Parental Permission Form

Title of Research Study: STUDY00000877– Ten Thousand Families Study

Investigator Team: Logan G. Spector, PhD, Heather Nelson, PhD, DeAnn Lazovich, PhD, Jenny Poynter, PhD, Anna Prizment, PhD, Cavan Reilly, PhD and Bharat Thyagarajan, MD, PhD

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

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.

Who can I talk to?
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

<table>
<thead>
<tr>
<th>Researcher Name: Logan G. Spector, PhD</th>
<th>Study Staff (if applicable): Michelle Roesler</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone Number: 612-626-2902</td>
<td>Phone Number: 1-866-434-9879</td>
</tr>
<tr>
<td>Email Address: <a href="mailto:spector@umn.edu">spector@umn.edu</a></td>
<td>Email Address: <a href="mailto:TenKFS@umn.edu">TenKFS@umn.edu</a></td>
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What is medical 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 about our world. Medical 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. You, as an individual, may or may not be helped by participating in a research study.

As the parent or guardian, what should my child and I know about being in a research study?
- Someone will 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 my child being asked to take part in this research study?
Your child may be eligible to participate in a research study--the 10,000 Families Study--at the University of Minnesota. We are inviting your child to participate in a pilot study that will inform a large family-based cohort study being done all across Minnesota. We are contacting you because you enrolled in the study and you told us you have a child between the ages of 12 and 17 who may be interested in participating.
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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.

What is a pilot study?
A pilot study is a smaller study done to test feasibility, time, and cost of doing a study and to learn about unexpected results. Pilot studies are important because they allow researchers to improve study procedures and participant experiences before a large cohort study is conducted.

What is a family-based study?
A family-based study includes at least two biological relatives from at least two different 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.

Why is this research being done?
Studies similar to the 10,000 Families Study have helped our understanding of many conditions, diseases, and risk factors that arise in birth, childhood, and adult years, into old age. We are starting a new Minnesota family-based study because we want to use new, modern tools that will help us understand why some people stay healthy and others develop heart disease, cancer, diabetes, and other related diseases in adulthood. Multigenerational studies are important because some risk factors are experienced by more than one generation in a family due to inheritance or experiences shared by family members.

How long will the research last?
We expect that your child’s participation in this research study will continue as long as you and your child agree while the study is active.

How many children / parents will be studied?
One hundred families will be invited to participate in the pilot of what will eventually become a study of ten thousand families. The pilot will include approximately five hundred people including approximately 150 children.

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 a 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. Parents may complete the questionnaires on-line or on paper before the Family Health Fair or in-person at the Family Health Fair. The initial parental questionnaires will take about 45
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minutes to complete. At the Family Health Fair, your child will be asked to complete a questionnaire about smoking, drinking, drug use, diet and physical activity. Your child will need about 20-30 minutes to complete this questionnaire.

2. **Family Health Fair**: Your child will be asked to attend a family health fair at a location reasonably convenient to you. A parent, guardian or designated adult (e.g., aunt, grandparent) must accompany the child. The purpose of the Family Health Fair is to take in-person measurements and biological samples. These are described below.

- **Height, weight, waist and hip size, percent body fat measurements, pulse, lung function, grip strength 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 will be asked to complete a hearing test.
- **3-dimensional photo**: We will take your child's picture with a 3D Facial Imaging Camera. The camera creates a three-dimensional image of the participants face, including images of facial skeleton, soft tissue, and teeth.
- **Saliva sample**: We will collect a sample of your child's saliva using a ‘spit’ kit.
- **Urine sample**: We will collect a sample of your child’s urine.
- **Blood Sample**: A trained technician will draw samples of your child’s blood (15-30 milliliters or approximately 1 to 2 tablespoons) 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 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 will 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 gut and the remaining sample will be used for future research studies.

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 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 for your child. If you decide you would like these kinds of results and if our laboratory should identify a genetic variant that impacts medical care, called “medically actionable findings”, we will confirm these results in a clinically certified laboratory before we return results to you. If you decide to receive potentially medically actionable results for your child, the genetic test results will be given to you and your child’s primary physician by a Genetic Counselor. Costs of follow up tests including confirmation of research findings and medical care would be billed in an
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ordinary manner to you or your insurance company and you will be responsible for these costs.

5. **Release your child’s 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. **Allow researchers to link information** from state cancer registries or similar systems about diseases your child may have had or may develop in the future.

7. **Agree to be contacted in the future:** We will contact you by phone about 6 months after your child’s participation in the Family Health Fair 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 answer questions for you about your child. We may ask you to update this person’s name during this interview. If in the future we do not have updated information to locate you, 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 your child’s annual follow up interview. 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 at any time and it will not be held against you. If you decide to leave the research study, contact the study staff so we can discard your child’s samples and withdraw your child's information from study databases. If you decide to withdraw your child from this study after your child’s DNA has been analyzed, your child’s genetic information will be discarded and will not be used in this portion of the study. However, research already done on those samples cannot be undone.

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 their smoking, drinking, drug use, diet and physical activity which might make them feel uncomfortable.

- **Medical care during the Family Health Fair:** In the unlikely event that during the family health fair your child should require medical care, first aid will be available.

- **Blood draw:** A skilled technician will draw your blood. 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.
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- **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.

- **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.
  - 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.

**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.

**Will it cost me anything for my child to participate in this research study?**
We will not charge you for costs associated with your child’s health measurements and biological sampling. We are unable to reimburse you for costs related your and your child’s time to participate, or for your family’s travel costs to the Family Health Fair.
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Will being in this study help me or my child in any way?
There will be no direct benefit to you or your child. We hope that the information learned from this study will benefit other people in the future.

What happens to the information collected for this research study?
A report from the Family Health Fair may be given to you or mailed to you. It is recommended that you discuss the findings with your child’s primary care physician. If your child does not have a personal health provider, our staff will 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 your child would receive from your health care 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 the results. Results from genetic tests will not be reported. Because we are measuring your test results at a research laboratory, obtaining the results may take longer than for a typical medical exam.

Your child’s specimens will be securely stored with limited access. We will hold them until no longer needed or until you tell us to destroy them. Blood, saliva, cells, hair, finger or toe nails and DNA samples will be identified only with a numerical code and sent to our laboratory for storage, or for detailed analysis. Some of the samples will be stored for an unlimited time, for future use in studies or in other research projects that have been approved by our research team.

In order for science to progress, researchers exchange scientific resources and information with strict precautions of confidentiality. We are asking for your permission to share your child’s data and samples, in a way that cannot be used to directly identify him or her, with researchers who are not part of this study.

We will not ask about child abuse, but if your child tells us about child abuse or neglect, we are legally obligated to report it to state authorities.

- **Use of data and samples:**
  - In addition to study information and genetic data, portions of samples 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.
  - 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).
  - Neither your child nor you or 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
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ten 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 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, address, is removed. Access to this stored information will be controlled by the National Institutes of Health.
  - The National Institutes of Health is committed to protecting the confidentiality of all the information it receives, but will also comply with relevant laws, which might include Freedom of Information Act (FOIA) requests for de-identified information. This is explained on the following website: [http://www.nih.gov/icd/od/foia/efoia.htm](http://www.nih.gov/icd/od/foia/efoia.htm).

- **Use of medical record information**
  - We will ask for your child’s well-child visit medical records from records so that we can learn about his or her health. We will request your signed permission for our research staff to get a copy of the records.
  - If your child is seen at an emergency room, urgent care or clinic, or admitted to a hospital, we will ask that institution for his or her medical records so that we can learn about his or her health. We will request your signed permission for our research staff to get a copy of the records from the hospital, clinic, emergency department/urgent care or cancer registry.
  - We may ask for records from your child’s doctor for certain office or clinic visits that are related to the health questionnaire if your child has been diagnosed with one of the diseases that we are studying.
  - We will use a signed medical release to obtain these records. You can cancel this authorization at any time by contacting study staff listed at the top of this form.
  - 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.

**Who do I contact if my child or I have questions, concerns or feedback about our experience?**

This research has been reviewed and approved by an Institutional Review Board (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 or go to www.irb.umn.edu/report.html. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach 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 input about this research.
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Will my child or I have a chance to provide feedback after the study is over?

At certain points during the study, you and your child might be asked to complete a survey about your experience as research participants. You or your child do not have to complete the survey if you do not want to. If you or your child do choose to complete the survey, your responses will be anonymous.

If you would like to share feedback, please contact the study team or the Human Research Protection Program (HRPP). See the “Who Can I Talk To?” section of this form for study team and HRPP contact information.

What else do my child and 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 team know right away.

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 or your child based on genetic information. This law generally will protect you and your child in the following ways:

- Health insurance companies and group health plans may not request genetic information that we get from this research.
- Health insurance companies and group health plans may not use genetic information when making decisions regarding eligibility or premiums.
- Employers with 15 or more employees may not use genetic information that we get from this research when making a decision to hire, promote, or fire your child or when setting the terms of employment.

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

Will I be compensated for my participation?

You, your child or your family members will not be compensated for participation in this study.

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.
## Parental Permission Form

### Ten Thousand Families Study

Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

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<thead>
<tr>
<th>Please initial one box per question number.</th>
<th>Contact by research staff (required):</th>
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<tbody>
<tr>
<td>1.</td>
<td>I agree to allow research staff to contact me in about six months and routinely (not more than once a year) to ask questions about my child’s health and where he/she lives.</td>
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<th>2.</th>
<th>Release of my child’s study results to a person I indicate (optional):</th>
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<td></td>
<td>I (agree/do not agree) to allow research staff to release my findings from participation and <strong>non-genetic</strong> tests to the physician, clinic or person that I designate.</td>
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<th>3.</th>
<th>Use of my child’s biological samples by research staff (required):</th>
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<td></td>
<td>I (agree/do not agree) to allow the <strong>study researchers and research team</strong> to study my child’s samples (blood, cells, saliva, urine, stool, nail and hair) in current and future research.</td>
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<th>4.</th>
<th>Use of my child’s biological samples by <strong>other scientists</strong> (optional):</th>
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<tr>
<td></td>
<td>I (agree/do not agree) to allow <strong>scientists not associated with</strong> future research of the 10,000 Families Study.</td>
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<th>5.</th>
<th>Use of samples of my child’s <strong>genetic material</strong> by research staff (required):</th>
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<tr>
<td></td>
<td>I (agree/do not agree) to allow the research study staff to work with and use stored genetic material (DNA/RNA) for current and future research.</td>
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<th>6.</th>
<th>Use of my child’s samples of <strong>genetic material</strong> by <strong>other scientists</strong> (optional):</th>
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<td></td>
<td>I (agree/do not agree) to allow scientists and specialized laboratories not associated with this research study to study de-identified stored <strong>genetic</strong> data, information, and samples.</td>
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<th>7.</th>
<th>Use of my child's genetic and non-genetic information by <strong>commercial or for-profit companies</strong> (optional):</th>
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<td></td>
<td>I (agree/do not agree) to allow <strong>commercial or for-profit companies that are not part of this research study</strong> to use my child’s de-identified stored genetic and non-genetic information and samples to develop new diagnostic tests and</td>
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<th><strong>medical treatments that may benefit people.</strong></th>
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<td>8.</td>
<td></td>
<td><strong>Contact about future studies that may interest my child (optional):</strong></td>
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<td></td>
<td></td>
<td>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.</td>
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<tr>
<td>9.</td>
<td>Yes</td>
<td><strong>NOTE: Genetic testing is NOT planned at this time. These results may not be available for a long period of time.</strong></td>
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<td></td>
<td>No</td>
<td>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 and 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.</td>
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<td>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:</td>
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<td>- What type of medically actionable information was found in your child’s sample.</td>
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<td>- 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.</td>
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<td></td>
<td></td>
<td>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.</td>
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<td></td>
<td></td>
<td>We will NOT report ANY medically actionable genetic findings for adult onset diseases to parents of children (age &lt; 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.</td>
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<tr>
<td></td>
<td></td>
<td>Would you like to receive potentially medically actionable information?</td>
</tr>
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</table>
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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  
Date

Signature of parent or guardian  
Date

Signature of person obtaining consent and assent  
Date

Printed name of person obtaining consent and assent