Site Study Title: PreciselyYou: A Helix Research Network study

Site Principal Investigator: David Kirk, MD

Member Site Consent Form (HRN Version 6, 03/15/2024)

Consent and Authorization to Participate in a Research Study

Study Summary

We are asking you to consider taking part in a research study being conducted by Dr. David Kirk at WakeMed *and sponsored by Helix, Inc., a clinical laboratory and population genomics company ("Helix")*. The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team may also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this research study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends, and health care team.

Purpose of the study: The researchers want to study DNA and its connection to your health. DNA is in your blood, your saliva, and other tissues in your body. DNA is the unique instructions you are born with that tell your body how to work. By looking at DNA, you can learn information about your health, certain traits, and even your ancestral roots. DNA is also called your genetic information. DNA is mostly the same from person to person, but there are slight differences. Some of these differences may be important. We are still learning how DNA impacts health. The study will look at the DNA of many different people from many different backgrounds and combine it with information from their health records. The study's primary goal is to understand how learning about DNA can help improve health care for individuals, families, and communities.

This study is part of a research network. This means that information and samples collected as part of this study will be entered into a database and will be used by approved researchers to perform many studies over time.

Study Procedures: In order to participate in this study, you must be 18 years of age or older, and have not received a stem cell transplant or a bone marrow transplant from a donor. You will provide a sample for DNA sequencing. Sequencing is the process of reading the letters of your DNA. This study may sequence your whole genome. We provide more information about what "whole genome" means later in this consent form. Once you have given us your sample, your participation will not take a lot of your time. The research team will collect health information about you from your medical record and may ask you questions about your health using surveys or other data collection tools. Over time, you may be asked to provide additional samples for research. There is no planned end date for this study. If you choose to enroll, you will be part of this study until you withdraw or until the study ends.

Possible Risks: There are risks to participating in a research study. Some of the most likely risks of participating in this study include:

- The main risk of participating in this study is loss of privacy. We take many steps to protect your information, but as with any research study, there is always a chance that your identity could become known.
- There is a small physical risk if you give a blood sample. The most common risks are brief pain and bruising. There is also a small risk of infection. Some people may feel dizzy or rarely faint.
- Because this study includes the return of genetic results, you may experience worry or concern if a result is returned to you which may impact your health or the health of your family members. You may have additional healthcare expenses as a result of learning these results if they require you to seek additional care.
- There is a risk that companies that sell life insurance, disability insurance, or long-term care insurance could use your genetic information to make coverage decisions. However, there are laws that prevent health insurance companies and certain employers from using your genetic information to discriminate against you.

Possible Benefits: The main benefit of this study is to help researchers learn more about health and disease. You may benefit from participating in the study, but this cannot be guaranteed. You may consider the following to be potential benefits of participation:

- Learning information that could be important to your health.
- Learning information that could impact the health of your family members.

Your Other Options: You do not have to participate in this study. Your other choices may include taking part in another study. You may find it helpful to talk to your healthcare provider about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

Detailed Study Information

Introduction

We are asking you to consider taking part in a research study. Before you decide, it is important for you to know why the research is being done and what it will involve. This consent form contains important information about this study and what to expect if you decide to participate.

You can decide to participate by signing and dating the end of this form. If you decide to participate, you will receive a copy of this form for future reference.

Why am I being asked to take part in a research study?

You are being asked to participate in this study because you are a patient at WakeMed or you have learned about this study and are interested in participating. You must be at least 18 years old to participate.

Why is this research study being done?

Generally, the purposes of this study are:

- To collect samples, like blood and saliva, and health information from you in order to learn more about DNA (your genetic information) and its connection to health. Your DNA provides instructions for things like eye or hair color, height, and sometimes affects your health. The study will look at the DNA of many different people and combine it with information from their health records. This combined information may support research to discover the underlying causes of disease, to help understand who is at risk, what steps can be taken to prevent disease, and what treatments may work best for patients.
- To establish a research network, called the Helix Research Network, to help learn more about medical conditions and to improve human health through DNA research. A research network is a group of researchers, doctors, and institutions working together to share information and study human health.
- To return individual results about your DNA to you, your health care providers, and researchers in order to better understand how your DNA might impact your health both now and in the future.

WakeMed seeks to enroll approximately one hundred thousand people in this study over time, and Helix seeks to enroll at least one million people across all U.S. research sites.

What happens during the study, how long will it last, and what am I being asked to do?

When you agree to participate in PreciselyYou, you agree to:

- Collect a sample (saliva or blood) from you for DNA collection.
- Send your sample to our partner Helix, the sponsor of this study. Your sample will be linked to information that identifies you, like your name and date of birth, when it is sent.
- Helix is a clinical laboratory and population genomics company that will sequence the DNA in your sample. DNA sequencing is a process that is used to read your DNA. Helix will securely store your genetic information after sequencing your DNA and ensure it is correctly linked to you. We will study your DNA using whole exome or whole genome sequencing. **Whole exome sequencing** is a way of studying your genes, the parts of your DNA that tell your body how to function. **Whole genome sequencing** is a way of studying all the parts of your DNA, including the DNA in between genes. Because this study will last for many years, it is possible that some of the methods we will use to study DNA may not have been invented yet.
    - If Helix tested your DNA before you agreed to join this study, you may be able to contribute your genetic information to the study without providing a saliva sample.
    - In the future, if your healthcare provider orders a DNA test to help inform your healthcare, your provider may have the option to use the genetic information that was generated as part of your participation in the Helix Research Network that is stored by Helix to perform additional clinical tests, if you agree that your provider may do so. This means you would not need to submit another sample for testing,

and it means you may receive test results more quickly. If your healthcare provider orders this type of test (called a clinical or diagnostic test), they will ask you for your consent to the test and use of your genetic information at that time. Any future clinical or diagnostic test would be separate from this research study and would be billed to you or your insurance. **You always have the right to choose where you obtain healthcare services and determine how your genetic information is used for future clinical and diagnostic testing. Nothing in this consent form is intended to require or obligate you to agree to clinical reuse of the genetic information stored for you by Helix or to seek care from WakeMed or a particular healthcare provider.**

- Share your medical record information with Helix for research purposes on an ongoing basis. This information might include diseases or symptoms you have, results of medical tests, and medicines you are prescribed. To protect your privacy, before the information is added to the Helix Research Network Database, information that directly identifies you (such as your name) will be removed and replaced with a code. Helix will use this code, instead of your name, to combine your medical record information with your genetic information and store it securely in the Helix Research Network Database.
- Ask you questions about your health and your experiences using surveys or other data collection tools. Participating in follow-up surveys or additional data collection activities is optional.
- Tell you about results we get from studying your samples and information that might be important for your health and health care decisions.
- Request additional samples from you, like blood or urine, or cheek swab, or collect samples that were collected for clinical testing and are left over after clinical testing is complete. Providing additional samples is optional. These samples will be used for research.
    - If you agree to provide a blood sample, it may be collected during an already scheduled blood draw or you may be asked to give a sample separate from a scheduled draw (not more than two teaspoons at one time)
- Store your samples, health and genetic information in a research database at WakeMed for future research studies. The research database may include information that could directly identify you. WakeMed will control access to this database and only give access to approved researchers who work with WakeMed.
- Store your samples, health, and genetic information in a shared research database at Helix, the Helix Research Network database, and biobank and use this information for future research studies. This database will include information from Helix, WakeMed and the other health systems and institutions that are part of the research network. Your genetic and medical record information will be added to the Helix Research Network database, but will not include information that can directly identify you, such as your name.
    - Researchers that conduct future research using your samples, health and genetic information may work at many different types of institutions or companies.

This may include:

- WakeMed and its affiliates, providers, collaborators, and partners
- Helix and its collaborators and partners
- Other healthcare institutions participating in the Helix Research Network
- Health systems, universities, medical schools, or other research facilities
- Government agencies like the National Institutes of Health (NIH)
- Public agencies, foundations or other groups that conduct or sponsor research
- Companies that do medical research, like companies that develop medications or medical devices
- Other types of healthcare, technology or research companies
- Individuals and entities with access to public research databases into which the research data is placed

- Contact you in the future by WakeMed electronic portal, in-person, by phone, email, mail, and/or other means of communication used by WakeMed to get more information or tell you about other research studies. If you sign up for the optional Helix Account (explained in more detail below), you are also agreeing to let Helix re-contact you directly through your account. Helix may re-contact you for requests that may not be specific to WakeMed. For example, Helix may reach out to you about other research opportunities, including research studies matched to your personal genetic information. These requests and research opportunities are always voluntary. Any time you are re-contacted, you may choose not to participate, and it will not affect your overall participation in this study.
- Contact you for a new sample if the first sample you provide doesn't allow us to successfully sequence your DNA. Usually, this happens because of a quality issue with your first sample. Your WakeMed will reach out to you to collect another sample if one is needed. In some cases, you might also be contacted directly by Helix for another sample.

Currently, the study does not have a planned end date. If you no longer visit WakeMed for your healthcare, your samples and information will remain with Helix and/or WakeMed unless you withdraw from the study or until the study ends. We will not inform you of the details or purpose of specific research studies that will be conducted in the future with your samples, health and genetic information. Helix and/or WakeMed may provide summaries every so often, like a newsletter, with updates on how the study is progressing and any new discoveries.

In general, WakeMed and Helix will not reach out to you for your permission to participate in future studies that will use your samples and/or your health and genetic information unless WakeMed or Helix determines that your additional consent is required. If you do not want your information or samples to be used for future research, you should not participate in this study. In most cases, because the results from future research will not directly affect your health care, we will not share the individual results from these studies with you or your healthcare providers.

What health-related results will I get?

You may learn if you have inherited certain risk factors in your DNA that you might not otherwise know about because your family history or standard medical screening tests do not always identify risks for these conditions. Specifically, the genetic sequencing test, called “Helix Health”, will tell you about three actionable conditions. Actionable means if you know you have an increased risk based on your DNA, there are steps you and your healthcare providers may take to reduce or address your health risks. The three conditions are:

- A hereditary form of very high cholesterol that causes heart disease at an earlier age than the general population, known as *familial hypercholesterolemia (FH)*
- A hereditary form of breast and ovarian cancer syndrome (*HBOC*), specifically the BRCA1 and BRCA2 genes. Women with HBOC have an increased risk of developing breast, ovarian and certain other cancers. Men with HBOC have an increased risk of developing prostate, pancreatic and male breast cancer
- A hereditary type of colorectal cancer known as *Lynch Syndrome.* People with Lynch syndrome are more likely to get colorectal cancer at a younger age and are also at an increased risk of developing endometrial, ovarian, upper GI, brain, pancreatic and/or other cancers.

This information may allow you to screen for, prevent, or minimize the impact of these conditions. Only about 1-2% (1 or 2 people out of 100) will be found to have a risk for one of these conditions. This means that 98-99% of people (98-99 out of 100) will learn that they do not have an increased risk for one of these conditions based on the test. In addition, it is important to note, this is a screening test which means it does not evaluate all genes associated with cancer and heart disease. Also, this test may not identify all DNA variants in the genes that are tested.

You may receive these results in two ways:

- First, these results will be returned to your medical record. You cannot opt out of having your DNA health results placed in your medical record. Once this information is in your medical record it cannot be removed even if you withdraw from the research study.
- Second, you will also be able to access these results through your Helix Account, if you choose to create one. There may be a delay between when your results are available in your medical record and when you are able to access them through your Helix account.

If your test reveals a positive (or clinically actionable) result for any of the three conditions above, the study team will reach out to you, and you will have the opportunity to speak with a genetic counselor at no charge to you. A genetic counselor is a medical professional specifically trained to help you understand how your genetic information may impact your health and the health of your family members, discuss medical recommendations, and discuss how you can approach sharing any important information with others. An initial discussion between you and a genetic counselor will be coordinated by Helix and WakeMed.

You may also want to speak with your healthcare provider about the results of this test, and whether additional or different genetic testing and general screening may be appropriate for you. In addition, if you have a personal or family history of a condition covered by this test, it is important to know the results of this test do not change a previous diagnosis or any family history risk you might have. Results from this research study do not take the place of regular screening guidelines such as colonoscopies or mammograms. You may contact your healthcare provider at WakeMed (if you have one) or any healthcare provider, and your participation in this study does not require that you contact a WakeMed healthcare provider regarding any of your results.

In rare circumstances the interpretation of the results you receive may change. This may be due to updates to what is known about a genetic variant you may carry that may change how it is understood to affect your risk for one of the listed conditions. If new information becomes available and your report is updated, you will be contacted by the study team to discuss what this may mean for you. The vast majority of people will not see any change in their initial results.

Over time, more health-related results may be returned to you as researchers and clinicians learn more about how DNA impacts human health.

What is a Helix account and what other results may I get?

When you agree to participate in PreciselyYou you will have the option to create a personal account with Helix (the laboratory and research sponsor). This account will allow you to:

- Access easy-to-understand information about your DNA, including information about your ancestry and non-medical traits (such as how you process caffeine and what type of ear wax you have).
- Receive updates or questions directly from Helix. Updates might include new discoveries from the research, stories of other participants, and stories about researchers.

Creating a Helix account is the only way to access the results from your ancestry and non-medical traits. Your ancestry and non-medical traits will not be placed in your medical record.

The results about ancestry and traits will be available for you to review before your DNA health results are available. Your DNA health results will take longer because they go through additional quality and scientific review.

Please note: The results of your ancestry and traits may be different from what you understand to be true about yourself. It is important to understand that trait and ancestry results are estimates based on DNA patterns rather than definitive information. This is different from Helix Health testing that looks for the presence or absence of specific genetic variants. Such variants have extensive evidence from the medical community linking them to risk for disease.

What are the possible risks of participating in this study?

There are risks to participating in any research study. Some of the more commonly known risks are described below. Taking part in the study, including use of your information in the Helix Research Network, may have additional risks that we don't know about yet. We will tell you if we learn anything that might change your decision to take part in the study.

Loss of Confidentiality/Privacy: The main risk of participating in this study is to your privacy. Both Helix and WakeMed take many steps to protect the confidentiality of your information, but as with any research study, we cannot guarantee that your identity will never become known. Information about you that does not directly identify you, including genetic information, may be placed into public databases where the information might be capable of re-identification if combined with other data sources. Through such databases, researchers from around the world would have access to your data for future research. There is a risk that researchers may connect information from this study to your personal information, even if the study data does not contain directly identifying information about you. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. As a result, it may be possible that genetic information from you could be used to identify them.

While the databases developed for this study will have processes in place to keep information secure, there is always a chance that a data breach might occur. This is when someone who does not have permission accesses your information. While the risk of someone misusing your information is very low, there is still a possibility.

Sample Collection: There is a small physical risk if you give an [optional] blood sample. The most common risks are brief pain and bruising. There is also a small risk of infection. Some people may feel dizzy or rarely faint. There are no known risks to providing a saliva sample, urine sample or cheek swab.

DNA Results: Medical information created by this research study, such as genetic findings that may be important for your health care, may become part of your hospital medical record and may be forwarded to your healthcare provider. You may experience anxiety or concern if a result is returned to you which may impact your health or the health of your family members. You may have additional health care expenses if you decide to seek care based on your results. Some of these medical steps may not be fully covered by insurance and may result in costs for you. Learning about inherited risks can also have an impact on risks to your biological relatives.

Genetic Information Nondiscrimination Act (GINA): GINA is a federal law that 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. However, they may request results that have been put into your medical record.

- 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 when making a decision to hire, promote, or fire you, or when setting the terms of your employment.

All health insurance companies, and group health plans must follow this law, but this law doesn't protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Some states have added laws that further protect against discrimination from these companies. Neither WakeMed nor Helix will sell your genetic information to insurance companies.

Please note: Members of the US military, Veterans, Indian Health Services and Federal employees may not have the same protections under this law. More information about GINA can be found at www.ginahelp.org or you can ask a member of the research team to give you additional details about GINA.

Additional incidental results about you:
There is a small chance that during the genetic testing (i.e sample analysis) portion of this study, researchers could discover something unexpected that might be very important to your health or medical care right now, or that may affect how your sample is being processed in the lab. If this happens, the WakeMed study team may contact you to discuss the result and see if you want to learn more. Learning or providing a new sample more is always optional. The cost of any testing or follow up related to incidental results would not be covered by this research study. Any resulting costs will be billed to you or your insurance company.

In addition to the risks noted above, taking part in the Helix Research Network may have additional risks that we don't know about yet. We will tell you if we learn anything that might change your decision to take part.

What are the possible benefits for participating in this study?

The main benefit of this study is to help researchers learn more about health and disease. The more we understand, the more we can improve the health of individuals and communities.

There are no direct benefits to you for participating in this study. There is a chance that researchers might find information that could be important to your health. Over time, it is possible that other results will be made available to you. Some of this information could also have an impact on your health. There is also a chance that information you learn could impact the health of your family members. Most people will not learn information from the study that will immediately impact their or their family's health care.

Will I be paid to take part in the research?

You will not be paid to participate in the study. We may use your samples and information to develop new products or medical tests to be sold. Helix and WakeMed may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

It is possible that researchers and their organizations may potentially benefit from the sharing of the information or sale from the discoveries they make. You will not have any financial or other rights to these discoveries.

Does it cost me anything to participate in the study?

There is no cost to you or to your insurance company for being a part of this study.

If the test (described above) finds that you have a clinically actionable result, you will be able to speak with a genetic counselor at no charge to you. Any other medical appointments or testing you pursue will be billed to you and/or your health insurance provider. For example, if a test result shows that you may have an increased chance of getting cancer, then your healthcare provider may want you to have earlier or more frequent screening. The cost of screening may be covered by your health insurance or, if your health insurance policy does not cover them, you will have to pay for the screenings.

Do the researchers have monetary interests tied to this study?

It is possible that certain researchers, or the institutions taking part in this study, may have a financial interest in the outcome of this study. This means that Helix, the sponsor of this study, and the institutions participating in the study may receive payments based on the success of this research project.

However, Helix and the researchers and institutions who participate in the research network are committed to conducting research with integrity and without bias. If you have any questions about this, please contact WakeMed.

How will you protect my privacy and confidentiality?

Your privacy is very important to us, and we take many steps to protect it. Here are some of the steps we will take:

- Your samples will be stored in a secure biobank by Helix or WakeMed.
- Your information (your genetic information and your medical record information) will be stored in secure databases.
- Your genetic information and your medical record information will be assigned a unique code before the information is transferred to the Helix Research Network Database.
- We will limit and keep track of who can see this information.
- We will limit who is allowed to see information that could identify you, like your name or contact information.
- Researchers who have access to your information must be trained to work with this type of information.

- Researchers must agree to follow certain rules, like agreeing to not re-identify you.
- We will tell you if we become aware of a data breach that impacts your information.
- All researchers go through an approval process before gaining access to your information. The lead researcher for the study (the Principal Investigator) will participate in a committee that includes researchers from other health systems that do similar research. This committee is responsible for setting standards for access to your information.
- Researchers plan to publish the results of their research. As part of the publication process, researchers may be asked to make certain information available to other researchers. We will not include information that directly identifies you in any publications.

Your identity will be kept as confidential as possible as permitted within the law. However, people from Helix, regulatory authorities (including the United States Food and Drug Administration), and the Institutional Review Board (who protects the rights of research participants) have the right to inspect study records, including identifiable information about you, to verify the compliance of study procedures and data.

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

Do I have to participate in the study and what are my alternatives?

No, participation in this study is completely voluntary. Whether or not you choose to participate, it will not impact the care you receive at WakeMed. Your decision to not take part will not result in any penalty or loss of benefits and will not affect the medical care or benefits to which you are otherwise entitled.

If you decide you do not want to participate in this research study, you may still participate in other studies. Your alternative to participating in this study is not to participate.

What if I participate now and change my mind later or I am removed from the study?

You may withdraw from the study at any time for any reason. Your decision to withdraw will not result in any penalty or loss of benefits and will not affect the medical care or benefits to which you are otherwise entitled.

In order to withdraw, please send an email to PreciselyYou@wakemed.org. If you withdraw from the study, you will no longer receive any emails or other communication as part of the study. Any information that has already been added to your medical record will remain in your medical record. However, no new information from the study will go into your medical record.

Additionally, you may ask us to delete your information and destroy any stored samples. Any information and samples that WakeMed has stored that are linked to you will be deleted, although it may take some time for this request to be processed and fulfilled because certain laws may require WakeMed and Helix to retain the information for a certain amount of time. If this is the case, we will let you know. This will not impact or delay your withdrawal from the study. If you ask us to delete your genetic information, you and your healthcare providers will not be able to use it for future clinical DNA tests.

As part of this study, some of your information has been stripped of direct identifiers, meaning the information is no longer linked to you directly. Any of your information that has already been stripped of direct identifiers and shared with researchers cannot be withdrawn or deleted because the researchers have no way to know that it is your data. That means that your genetic and health information, without any direct identifiers, will continue to be used by the researchers and may be used for future research.

You may be taken off the research study for any reason including:

- If the sample(s) you provide are not able to be successfully analyzed
- It is considered to be in your best interest
- A decision is made to end the study
- Other unforeseen reasons that make it necessary to stop your participation in the research study

What happens if I become sick or injured because I took part in the study?

If you think you may have been injured due to your participation in this study, you should tell the Principal Investigator about it as soon as possible.

Your healthcare provider will offer you the care needed to treat injuries directly resulting from taking part in research. These treatments will be billed to you or your insurance company. You will be responsible for any payments from this treatment, including co-pays or deductibles. There are no plans to give you compensation for any injuries.

Helix, the sponsor of this study, has not set aside any money to pay for research-related injuries or treatments. You do not give up any of your legal rights by signing this form.

Who can answer questions I have about the study?

If you have questions about the study, concerns, or complaints, to offer input or to report a research-related injury or harm, you should contact the Principal Investigator or study staff as listed below:

WakeMed
Dr. David Kirk – Principal Investigator
919-350-9696

If you have questions regarding your Helix account, you may contact Support@helix.com or by calling toll-free at 1-844-211-2070.

If you have questions about your rights as a research participant or do not want to talk to the study staff, you can contact the Institutional Review Board (IRB). The purpose of the IRB is to review studies to ensure your rights as a research participant are protected:

Salus IRB
800-472-3241 or subject@salusirb.com
Reference study: 21143

Documentation of Consent:

My signature below indicates that I agree to the following:

- I have had all of my questions answered about the study
- I have had time to review the study and read the consent form
- I am willing to participate in the study
- I have been told my participation is voluntary, will not affect my care, and that I can withdraw at any time
- My contact information may be used to tell me about studies that are not part of the Helix Research Network
- Researchers will do future studies using the information and samples collected as part of this study. Their research may be on nearly any topic.

Documentation of Eligibility:

My signature below confirms that the following are true:

- I am 18 years and older
- I am willing and able to comply with all aspects of the protocol
- I have not had an allogenic (“donor”) bone marrow transplant
- I have not had an allogenic (“donor”) stem cell transplant

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

For adult participants unable to consent, permission is given by the Legally Authorized Representative (LAR):

Name of LAR (Please Print)	*LAR Signature*	*Date*

**Provide description below of LAR’s authority to serve as the participant’s representative (parent, guardian, power of attorney, Etc.):*

Individual Conducting the Consent Process:
(This section to be completed when consent process is conducted by study team either in person or remotely.)

Date consent discussion was initiated: _____

Signature of individual obtaining consent: _____

Printed name of individual: _____

Date: _____

Authorization to Use and Disclose Health Information

In order to conduct the research study described in this form, the Principal Investigator and study staff must obtain, use, and share personal information about you, including your health information and information that can identify you. Protected health information (PHI) is information about your health or your medical care that was collected by a healthcare provider that can be used to identify you. WakeMed, where you are participating in this study, is required by law to protect your health information and must have your permission to use or share health information that identifies you for this research study.

What PHI will be shared?

- Existing and future medical records and the data contained within such records, including mental health records and other records linked to your medical records
- New health information created from study-related tests, procedures, visits and/or questionnaires.
- The information you give will include your entire medical record. This includes the following information. If you do not want to share this information, you should not participate in the study.
    - Information pertaining to drug and alcohol abuse, diagnosis or treatment.
    - Information pertaining to HIV/AIDS testing and treatment.
    - Genetic testing information.
    - Information pertaining to mental health diagnosis or treatment.

Your PHI will be shared in order to do the following:

- Conduct the research as described in this form, including future research and related research
- To contact you about future research studies
- For purposes of creating a Helix account
- To ensure the research meets legal and other requirements
- Conduct public health activities which include reporting of adverse events or situations where you may be at risk or harm
- Better understand the diseases being studied and to improve the design of future studies
- To evaluate the results of the study

Who will your PHI be shared with?

- WakeMed and its affiliated clinicians, providers and entities participating in the research
- Helix, the study sponsor, including any entity or contractor engaged by Helix to support the research
- Helix's interpretation partners and other entities or contractors engaged by Helix to support the clinical return of genetic results
- Members of the Helix Research Network
- Individuals and entities with access to publicly accessible research databases into which the study data are placed

- Federal and state agencies or other domestic government bodies if required by law and/or necessary for oversight purposes. A representative from the FDA may review your medical records.
- Hospital accrediting agencies
- The Institutional Review Board

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

What if I decide not to allow the use of my PHI?
You do not have to sign this form. If you do not sign this form, you cannot take part in this research study. Choosing not to give this Authorization or canceling your authorization will have no effect on your regular health care treatment, payment, or benefits.

May I withdraw or revoke (cancel) my permission?
Yes. You may withdraw your permission to use and disclose your PHI at any time for any reason. You can do this by sending written notice to the Principal Investigator. If you withdraw your permission, you will not be able to continue being in the research study.

What happens if I want to withdraw my authorization?
Information that has already been gathered may still be used and given to others. If you withdraw your permission, no new PHI will be gathered.

Will my authorization expire?
This Authorization will continue until the end of the study, unless you withdraw it in writing before then.

Documentation of Authorization:

- My signature below indicates I authorize you to use and disclose PHI about me for this study, as you have explained in this document.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

For adult participants unable to authorize, permission is given by the Legally Authorized Representative (LAR):

Name of LAR (Please Print)	LAR Signature	Date

*Provide description below of LAR's authority to serve as the participant's representative (parent, guardian, power of attorney, Etc.):