Study Title: Engaging Adolescents in Decisions About Return of Genomic Research Results

NCT ID: NCT04481061

ASSENT

IRB Approved 8/7/2023

Title of research study: Engaging Adolescents in Decisions about Genomic Results (2020-0517)

Key Information:

The following is a short summary of this study to help you decide whether to participate in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about how teens and parents or legal guardians make decisions when it comes to learning genetic information for the teen. We also want to understand how teens and their parents/legal guardians respond to learning the teen's genetic information. The research is being conducted at Cincinnati Children's and Mayo Clinic.

You are being asked to join this research study because you are between 13-17 years of age.

Investigator:
Dr. Melanie Myers, PhD
Dr. Michelle McGowan, PhD

Contact Info:
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Funding:
National Human Genome Research Institute

Reason for the study:

This is a research study. In this research, we want to find out what genetic information teens and young adults want to learn about themselves. We also want to learn if parents/legal guardians make the same or different choices for their child. Genetic information is inherited from parent to child, and genetic information that can be learned in this study may impact current or future health and health decisions.

We expect that most participants who choose to learn results will receive negative results, meaning they won't receive genetic information that impacts current or future health and health decisions. Because you are under the age of 18, your parent/legal guardian must give their permission for you to participate. They will also participate in this research study with you.

Procedures:

If you agree to join this study, you will be asked to watch short videos about genetic testing (https://www.youtube.com/channel/UC8j0uePdTwJxf96u7MD_H9A). During the

informed consent process, study 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. If you choose to be in the study we will ask you to sign the assent form. You can stop being in this study at any time.

Study visits can happen in person or remotely. In person study visits will happen at CCHMC or a community site. You, and your parent/legal guardian, will each be asked to complete some forms which will include your contact information, some basic information about you (age, race, sex, ethnicity, health status) and study related questions.

When you and your parent make decisions about the type of genetic results you want to learn about yourself the following will happen:

1. We will ask you to use a decision tool to help you make your choices. We may ask you to watch one or more of our videos before you use the decision tool.
2. We will ask you and your parent/legal guardian to make your choices on your own, in separate locations if possible. If the study visit takes place remotely, we will break you and your parent/legal guardian off into separate breakout rooms. Each of you will be asked to complete a brief survey about how you made your decisions.
3. Once you and your parent/legal guardian decide which results you would like to learn separately, we will ask you to share and talk about your choices. You will have the option to change your choices. We may audio record this information. After you talk with one another, you will decide on a set of conditions you want to learn about yourself. If you are not able to agree, we will only return choices that overlap.
4. After the discussion, we will ask you to sign and date a "joint" decision tool that shows your final choices. We will ask your parent to sign it as well. This will serve as the official record of your joint decisions.
5. After you have made your final decisions, we will ask you and your parent/legal guardian to answer survey questions about the decision making process.
6. If you choose to learn results, we will collect a saliva (spit) or blood sample that contains your DNA. You can choose whether to give a saliva or blood sample. The blood sample will be 3 ml, which is about one teaspoon.
7. After the study visit is over, you will have 2 weeks to change your decision. A member of the study team will reach out to ask if you and your parent/legal

guardian would like to change your choices. If yes, a study team member will talk with you and your parent/legal guardian about changes you want to make. As an alternative, if you and your parent/legal guardian want to make changes to your choices, you may mail your request with your signature to the study team (Dr. Melanie Myers, Human Genetics, 3333 Burnet Ave, Cincinnati, OH 45229 MLC4001), you may also scan and then email the request to (Melanie.Myers@cchmc.org), however, it will still require both signatures on the request.

8. Your DNA sample will be sent to the study laboratory (Laboratory of Molecular Medicine in Cambridge MA) after we know your final decision and we receive any necessary signed and dated forms if you decide to change your choices.
9. If you receive a positive result, we will share the result with you, your parent/legal guardian, and your doctor and we will place the result in the electronic health record associated with this study. You will be able to choose whether you want to share negative results with your doctor.

The study laboratory will sequence your DNA. However, the laboratory will only look for variations in the set of genes approved by Cincinnati Children's Institutional Review Board (IRB) for this study and that you choose to learn. An IRB is a group of scientists and non-scientists who look at research projects like these and make sure research participants' rights and welfare are protected. It may take up to 6 months before the results are ready to share with you. Results will be returned by either a scheduled phone appointment or by certified mail.

Return of results:

Negative results mean that the test did not show any gene changes that can increase the risk for the diseases you selected. If you receive negative results, we will send those results to you and your parent/legal guardian, either via secure email and/or send via the post office. If you ask us to, we will mail a copy of the same results to your doctor and place them in your electronic medical record at CCHMC. You can also choose to share your negative results with your doctors.

Two types of positive results are possible. A positive result may be a change or "variation" in a gene that can increase the risk for a disease that was included in your choices. A positive result may be a variation in a gene that will not increase risk for a disease in you but may increase risk for a disease in your future children. If you receive a positive result that matches your choices, we will schedule a time for you and your parent/legal guardian to learn about the results by phone and speak with a licensed

genetic counselor via telehealth and/or videoconference (through Microsoft Teams). After we talk to you about the results, the results 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 learn the results, 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 participants who receive a positive result to complete the online questionnaire a second time about 12 months later. Your answers will help us understand if opinions and reactions to learning genetic information change over time. If completing an online questionnaire is difficult for you, we will mail paper questionnaires to you and give you a pre-addressed, postage paid envelope to return the completed questionnaires. If you prefer, a study team member will call you and ask you survey questions over the phone.

We may also invite you to do an interview with us on the phone, remotely through the internet, or in-person. These interviews may focus on the impact of learning genetic information or reasons for choices or changing choices. We will audio record interviews.

We expect that you will be in this research study for up to two years.

More detailed information about the study procedures can be found under ***"(Detailed Procedures)"***

Risks to Participate:

- If you choose to give a blood sample, and blood is drawn from you, 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.
- Sometimes the DNA we get from a spit sample is not enough for the genetic testing we need to do. We may need you to provide a second spit sample it that is the case.
- Travel and time required for an in person 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 sense of security 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 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. We will not contact you if results change after this study. Learning that knowledge about genetic test results have changed in the future may cause confusion, emotional distress, or possible clinical, behavioral, and economical consequences.
- The lab may report gene associations with conditions that are not on our list. These conditions will be returned if they match your final choices.
- Your insurance company will have access to genetic test results that are placed 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 unknown or unforeseen risks associated with participating in the study

More detailed information about the risks of this study can be found under ***"(Detailed Risks)"***

Benefits to Participate:

We do not know if being in this study will help you. We may learn something that will help other teens and parents make decisions about genetic testing.

You may feel relief if you learn negative results. Learning you have a positive result may help your doctor prevent the related disease or catch it early so it can be treated.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive at Cincinnati Children's.

Your alternative to participating in this research study is to not participate.

Take all the time you need to make your choice. Ask us any questions you have at any time.

Cost to Participate:

Taking part in this research study may lead to added costs to you. You may have to pay for transportation costs if you need to come into our clinic for a study visit. If the study visit takes place remotely, you may have to pay for additional internet charges in order to access the remote study technology.

Payment:

If you agree to take part in this research study, we will pay you $50 for the study visit, providing a sample for DNA (if applicable), and completing all required baseline surveys. You will receive an additional $25 after completing the first follow up survey, and $35 for completing the second follow up survey, if you qualify for a second follow up survey. If you are asked to participate in an interview with the study team, we will pay you $35 per interview.

You will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you a handout that will explain how to use the card.

Because you are being paid for your participation, Cincinnati Children's is required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your Social Security number. This form will be given to the Cincinnati Children's business office. It will not be kept as part of your study chart. If you move, you will need to complete another W-9 with an updated address.

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to...	**You can call ...**	**At ...**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Kristin Childers-Buschle** **Clinical Research Coordinator**	Phone: 513-636-4256 (office) 513-560-8051 (text)

Who to talk to...	You can call ...	At ...
• Emergencies • Research-related injuries • Any research concerns or complaints	**Dr. Melanie Myers, PhD** **Primary Investigator, CCHMC** **Dr. Michelle McGowan, PhD** **Primary Investigator, Mayo Clinic**	Phone: 513-636-8195 Phone: 507-293-7787
• Your child's rights as a research participant	**Cincinnati Children's Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: 513-636-8039

Detailed Procedures:

If you would like to see a copy of the study timeline for additional information about the study and potential study visits, please ask a member of the study team and it will be provided.

Change of Mind/Study Withdrawal:

You can leave the research at any time. If you decide to leave the research, contact the study team so that the study team can formally withdraw you.

Privacy:

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Samples and/or data collected for or generated from this study could be shared and used for future research. Samples and /or data may be shared with other collaborators at Cincinnati Children's, collaborators at Mayo Clinic, and possibly with outside collaborators, who may be at another institution or for-profit company.

If information that could identify you is removed from your information or samples collected during this research, that information or those samples could be stored and used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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 sign below if you agree to participate.

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

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent or Assent — Date

_____ _____
Signature of Individual Obtaining Consent — Date