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

NCT ID: NCT04481061

PARENTAL PERMISSION / ADULT CONSENT

IRB Approved 8/7/2023

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

Key Information:

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Funding:
National Human Genome Research Institute

The following is a short summary to help you decide whether to be a participant in this study. You also have the option to permit your teen to be a participant in this study. 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/legal guardians make decisions when it comes to learning genetic information for the teen. We also want to understand how teens and parents/legal guardians respond to learning the teen's genetic information. The research is being conducted at Cincinnati Children's and Mayo Clinic.

Parents/legal guardian's permission for their teen between the ages of 13-17: You have the option of having your teen join this research study. Because your child is under the age of 18 they must have your permission in order to participate in this study. This is a parental permission form and it will explain this research study. If you decide that you and your child can be in this study, you will sign this form or provide electronic signature through REDCap to show that you agree. If you decide to give permission for your child to participate you will receive a copy of this consent for your records.

Parent/legal guardian consent: You have been invited to participate in this study. Your child is aged 18 or older, and therefore does not need your permission to participate in this study. However, your child has invited you to participate. This is a consent form and will explain the research study. If you decide that you would like to participate, you

will sign this form or provide electronic signature through REDCap. If you decide to participate you will receive a copy of this consent for your records.

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 know how young people choose to involve their parents/legal guardians in the decision. 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 chose to learn results will receive negative results, meaning they won't receive genetic information that impacts current or future health and health decisions.

If your child is under the age of 18 you must give them permission to participate. You must also participate in the study with them.

Procedures:

If you agree to join this study, you and your child 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 your child, and you both will be able to ask questions to make sure that you understand what is involved in the study. If you and your child choose to be in the study we will ask you both to sign the consent 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 Cincinnati Children's or a community site. You and your child will 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 make decisions about the type of genetic results you want to learn about your child, the following will happen:

1. We will ask you and your child to use a decision tool to help you make your choices. We may ask you to watch one or more short videos before you use the decision tool.

2. We will ask you and your child to make your choices independently. We will ask you and your child 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 child 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 child decide which results you would like to learn separately, we will ask you to share and discuss your choices together. You both will have the option to change your choices. We may audio record this information. You and your child will have the option to jointly come to agreement on the set of conditions you want to learn about.
    a. If your child is 18 years or older and you are not able to agree on results returned, we will consider your child's individual choices to be the final decision;
    b. If your child is under the age of 18, and you are not able to agree, we will only return results that overlap.
4. After the discussion, we will ask you and your child to sign and date a decision tool that will serve as the official record of your decisions.
5. After you have made your final decisions, we will ask you and your child to answer survey questions about the decision making process.
6. If you and your child, or just your child if they are aged 18 or older, choose to learn results, we will collect a saliva (spit) or blood sample that contains your child's DNA. Your child 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 and/or your child will have 2 weeks to change your decision. A member of the study team will reach out to ask if you and your child would like to change your choices. If yes, a study team member will talk with you and/or your child about changes you want to make. As an alternative, if you and/or your child 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).
8. Your child's 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 your child receive a positive result, we will share the result with you, your child, and your child's doctor. 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 child's doctor. If your child is aged 18 or older, we will share the positive result with your child first, and they may choose to share the result with you.

If your child receives a positive result, we will share the result with you and your child's doctor and we will place the result in your child's electronic health record associated with this study. You will be able to choose whether you want to share negative results with your child's doctor.

The study laboratory will sequence your child's 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 and/or your child. Results will be returned by either a scheduled phone appointment, secured e-mail message, or by certified mail.

Return of results:

Negative results mean that the test did not show any gene changes that can increase your child's risk for the diseases you or your child selected. If your child receives negative results, we will send those results to you via secure email and/or mailed via the post office. If you ask us to, we will mail a copy of the same results to your child's doctor and place them in your child's electronic medical record at Cincinnati Children's. You can also choose to share your child's negative results with their doctor. If your child is 18 years of age or older, they will have the opportunity to tell us if they want their results mailed to their doctor or placed in their electronic medical record.

Two types of positive results are possible. A positive result may be a change or "variation" in a gene that can increase your child's risk for a disease that was included in your child's choices. A positive result may be a variation in a gene that will not increase risk for a disease in your child but may increase risk for a disease in their future children. If your child receives a positive result that matches their choices, we will schedule a time

for you or your child to learn about the results by phone and speak with a licensed genetic counselor via telehealth and/or videoconference (through Microsoft Teams). If your child is under 18 you must be present on that call. After we talk to you and/or your child about the results, the results will be placed in your child's electronic medical record at Cincinnati Children's. 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, you will be e-mailed or sent a text message with a unique link to an online questionnaire. Your and your child's answers to the questions will help us understand what you both thought about the results, and what you and your child thought 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 and your child's 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 and/or your child, we will mail paper questionnaires to you and/or your child, and give you a pre-addressed, postage paid envelope to return the completed questionnaires. If you and/or your child prefers, a study team member will call you and ask you and your child survey questions over the phone.

We may also invite you and your child 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 and your child 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 your child chooses to give a blood sample, and 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.
- Sometimes the DNA we get from a spit sample is not enough for the genetic testing we need to do. We may need your child 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 and/or your child.
- 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 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. We will not contact you if your child's 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.
- Your insurance company will have access to 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 or your child 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.
- 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.
- 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 your child. We may learn something that will help other teens and parents make decisions about genetic testing.

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

Other Options:

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

Your child's alternative to participating in this research study is for them not to 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 with your child 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 your child agrees to take part in this research study, we will pay your child $50 for the study visit, providing a sample for DNA (if applicable), and completing all required baseline surveys. You will also receive $50 for your participation. You and your child will receive an additional $25 after completing the first follow up survey, and $35 for completing the second follow up survey, if you and your child qualify for a second follow up survey. If you and your child are asked to participate in an interview with the study team, we will pay you both $35 per interview.

You and your child 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 and your child 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 both you and your child, for this income tax reporting. This form requires your Social Security number, as well as your child's Social Security number. If you or your child does not have a Social Security number you cannot participate in this study. 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)
• 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

Who to talk to...	You can call ...	At ...
• 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 one will be provided.

Change of Mind/Study Withdrawal:

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

Privacy:

Efforts will be made to limit the use and disclosure of you and your child's 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 you and your child's 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 and/or your child is removed from your child's 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 you and your child's 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 or your child. At most, the website will include a summary of the results. You can search this website at any time.

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 child's "protected health information" (called PHI for short).

To be in this 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?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) and Mayo Clinic will need to use and share your or your child's PHI as part of this study. This PHI will come from:

- Your child's Cincinnati Children's medical records
- Your child's research records
- Research procedures, including research office visits, tests, interviews, and questionnaires

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

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Who will share, receive and/or use you and/or your child's protected health information in this study?

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you and your child as part of this study
- Other individuals and organizations that need to use you and/or your child's 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 Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that you and your child's PHI is not misused?

People that receive you and your child's PHI as part of the research are generally limited in how they can use you and your child's PHI. In addition, most people who receive you and your child's PHI are also required by federal privacy laws to protect you and your child's PHI. However, some people that may receive you and your child's 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.

While taking part in this study, you and your child will be assigned a code that is unique to you and your child but does not include information that directly identifies you or your child. This code will be used if your or your child's study information is sent outside of Cincinnati Children's, Mayo Clinic, and Laboratory of Molecular Medicine. The groups or individuals who receive your or your child's coded information will use it only for the purposes described in this consent form.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share you and/or your child's 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 and/or your child 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.

Will you and/or your child's other medical care be impacted?

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

While your child are participating in this research study you may not be able to access some of your child's health information that is related to the study. Any request for this information can be fulfilled once the study is completed.

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 and/or your child 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.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent Date

If child is 18 years of age of older no additional information is needed.
If child is under the age of 18:

_____
Printed name of minor participating in the research study

Do you give permission for your child to participate in this study?
□ Yes, I give permission

□ No, I **DO NOT** give permission

_____ _____

Signature of Parent or Legally Authorized Representative* Date

_____

* If signed by a legally authorized representative, a description of such representative's authority must be provided. Please describe your authority on the line above.

_____ _____

Signature of Individual Obtaining Consent Date

If you opt into receiving your child's results, would you like these results shared with your child's doctor?

□ **Yes**, please share my child's results with their doctor
□ **No**, I do not want you to share my child's results with their doctor