time for a phone call.

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

About a week after you and your parent learn the results, we will email or text you a link to an online survey. Your answers to the questions will help us understand what you think about the results. The survey will also tell us what you think about the way you learned the results. We will ask you to complete the online survey a second time about 6 months later. Your answers will help us understand if opinions change over time. If you cannot do the survey online, we will mail paper surveys to you and your parent with an envelope so you can send it back.

You might be in this study for up to 2 years. Researchers may spend an additional 2 years analyzing data and publishing the results. If your turn 18 before you receive genetic results or answer all the study questions, we will ask you for written permission to continue in the study. You will also have to decide if you want your parent to continue to have access to your information in MyChart.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Your participation may help others in the future who are given choices to learn genetic test results. You may have good feelings about learning your negative results. Learning a positive result may help you and your 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 you may feel brief pain from the needle. You may have some bruising or swelling. Infection, light-headedness and fainting are also possible but unlikely.
- Travel and time needed for the visits may be difficult for you.
- There is a risk of error in the results. Errors could be due to the test making a mistake 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 a false sense of wellness if you receive negative results because the test can't find all the changes in genes that might lead to a disease.
- There may be emotional 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 insurance company will have access to the genetic test results that are put in your 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 other risks associated with participating in the study that we do not know about.

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. 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 you when we store the DNA. We will also use a barcode when we send a portion of your 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 you. The barcode numbers linked to your study number will be kept in an electronic file that requires a password.
- Use a study ID number to identify your study data. This will also be kept in an electronic file that requires a password.
- Keep your 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 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 your insurance.

WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?

You will be reimbursed up to $50 for being in the study, $30 for the study visit and $10 for each follow-up survey you complete. We will use the ClinCard payment system to reimburse you for your time and effort while you are in this research study. We are required by the Internal Revenue Service (IRS) to collect your Social Security number (SSN) and track the amount of money we pay you. We will not use your SSN for any other reason or for any study purposes.

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.

As a part of this study, your de-identified data may also be shared with other researchers or public databases for studies in human health.

We would like to freeze and store your left over DNA in the Cincinnati biobank. A biobank is a large collection of health data and samples that can be used for research. Stored DNA in the biobank are made available for other researchers at CCHMC and researchers outside of CCHMC doing studies that will help us understand human health and disease. The stored materials are de-identified. They are not linked to any personal identifying information.

Researchers who use stored biobank materials for research funded by the National Institutes of Health may have to share de-identified genomic data in public databases called repositories. De-identified means personal identifying information (like your name or date of birth) will not be given with your data.

(initial if agree) _____. Yes, I give permission for my left over samples to be stored in the CCHMC biobank for future research. I understand de-identified data from my samples may be shared with public databases.

- You will not know when other researchers use your de-identified samples or de-identified data. It is possible a researcher may find a result that could change your medical care. The CCHMC biobank will be able to find out if the sample was yours if you want to be told about the results. If you want to be told, a doctor at CCHMC who understands the results would try to reach you to talk to you about the result/s.

  If possible, do you want to be contacted if other researchers' have IRB approved results that may impact your health?
  Yes_____ (initial)
  No_____ (initial)

(initial if disagree) _____. No, I do ***not*** give permission for my left over samples to be stored in the CCHMC biobank for future research.

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 medicines
- 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 your 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 say exactly what will happen. Once you have had enough time to decide if you want to be in this research you will document your permission by signing below.

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

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Assent — Date

_____ _____
Signature of Individual Obtaining Consent — Date