

Parental Permission Form

Title of Research Study: Ten Thousand Families Study (STUDY00000877)

Investigator Team: Jenny N. Poynter, PhD, Principal Investigator

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: Co-sponsored by the National Institutes of Health, the University of Minnesota Masonic Cancer Center, the Coordinating Centers for Biometric Research, and the University of Minnesota Academic Health Center.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is provided later on in this form.

What is health research?

Research consists of making educated guesses called hypotheses about how the world works and testing those hypotheses by collecting data. The goal is to learn new information to help groups of people in the future. Health research is research that focuses on identifying causes of disease, improving the quality of life and extending the life of those with illnesses. To do this, some researchers conduct studies that involve human subjects. The top priority of this kind of research is the safety of human subjects. All studies that involve human subjects are reviewed by experts whose goal is to ensure the safety of the participants and prevent other negative outcomes. Your child, as an individual, may or may not be helped by volunteering for a research study.

Why is my child being asked to take part in this research study?

We are inviting your child to participate in a large family-based cohort study being done all across Minnesota and including the neighboring states of Iowa, North Dakota, South Dakota, and Wisconsin because you enrolled in the study and you told us you have a child between the ages of twelve and seventeen. Your child may be eligible to participate.

What is a cohort study?

A cohort study is where a large group of individuals is enrolled and then regularly followed for many years to learn about changes in health over time. Using this type of design, researchers can more accurately determine what exposures and lifestyle factors impact health later in life.

At enrollment into a cohort study, participants complete questionnaires and health assessments to provide information on where people live, what they eat, how much they exercise, whether they smoke, genetic factors, and other factors that may influence disease risks later in life.

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What is a family-based study?

A family-based study includes at least two family members from one or more generations from each participating family. Family-based studies can help us understand how genetics and environment contribute to health and disease. Family-based studies also look at factors that may be important to health across generations.

As the parent or guardian, what should my child and I know about being in a research study?

- You can ask us to explain this research study to you and your child.
- Whether or not your child takes part is up to you and your child.
- You can choose not to have your child take part.
- You and your child can agree to take part and later change your mind.
- Your decision will not be held against you or your child.
- You and your child can ask all the questions you want before you decide.

Why is this research being done?

We are conducting this study because health, diseases and risk factors can run in families. A family study will help us understand how genetics, shared habits and exposures contribute to health and disease.

How long will the research last?

The 10,000 Families Study is an ongoing study and we expect that your child's participation in this research study will continue as long as you and your child agree to participate while the study is active.

What will my child need to do to participate?

You will be asked to complete questionnaires about your child's health and allow us to collect physical and biological measurements from your child over time. DNA will be extracted from biological samples for genetic analyses. We will also ask your child to wear a silicone wristband for 7 days and mail it back to us. You will be asked to give us permission to get health-related records about your child.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want my child to be in this research?"***

Is there any way being in this study could be bad for my child?

The procedures and tests used in this study are considered safe, though there are some minor risks to participation, that are described below under ***"What are the risks of this study? (Detailed Risks)"***

While we are not planning to give out any results from genetic testing that may be performed on your child's biological samples, there may be rare situations where we find genetic changes or non-genetic results (e.g., cholesterol) that could significantly impact your child's medical care or that of your family. At the end of this form we will ask you if you would like these kinds of results.

We will make every effort to protect your child's identity and privacy, yet we cannot absolutely guarantee that information about your child will never become known.

Will being in this study help my child in any way?

Receiving test results from your child's Family Health Visit may be of benefit to some participants. You may also

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choose to receive information about chemicals your child has been exposed to from the study. If you decide to receive information about these chemical exposures, please note that right now we do not know whether these chemicals could cause problems with human health. In addition, we hope that the information learned from this study will benefit other people in the future.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

Over time, ten thousand families will be invited to participate in this study.

What happens if I say “*Yes, I want my child to be in this research*”?

Parents or guardians who agree to enroll their child in the study will do the following:

1. Health Questionnaires: Parents will be asked to complete an online health questionnaire for their child that asks questions such as the child’s medical history, lifestyle questions (like diet, physical activity, and sleep), and family health history. The initial parental questionnaire will take about 30-45 minutes to complete. We will also invite your child to complete an adolescent questionnaire (survey), which includes questions about skincare, smoking, drinking, drug use, gender identity, sexual behavior, diet, physical activity, and other experiences. This survey is very similar to, but shorter than, the Minnesota Student Survey that middle and high school students complete every few years. All information you provide as part of 10,000 Families is confidential.

2. Biological Sample Collection: We may send a biological sample collection kit to your home for simple-to-collect blood (optional for children under 18) and stool samples. We will provide instructions and prepaid postage. The biological sample collection will take you about 15-20 minutes to complete.

3. Family Health Visit: Your child will be asked to attend a family health visit at a location reasonably convenient to you, such as a clinic, community center or your home. A parent, guardian or designated adult (e.g., aunt, grandparent) must accompany the child. The purpose of the Family Health Visit is to take in-person measurements and biological samples.

The full list of measurements that may be collected at the Family Health Visit are described below. We will not collect all measurements from all study participants.

- **Height, weight, waist and hip size, percent body fat measurements, pulse, lung function, grip strength, electrocardiogram and blood pressure:** If the child has an implanted device (such as a pacemaker or defibrillator), his or her weight will be measured using a non-electronic scale.
- **Hearing test:** Your child may be asked to complete a hearing test.
- **Saliva sample:** We may collect a sample of your child’s saliva using a ‘spit’ kit.
- **Urine sample:** We will collect a sample of your child’s urine.
- **Optional Blood Sample:** A trained technician will draw samples of your child’s blood (up to 55 milliliters or 3.7 tablespoons for children weighing 56 pounds or more; 42 milliliters or 2.8 tablespoons for children weighing 46-55 pounds) for tests that will include cholesterol and other blood fats, glucose (sugar) level, kidney function and other factors. With your permission, some of your child’s blood will be stored for future research studies. These samples are not available in the future for your child’s

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personal use or clinical (diagnostic) purposes. **We will not test for HIV, AIDS or sexually transmitted diseases.**

- **Hair and finger or toe nail collection:** Your child's hair and finger or toe nail samples will be used only for research studies and these samples will be stored for future studies.
- **Stool sample:** We may send a kit home with you for stool sample collection for your child, which will be used to measure the types of microorganisms in your child's gut, and the remaining sample will be used for future research studies.
- **Silicone wristband:** We will send a silicone wristband home with you to be worn by your child for 7 days and returned to the study team. This will be used to measure chemicals that your child may be exposed to in the environment. We will store a portion of the wristband for future research studies.
- We may invite your child to complete certain interviews or procedures if the information collected during a procedure is incomplete. Or, we may ask your child to repeat certain interviews or procedures for quality control purposes. Repeating procedures is optional and will be shorter than the original visit.

4. Testing of your child's blood/saliva for DNA.

- We will collect and store genetic material (DNA and RNA) from your child's biological samples for research studies and long-term storage. DNA is material in our bodies that contains genes. RNA is another material that plays a role in the way genes work.
- In the future, we will examine the DNA to learn whether genes and gene products can help us understand the risk of diseases in adults, particularly cancer, heart disease, stroke, brain function, lung disease, and others. We may look at specific genes and the entire sequence of DNA for their contribution to risk of various diseases. We will also use your child's samples to make new cells that can be grown in a laboratory and turned into different types of cells. **We will not examine DNA to diagnose diseases nor to do clinical genetic testing or genetic counseling.**

While we are not planning to give out any results of genetic testing, there may be rare situations where we find genetic changes that could significantly impact medical care. At the end of this form we will ask you if you would like these kinds of results. If you decide to receive potentially medically actionable results, the genetic test results will be given to you and your primary health care provider by a Genetic Counselor. Costs of follow up tests including confirmation of research findings and medical care would be billed in an ordinary manner to you or your insurance company, and you would be responsible for these costs.

5. **Medical records:** We will ask for your permission to request records from your child's well-child visits, and emergency room, urgent care and clinic visits, as well as records from admissions to hospitals. If your child has been diagnosed with one of the diseases that we are studying, we will request doctor's office and clinic visit records related to the condition. We will also request birth certificates and hospital records related to births.
6. **Link information** from state cancer registries or similar systems about diseases your child may have had or may develop in the future.
7. **Future contact:** We will contact you by phone, regular mail, text or email to notify you and your child of study events, provide updates and ask you about your child's health since we last contacted you. If you are unable to answer questions yourself, we may contact a person you have named who could

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answer questions for you. We may ask you to update this person's name during follow-up. If in the future we do not have updated information to locate your child, we will attempt to obtain that information from your contact(s), internet searches, public directories, social media or a visit to your last known address. If you provide your telephone number and/or e-mail address with your consent, we will use text messages and/or e-mail to send reminders of follow-up questionnaires and other needed information from you. If your child provides us with their email address and cell phone number for the adolescent survey, we will be in direct communication with them for that purpose. We cannot guarantee the confidentiality of text messages, which means text messages should not include any private information about your child or their health. When your child reaches the age of 18 we will ask him/her about whether or not he/she would like to continue study participation.

What happens if I do not want my child to be in this research?

Participation is voluntary. If you do not want your child to participate, just let us know.

What happens if I say "Yes", but my child or I change our mind later?

You and your child can leave the research study at any time and no one will be upset by your decision. If you decide to leave the research study, contact the study staff so we can remove your child's name from our participant list and stop further contact with you. We will continue to analyze the data you provided prior to your withdrawal unless you instruct us in writing to delete all information we have about your child. Research already done on data or samples cannot be undone.

Choosing not to be in this study or to stop being in this study will not result in any penalty to your child or loss of benefit to which he or she is entitled. This means that your choice not to be in this study will not negatively affect your child's right to present or future medical care, his or her academic standing as a student, or his or her present or future employment.

What are the risks of being in this study? Is there any way being in this study could be bad for my child?

- **Questionnaires:** We are asking parents to complete a health questionnaire that asks questions about the child's medical history, lifestyle questions, such as diet, physical activity, and sleep, and family health history. Teens will be asked about **skincare, smoking, drinking, drug use, gender identity, sexual behavior, diet, physical activity, and other experiences. You and they can refuse to answer any questions that cause discomfort.**
- **Medical care during the Family Health Visit:** In the unlikely event that during the family health visit your child should require medical care, first aid will be available.
- **Blood draw:** A skilled technician will draw your child's blood (optional). Minimal bruising, pain, fainting, temporary bleeding or infection may occur as a result of the blood draw.
- **Blood pressure:** There may be some discomfort from the repeated blood pressure measurements.
- **Other risks and sources of discomfort:** In addition to the risks and sources of discomfort mentioned above, and how they can be decreased, there may be other negative effects associated with some of the procedures that are performed during this study that are currently unknown. If your child experiences any negative effects, it is extremely important that you make us aware of it.
- **A new health problem:** You may also learn of a health condition that you did not know your child had or that may require you to consult with a physician for further evaluation and treatment. No personal medical results will be released by the research study.

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- **Data Sharing:** We will make every effort to protect your child's identity and privacy, yet we cannot absolutely guarantee that information about you or your blood relatives will never become known. **However, researchers are strictly prohibited from attempting to identify you.**
- **Genetic information:** Though there are no plans to perform any genetic analysis at this time, we anticipate that we will perform genetic analysis on the collected samples in the future:
 - DNA sequence is like a fingerprint: it is unique to your child. All precautions will be taken to protect his or her privacy and confidentiality. All genetic information will be stored in a secure database that is labeled only with an identification number. Only the study team and qualified researchers will have access to these data.
 - The testing in some cases may reveal information not anticipated. For some DNA testing, this includes information about paternity or blood relationships between the people being tested. We will not tell you this type of information if we find it.
 - While there are no plans to perform any genetic analysis at this time, if you decide that you want to receive "medically actionable findings" for your child, it is *possible* that we will tell you that your child may be at high risk for a serious medical condition. In most cases, we do not expect to identify medically actionable results.

Risks to family members: *If medically actionable genetic results are returned to participants, these results may have implications for family members (even if the family members have elected NOT to receive medically actionable genetic results). You can decide whether to share the results of your child's tests with your family members. Family members can decide to change their option to receive or not receive medically actionable genetic findings at any time during the study.*

Some non-genetic tests (e.g. cholesterol levels) may indicate risks not only to your child but to other family members as well. You can decide whether or not you want to share your child's individual results with other family members.

- We will NOT report ANY medically actionable genetic findings for adult onset diseases to parents of children (age < 18 years). Once a child reaches the age of 18 years we will re-consent them regarding their preference for medically actionable genetic findings and report their results according to their preference.
- A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
 - Health insurance companies and group health plans may not request your genetic information that we get from this research.
 - Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
 - Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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Will it cost me anything for my child to participate in this research study?

We will not charge you for costs associated with the health measurements and biological sampling. We are unable to reimburse you for travel costs to the Family Health Visit (which should be minimal).

What happens to the information collected for this research study?

- **Use of data and samples:**

- Your child's specimens will be kept until we no longer need them, until they are used up or until you tell us to destroy them.
- In addition to study information and genetic data, portions of biological samples and DNA/RNA will be stored by the research study, and information about these samples may be stored on scientific databases at the National Institutes of Health for use by researchers. Any information that is shared in scientific databases will be de-identified and will not be able to be linked to your child.
- The study team will allow qualified researchers from the University of Minnesota, other universities, the government, and drug- or health-related companies to use or analyze your child's samples after your child's identity has been removed.
- Samples and data sent to other laboratories will be labeled only with a code number. No standard information that identifies your child, such as name, date of birth, address, etc., will be available to researchers not associated to the research study.

- **Commercial use of data and samples:**

- Researchers from private companies that develop diagnostic lab tests, or treatments for diseases, may request access to study information or samples. These researchers will not have access to personal information that identifies your child, such as name, date of birth, address, etc.
- Samples will not be sold to any person, institution, or company, and will not be used for cloning (creating body organs or tissues or fluids from genetic material).
- No one in your family would benefit financially from discoveries made using the information and/or specimens that you provide.
- The data provided may lead to inventions or patents in which private companies, study investigators or their universities may participate and may benefit.

- **Use of data and samples for genetic research:**

- We may place some of your child's biologic samples, genetic data and health information in scientific databanks at the National Institutes of Health, along with similar information from people participating in other studies. Information that could directly identify your child will never be included. Qualified researchers not associated to this study may request access to it for research. This information and all of your child's other data will be used by researchers to look for genes and other factors that affect the risk of developing diseases and may lead to better methods for prevention and treatment for diseases such as cancer and diabetes.
- The stored information will not include any identifying information such as name, date of birth, and address, etc.. Access to this stored information will be controlled by the National Institutes of Health.

Efforts will be made to limit the use and disclosure of 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 confidentiality. Organizations that may inspect and copy your child's information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research,

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and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance. To help protect your child's privacy, the National Institutes of Health has granted a Certificate of Confidentiality (CoC).

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. For selected tests from the Family Health Visit, a report will be given or mailed to you. If you have questions about the test results or if a test result is not in the normal range, it is recommended that you discuss the findings with your child's primary healthcare provider. If your child does not have a personal healthcare provider, our staff can provide you information on physicians and clinics in your community. Since this is a research study, any information you receive is not a substitute for care you would receive from your child's healthcare provider. We do not make a diagnosis, provide treatment, or give medical advice. Your child's health care provider is responsible for deciding any appropriate medical follow-up, testing, or treatment based on your child's results. Results from genetic tests will not be reported. Because we are measuring your child's test results at a research laboratory, obtaining the results may take longer than for a typical medical exam.

You will also have the option to receive information on chemical exposures from your child's biological samples (blood and urine). If you would like to receive information about the levels of chemicals, we will return the results to you by email and we will compare the levels in your child's samples to the typical levels found in other study participants. However, because this is a research study, those results can take a long time to process.

Whom do I contact if I have questions, concerns or feedback about my experience?

To reach the research team: Please see the "Investigator Contact Information" section at the beginning of this form.

To reach someone outside of the research team: This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at [612-625-1650](tel:612-625-1650) (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You are having difficulty reaching the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide feedback about this research.

Will I have a chance to provide feedback about the study?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What else do I need to know?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or insurance company. If you think that your child has suffered a research related injury, let the study

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team know right away.

In the event of death, information about the causes of death or events leading to death will be sought, including the coroner's report, medical records (if death takes place in a hospital), and the state health department death record.

Will I be compensated for my participation?

You as the parent/guardian will receive compensation for your child's completion of parts of this study. This includes \$15 for completing your child's online questionnaires (initial and follow-up), \$15 for your child's participation in a Family Health Visit, and \$5 for returning your child's silicone bracelet. The gift cards for completing the questionnaire and the health visit will be sent at the same time after your child has attended the health visit. Payment will be made through e-gift cards. If your child completes the annual adolescent survey, they will receive a \$5 e-gift card each time, delivered directly to them.

Use of Identifiable Health Information

We are committed to respect privacy and to keep personal information confidential. When choosing to take part in this study, you are giving us the permission to use your child's personal health information that includes health information in medical records and information that can identify him or her. For example, personal health information may include name, address, phone number or social security number. Those persons who get your child's health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings. No identifying information would be included in the reports.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality (CoC). The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

You can also find the CoC language on our website: <https://z.umn.edu/10KFS-CoC>.

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Final step to consent to be in the study

At this time, we ask that you indicate your willingness to participate in the study activities by checking the agree/do not agree or Yes/No option next to each. There are a total of eight activities for you to consider. **Please note that if you answer “No” or “I do not agree” to any of the required items, your child is not eligible to participate in the study.**

Please initial one box per question number.			
1.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Contact by research staff (required): I agree to allow research staff to contact me periodically to ask questions about my child’s health and where he/she lives.
2.	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree	Release of my child’s study results to a person I indicate (optional): I (agree/do not agree) to allow research staff to release my findings from participation and non-genetic tests to the physician, clinic or person that I designate.
3.	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree	Use of my child’s biological samples by research staff (required): I (agree/do not agree) to allow the study researchers and other scientists not associated with the 10,000 Families Study to study my child’s samples (blood, cells, saliva, urine, stool, nail and hair) in current and future research.
4.	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree	Use of my child’s de-identified data in scientific databases (required): I (agree/do not agree) to allow the research study staff to deposit my child’s de-identified data in scientific databases maintained by the National Institutes of Health.
5.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	I would like to receive information about the levels of chemicals found on my child’s wristband and in their urine and/or blood
6.	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree	Use of my child's genetic and non-genetic information by commercial or for-profit companies (optional) : I (agree/do not agree) to allow commercial or for-profit companies that are not part of this research study to use my child’s de-identified stored genetic and non-genetic information and samples to develop new diagnostic tests and medical treatments that may benefit people.

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7.	<input type="checkbox"/> I agree	<input type="checkbox"/> I do not agree	<p>Contact about future studies that may interest my child (optional):</p> <p>I (agree/do not agree) to allow research staff to contact me about my interest in my child's participation in future health-related studies.</p>
8.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<p>NOTE: Genetic testing is NOT planned at this time. These results may not be available for a long period of time.</p> <p>Rarely, the researchers may find that a genetic attribute could place your child at high risk for a serious medical condition. If we find this type of genetic attribute in your child's sample <i>and</i> there are steps you can take to prevent this condition from happening, we can tell you about this risk for a medical condition. You have the choice of whether or not you want us to tell you about this type of information if it is found in your child's sample.</p> <p>If our lab identifies a medically actionable finding in your child's sample and you want to receive these findings, we will ask that the healthcare team be contacted by a genetic counselor. The genetic counselor will explain the following:</p> <ul style="list-style-type: none"> • What type of medically actionable information was found in your child's sample. • If the genetic results we obtain are not found in a clinically certified laboratory, the results cannot be used for healthcare. The genetic counselor will help your healthcare team find a clinical laboratory. <p>The cost of confirming medically actionable findings in a clinical laboratory will not be covered by this study. Any medical care that arises from this finding is part of the regular medical care and will not be paid for by this study.</p> <p>We will NOT report ANY medically actionable genetic findings for adult onset diseases to parents of children (age < 18 years). Once a child reaches the age of 18 years we will re-consent them regarding their preference for medically actionable genetic findings and report their results according to their preference.</p> <p>Would you like to receive potentially medically actionable information?</p>

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Your signature documents your permission for you and the named child to take part in this research.

Printed name of child participant

Printed name of parent or guardian

Signature of parent or guardian

Date

Printed name of person obtaining consent

Signature of person obtaining consent

Date

Please note that you will received a signed copy of this consent form.