Site Study Title: In Our DNA SC: A Helix Research Network study

Site Principal Investigator: Daniel Judge, 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. Daniel Judge at the Medical University of South Carolina (MUSC) and in partnership with Helix, Inc., a population genomics company and clinical laboratory ("Helix"). The first part of this consent form gives you a summary of this research 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 tells 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. This study will look at the DNA of many different people from many different backgrounds and combine it with information from their medical records. This study's primary goal is to understand how learning about DNA can help improve health care for individuals, families, and the 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 larger 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 any 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 signed 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 MUSC or you have learned about this study and are interested in participating. You must be at least 18 years old and have not received a stem cell transplant or a bone marrow transplant from a donor 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 DNA of many different people and combine it with information from their medical 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 healthcare providers, and researchers in order to better understand how your DNA might impact your health both now and in the future.

MUSC's In Our DNA SC aims to enroll 100,000 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 **In Our DNA SC**, you agree to:

- Collect a sample (saliva or blood) from you for DNA analysis.
- Send your sample to our partner Helix. Your sample will be linked to information that identifies you like your name and date of birth, when it is sent.
- Helix 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 another 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 In Our DNA SC 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 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 MUSC 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 health and genetic information in a research database at MUSC for future research studies. The research database may include information that could directly identify you. MUSC will control access to this database and only give access to approved researchers who work with MUSC.
- 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, MUSC, and the other health systems and institutions that are part of Helix's 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 for many different types of institutions and companies. This may include:
    - MUSC 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 electronic portal, in-person, by phone, email, mail, and/or other means of communication used by MUSC 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 MUSC. 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 does not allow us to successfully sequence your DNA. Usually, this happens because of a quality issue with your sample. Helix will reach out to you to collect another sample if one is needed.

Currently, the study does not have a planned end date. If you no longer visit MUSC for your healthcare, your samples and information will remain with Helix and/or MUSC 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 or health and genetic information. Helix and/or MUSC may provide summaries every so often, like a newsletter, with updates on how the study is progressing and any new discoveries.

In general, MUSC 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 MUSC 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 healthcare, 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 provider may take to reduce or address your health risks. The three conditions are:

- 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.
- A hereditary form of very high cholesterol that causes heart disease at an earlier age than the general population, known as *familial hypercholesterolemia (FH).*

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 will 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 MUSC.

You may want to speak your healthcare provider, whether they are an MUSC provider or not, about the results of this test, and whether additional or different genetic testing and general screening may be appropriate for you.

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.

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 which may change how it is understood to affect your risk for one of the tested 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 In Our DNA SC you will have the option to create a personal account with Helix. 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 results will not be placed in your medical record.

The results about ancestry and non-medical 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 non-medical traits may be different from what you understand to be true about yourself. It is important to understand that ancestry and non-medical trait 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.

Loss of Confidentiality/Privacy: The main risk of participating in this study is to your privacy. Both Helix and MUSC 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 also 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 you and 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 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. 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, will become part of your medical record and may be accessible 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 need to take steps with your healthcare providers to address the health risk. You may have additional healthcare 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.

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 processed in the lab. If this happens, the MUSC study team may contact you to discuss the result and see if you want to learn more. Learning more or providing a new sample 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.

Risks related to insurance and employment

Federal law:

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 does not 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 MUSC 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.

South Carolina state laws: South Carolina law provides you with additional protection. SC law requires that your genetic information – from this research or from any test – be kept confidential. Our state law makes it illegal for an insurer to use your genetic information against you or any of your family. This applies to getting insurance or renewing insurance. Further, it prohibits us from sharing your genetic information with anyone except in a few narrow circumstances. One of these circumstances is sharing with a research study that you have consented to participate in, such as In Our DNA SC. This research must be approved by the Institutional Review Board and then we must take the steps described in this consent form to protect your identity.

You will still be responsible for paying for health care. Neither the Medical University of South Carolina nor Helix, will be responsible for your health care costs, even if care is needed for a condition revealed during research or clinical testing.

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

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 MUSC 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 medical institutions taking part in this study may have a financial interest in the outcome of this study. This means that the Helix 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 ensuring that its research and clinical activities are conducted with integrity and without bias. If you have any questions about this, please contact MUSC.

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.
- 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 and certified 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 getting 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 to 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.

Authorization to Use and Disclose (Release) Medical Information

As part of this research study, Dr. Daniel Judge and his research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Dr. Judge and his research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- Helix and any entity or contractor engaged by Helix to support the study, such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Health insurer or payer in order to secure payment for covered treatment; or
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

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. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and for conducting public health surveillance, investigations, or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

Medical Records

If you are an MUSC patient, you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

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

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time, for any reason. You should reach out to the study team if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care, will not result in any penalty or loss of benefits to which you are 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.

If you are an MUSC employee, your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

If you are a MUSC student, your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

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. 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 inourdnasc@musc.edu. 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 MUSC 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 MUSC 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 withdrawn from the research study by the Principal Investigator 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; or
- 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.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University of South Carolina, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study does not pay for your treatment, the Medical University of South Carolina and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Helix 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:

MUSC
Dr. Daniel Judge (843) 792-1659
Research Team (843) 876-0582

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

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Judge at (843) 792-1659. I may contact the Medical University of South Carolina Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of South Carolina Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

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 studies using the data and samples collected as part of this study. Their research may be on nearly any topic.

Documentation of Eligibility:

My signature below confirms that I meet 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.

Please scroll to the bottom of this form to provide an electronic signature.

Sign here only for paper (printed) consents.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

MUSC
Medical University of South Carolina

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

UNDERSTANDING YOUR PROTECTED HEALTH INFORMATION (PHI)
The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, MUSC Physicians Primary Care, MUSC Health Partners, MUSC Health Alliance, MUSC Strategic Ventures, LLC, and MUSC Strategic Ventures (MSV) Health, Inc.) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect, receive, or share this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

OUR PLEDGE REGARDING YOUR HEALTH INFORMATION
MUSC is committed to protecting the privacy of health information we create and obtain about you. This Notice tells you about the ways in which we may use and disclose health information about you. It also describes your rights and certain obligations we have regarding the use and disclosure of your health information. We are required by law to: (i) make sure your health information is protected; (ii) give you this Notice describing our legal duties and privacy practices with respect to your health information; and (iii) follow the terms of the Notice that is currently in effect.

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI) –

A. The following uses do NOT require your authorization, except where required by SC law:
1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
4. Business Associates. Your medical information could be disclosed to people or companies outside our Health System who provide services. These companies typically are required to sign special confidentiality agreements before accessing your information. They are also subject to fines by the federal government if they use/disclosure your information in a way that is not allowed by law.
5. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
6. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
7. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
8. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.
9. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement or for continuum of care when in the custody of law enforcement.
10. Military and Veterans. If you are a member of the U.S. or foreign armed forces, we may release your medical information as required by military command authorities.
11. Uses and disclosures about patients who have died. We may provide medical information to coroners, medical examiners and funeral directors so they may carry out their duties.
12. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.
13. Research. We may use and disclosure your medical information for research purposes. Most research projects are subject to Institutional Review Board (IRB) approval. The law allows some research to be done using your medical information without requiring your written approval.
14. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.
15. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.
16. Marketing. We may send you information on the latest treatment, support groups, reunions, and other resources affecting your health.
17. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.
18. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.
19. Disaster Relief Efforts. We may disclose your medical information to an entity assisting in disaster relief efforts so that your family can be notified about your condition.
Note: incidental uses and disclosures of PHI sometimes occur and are not considered to be a violation of your rights. Incidental uses or disclosures are by-products of otherwise permitted uses or disclosures which are limited in nature and cannot be reasonably prevented.

B. You may object to the following uses of PHI:
1. Inpatient hospital directories. Unless you tell us not to, we may include your name, location, general condition and religious affiliation in our patient directory so your family, friends and clergy can visit you and know how you are doing.

2. Information shared with family, friends or others. Unless you tell us not to, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.
3. Health plan. You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:
You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation.
1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.
2. Mental Health Records unless permitted under an exception in section A.
3. Substance Use Disorder Treatment records unless permitted under an exception in section A.
4. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:
A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**
B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI and/or appointment reminders in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.
C. The Right to See and Get Copies of Your PHI. You have the right to inspect and/or receive a copy (an electronic or paper copy) of your medical and billing records or any other of our records used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a cost-based fee. MUSC will act on a request for access or provide a copy usually within 30 days of receipt of the request. We may deny your request in limited circumstances. If you are denied access to your records, you may request that the denial be reviewed by a licensed health care professional. Additionally, we may use and disclose information through our secure patient portal which may allow you to view and communicate with certain health care providers in a secure manner. For more information see our https://mychart.musc.edu/mychart/
D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.
E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record. Notification will be provided within 60 days.
F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 349 / Charleston, SC 29425. The phone number is (843) 792-3881.
G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.
H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers, belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the U.S. Dept. of Health and Human Services, Office for Civil Rights. The address will be provided at your request or by visiting www.hhs.gov/ocr/privacy/hipaa/complaints/.

CHANGES TO THIS NOTICE

We reserve the right to change the terms of this Notice at any time. The changes will apply to all existing PHI we have about you.. This Notice will always contain the effective date and may be reviewed at http://academicdepartments.musc.edu/musc/about/compliance/privacy.html

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003 and was last revised on August 2018.