In Our DNA SC

A Community Health Research Project

VOLUNTEER OUTREACH TOOLKIT

MUSC
Medical University
of South Carolina

We appreciate your support in the In Our DNA SC research project. This Volunteer Outreach Toolkit is designed to provide you with the resources and details necessary to successfully volunteer with the In Our DNA SC project.

The mission of the **In Our DNA SC** community health research project is to reach as many South Carolina residents as possible to ensure access to genomic screening for all. We can't reach our goal without volunteers like you. Thank you for your support and commitment to the health of all in our state!

As a volunteer, you might support **In Our DNA SC** by:

- **staffing events and distributing In Our DNA SC brochures and program information** where **In Our DNA SC** is present, and/or
- **identifying and sharing opportunities for partnership** through your own community connections.

Have an idea that you think would work to get the word out? The **In Our DNA SC** team is always happy to collaborate on ideas that meet the needs of the community. Reach out via email at InOurDNASC@musc.edu.

Learn more about the diversity, equity, and inclusion efforts of the **In Our DNA SC** community health research project at www.web.musc.edu/inourdnasc.

How to Use This Toolkit

Due to the nature of research participant recruitment, this toolkit is designed to maintain recruitment compliance and integrity. When using the resources provided in this toolkit, we ask that the materials are used **as is without any modifications**. If you have any questions, comments, or concerns about the toolkit materials and their contents, please contact our team and a study staff member will be happy to assist: InOurDNASC@musc.edu or phone at 843-876-0582.

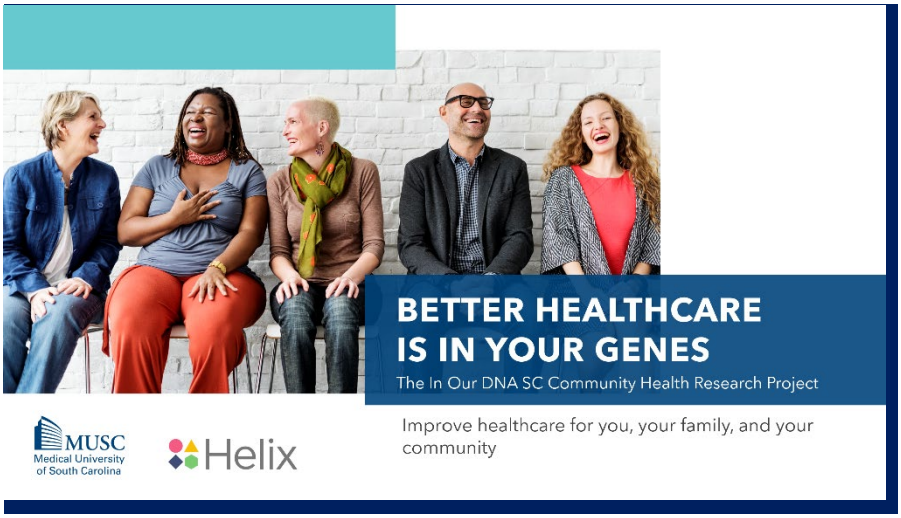
Materials included in the Volunteer Outreach Toolkit:

- **Study Overview PowerPoint Presentation**
- **Frequently Asked Questions**
- **InOurDNASC.org Website**
- **Brochure and Flyer**
- **Infographic**
- **Study Comprehension Questions Survey**

Helix

MUSC has teamed up with Helix, a leading population genomics company, to deliver genetic information to participants and their provider for proactive health care planning. This research program is part of the Helix Research network, which is combining genetic and health information from health partners across the country to power genetic discovery.

Study Overview PowerPoint Presentation



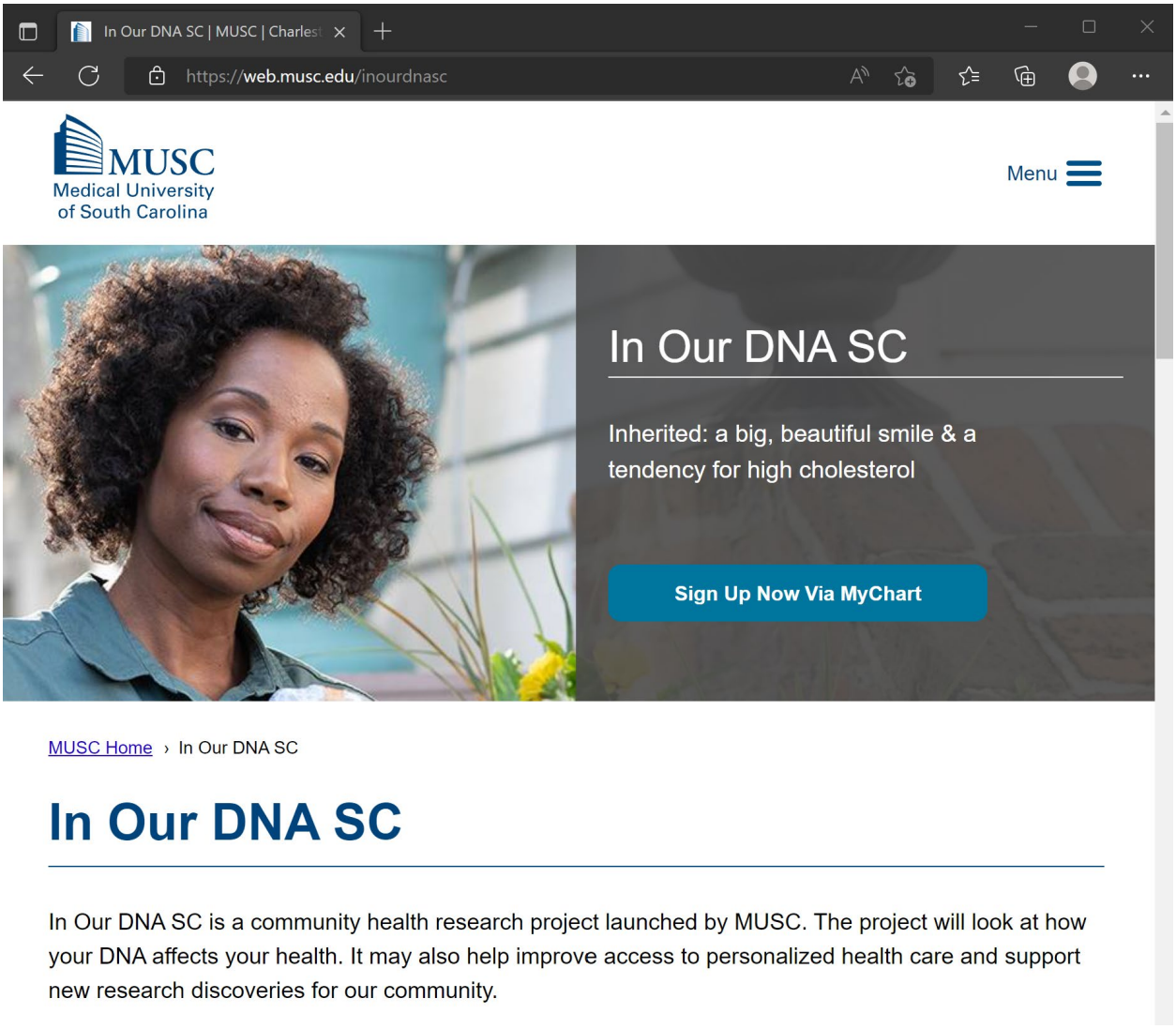
The **In Our DNA SC** Study Overview slide deck is designed to provide volunteers with the knowledge necessary to discuss study details with potential participants. **This slide deck is not to be shared with participants for recruitment purposes** but should be used as a reference for study details including consenting, sample collection, and return of results procedures.

Frequently Asked Questions

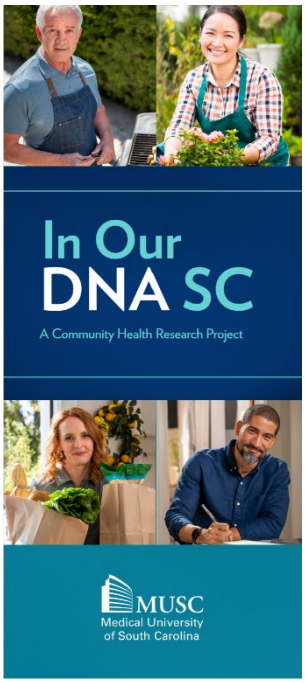
For additional guidance on how to discuss study details and answer questions about the study, we have provided a collective frequently asked questions document. The FAQ document highlights questions regarding several study topics: About **In Our DNA SC**, Eligibility & Recruitment, Genetic Test Results, Return of Result Processes, Privacy & Data Protection, and Research. Like the Study Overview Presentation, **this document should not be shared with participants for recruitment purposes** but should be used as a reference and/or script on how to answer study specific questions.

In Our DNA SC Website – InOurDNASC.org

The most important piece of information that can be given to potential participants is our website. Here, individuals can learn about the project, read frequently asked questions, review and sign the consent form, and receive updates about the study. All the recruitment materials provided in this toolkit contain the link and/or QR code to our website.

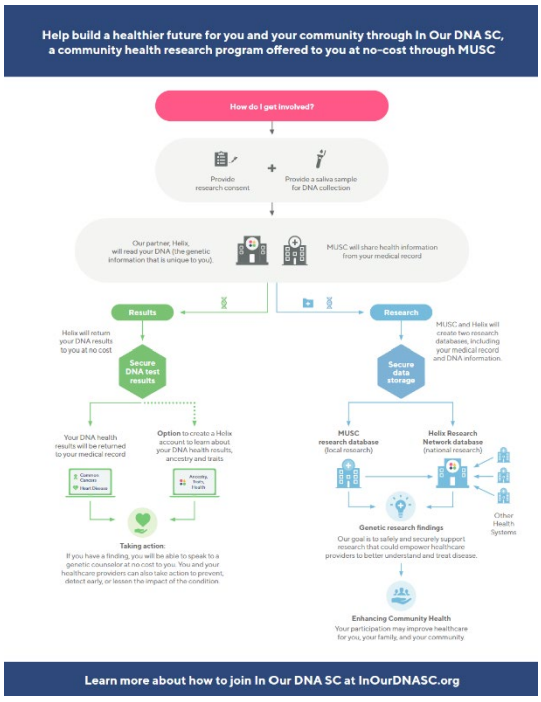


Brochure and Flyer



Our paper messaging is an easy way to communicate information about **In Our DNA SC**. It covers the basics of our study's premise, our relationship with Helix, and instructions on how to contact study staff members. The PDF files of our brochure and flyer can be found in this folder or on our website. We are also happy to send hard copies of brochures and flyers to any individuals who may want to display them or hand them out. Please reach out to InOurDNASC@musc.edu with a mailing address and an estimation of how many brochures and flyers would be needed.

Infographic



Before interested participants can review and sign the consent form, an infographic will be displayed on the e-Consent website to provide a streamlined visual of study details. The infographic walks readers through study specifics and outlines participation in study starting with providing consent and ending with result interpretation. Even though each participant that provides consent will have the opportunity to view the infographic, we have provided the infographic as additional material to be reviewed.

Study Comprehension Questions Survey

After reviewing the content of the Volunteer Toolkit interested volunteers should complete the Study Comprehension Questions Survey. The survey can be accessed here. The Study Comprehension Questions Survey will assess study volunteer knowledge and understanding about appropriately and successfully discussing study details with potential participants. This survey must be completed before a volunteer's first shift.

Thank You

We appreciate your interest and support for the **In Our DNA SC** research project. We recognize that our study would not be successful without the support of our community members and volunteers.

If you need assistance with information about **In Our DNA SC**, please do not hesitate to reach out to our study staff members by email or phone:

- InOurDNASC@musc.edu
- 843-876-0582

BETTER HEALTHCARE IS IN YOUR GENES

The In Our DNA SC Community Health Research Project

MUSC
Medical University of South Carolina

Helix

Help improve healthcare for you, your family, and your community

Bringing Our Mission to Life

MUSC is dedicated to providing high-quality, accessible healthcare to everyone in our community.

In Our DNA SC plays an important role in this mission.

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Your DNA can tell you about your risk for common cancers and heart disease.

Proactive genetic screening gives you a chance to:

Develop an action plan with your provider

Make preventative life changes

Encourage your family to test, as actionable risks can impact them as well

Take charge of your health!

Introducing
In Our DNA SC

In Our DNA SC is a community health research project, in partnership with Helix, that aims to analyze DNA from South Carolina residents to identify actionable hereditary health risks.

Residents 18 years + can sign up and consent online, submit a saliva sample for testing, and receive personalized genetic insights.

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In Our DNA SC
A Community Health Research Project

Why participate in In Our DNA SC?

Potentially improve healthcare for you and your family
by proactively screening your DNA for actionable health risks including:

Common cancers like breast, colorectal and ovarian

Heart Disease

You can also learn more about yourself, with insights on
your regional ancestry and wellness traits, like caffeine sensitivity.

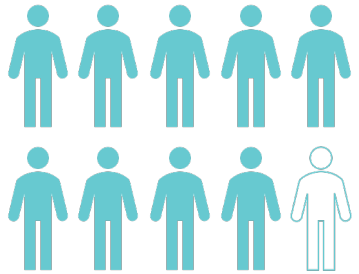
Knowing Your Risk

Among participants in similar community health research projects:

ONE IN 75

learned they were at higher risk for common cancers and heart disease

9 OUT OF 10



of at-risk individuals may have been missed based on current medical practice or family history alone

Source: https://www.nature.com/articles/s41591-020-0982-5

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Customize Your Care

A better understanding of your genetic risks can help you and your healthcare provider plan for a healthier future.

Participants with positive results may work with their provider regarding:

- Access to additional education and support resources
- More frequent monitoring
- Additional testing
- Specialist care referrals

Cause a Ripple Effect

In Our DNA SC could improve healthcare
for not only you and your family but also for your community.

Participants **contribute** their data
to community research

Over time, these secure
contributions **help researchers**
explore the relationship between
genetics and certain diseases

ABOUT PRIVACY

MUSC takes great care to keep your information safe and secure
and will not share personal data beyond what you have consented to.
Please visit the FAQs at InOurDNASC.org to learn more about privacy.

Signing Up is Quick and Easy

Get started at **InOurDNASC.org**

Review and sign **In Our DNA SC**'s electronic consent form.

Schedule a visit or request a kit to provide a saliva sample, which takes about 15 minutes.

Create a **Helix.com** account to learn about ancestry, personal traits and health-related DNA insights.

Your DNA results will be available for you and your provider in about 8-12 weeks.

Let Your DNA Lead The Way

Thank you in advance for taking steps to protect your wellness & enabling **In Our DNA SC** to help elevate the standard of personalized care for our community and generations to come.

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In Our DNA SC
A Community Health Research Project

Learn more at InOurDNASC.org

Scan the code below to get started.

Questions?

Study team members are ready to help.

Phone: 843-876-0582

Email: InOurDNASC@musc.edu

Community Outreach PowerPoint Script

Slide 1: In Our DNA SC is a community health research project being conducted by the Medical University of South Carolina in partnership with Helix, a leading population genomics company.

Slide 2: Personalized medicine is a growing field, and the Medical University of South Carolina believes it can transform healthcare. This approach customizes healthcare to the individual and looks at a patient's genetics, environment , and lifestyle . Genetic screening is a key part of this approach. Being a leader in defining this path is at the core of the Medical University of South Carolina's mission.

Slide 3: G enetic screening can help patients understand their risks for certain conditions, such as common cancers and heart disease, and learn ways to take action to improve their health. Taking action to improve health can help reduce the risk of developing disease. Families can discover any health risks they may share by using genetic screening.

Slide 4: The In Our DNA SC research project is a partnership between the Medical University of South Carolina and Helix, a leading population genomics company . In Our DNA SC hopes to enroll 100,000 participants with services offered at no cost to the individual. The goal of In Our DNA SC isn't only to improve our health, but to help improve the health of generations to come.

Participation in the study is easy. South Carolina residents 18 years and older can enroll by completing an online consent form, then providing a simple saliva sample for DNA testing.

Slide 5: In Our DNA SC will screen for 3 conditions: Hereditary Breast and Ovarian Cancer, Lynch Syndrome also knowns as Hereditary Colon Cancer, and Familial Hypercholesterolemia. If someone has one of these conditions, there are preventative measures that someone can take to help reduce the risk of developing disease.

Participants get screening results for these conditions, plus insights on regional ancestry and wellness traits through their optional, no- cost Helix patient portal.

Slide 6: Genetic screening can make a difference. One out of every 75 participants may learn they're at higher risk common cancers and heart disease. Screening based on current medical practice or family history alone can miss about 90% of at-risk individuals, so genetic screening is important.

Participants can share their results with family members to start the conversation about genetic health risks and how to prevent and manage disease.

Slide 7: By offering genetic screening at no-cost, In Our DNA SC hopes to empower the South Carolina community with knowledge of their genetic health. Patients who receive positive results are eligible for a session with a MUSC Genetic Counselor at no cost to the patient. Genetic

Counselors are professionals in the field of genetics and can provide guidance for positive patients on their results, care management, referrals, and testing for family members. Receiving results from DNA testing shouldn't be intimidating or lonely, In Our DNA SC study team members are available to provide insight on results and resources for both positive and negative patients.

Slide 8: In addition to empowering participants to learn more about their health through DNA, the In Our DNA SC research project also promotes future genetics and genomics research initiatives. Genomic information provided by In Our DNA SC participant sample and information from their medical record will be stored in secure and privacy protected databases that will be available for researchers in the futureWe recognize that many communities have concerns about research due to the lack of transparency and inappropriate use of data, but our hope is that working with community organizations and trusted leaders that we can build trust and partnership. Additional information in regards to transparency and data security can be found on the InOurDNASC.org website and in the frequently asked questions section of the website.

Slide 9: Signing up to participate in the In Our DNA SC research study is quick, easy, and at no cost to the individual. By visiting the InOurDNASC.org website, prospective participants can learn about the project, read frequently asked questions, and review and electronically sign the consent form. While completing the consent form, participants will be asked to indicate their preference for sample collection. In Our DNA SC is currently offering in person sample collection as well as at-home collection where a sample collection kit is mailed to a participant's home and returned to Helix directly for testing.

Once a participant completes their/signs their consent and provides their sample, results will be returned to the patient's medical record in about 8-12 weeks. During this time, participants may also create a Helix account to receive their ancestry, personal traits, and health-related DNA insights.

Slide 10: If you are interested in participating in the In Our DNA SC program, please visit the website using the link or the QR code. This program is an excellent opportunity to improve health care for you, your family, and our community.

In Our DNA SC
Volunteer Frequently Asked Questions

About In Our DNA SC

What is **In Our DNA SC**?

In Our DNA SC is a large-scale community research project investigating how DNA impacts health, with a broader goal of learning how to offer more personalized health care to our patients and community. This is a major population genomics initiative that is intended to last for at least 4 years, during which time we are hoping to enroll at least 100,000 participants across the system and in the greater community. The clinico-genomic data generated through this study can be used for both clinical and research purposes in the future.

Why did MUSC launch **In Our DNA SC**?

Genetics and genomics is a key enterprise priority of OneMUSC. This major population genomics initiative has the following objectives:

- Clinical: Improve patient outcomes, acquire new patients, capture revenue from downstream procedures
- Research: Build a secure clinico-genomic dataset to power local research, build commercial partnerships, drive translational discovery
- Market Positioning: Competitive differentiator, leadership in precision health / innovation

Who is running **In Our DNA SC**?

In Our DNA SC is an enterprise-wide program launched in collaboration with Helix, a population genomics company that works with major health systems across the US to launch similar programs. Dr. Daniel Judge is the Principal Investigator of this IRB approved research study.

Who is Helix?

Helix is a leading population genomics company with one of the world's largest CLIA/CAP next-generation sequencing labs, as well as the first and only FDA authorized whole exome sequencing platform. Helix's laboratory-developed test provides clinically actionable results to participants.

Eligibility & Recruitment

Who is eligible to participate in **In Our DNA SC**?

In Our DNA SC is currently welcoming all individuals 18 years and older who can read and write in English (*Further eligibility below).

*Eligibility Criteria:

- Never received an allogenic bone marrow transplant.
- Never received a stem-cell transplant
- Have not received a blood transfusion in the last 30 days
- Able to read and write in English or Spanish
- 18 years or older

How can interested participants enroll?

For interested participants who have not yet been recruited through MyChart, they can be directed to the study website where they can enroll online through MyChart. If a participant does not already have an established MUSC MyChart account, instructions on how to create a MUSC MyChart can be found on the study website under the "How to sign up" section.

How much does it cost to enroll in this program?

There is no cost to participate. Participation is free and the genetic testing provided will not be billed to your patient or their health insurance. For those found to be at increased genetic risk for the conditions being screened for, the program also provides genetic counseling at no cost.

Genetic Test Results

What results are provided by the study?

Participants receive genetic risk reports for three hereditary conditions recommended for screening by the CDC. These are known as the Tier 1 genetic conditions:

- **Familial Hypercholesterolemia (FH)**: A hereditary form of very high cholesterol that causes heart disease at an earlier age than the general population
- **Hereditary Breast and Ovarian Cancer Syndrome (HBOC)**: A hereditary form of breast and ovarian cancer, specifically linked with abnormalities in the 2 most common genes (BRCA1 and BRCA2); individuals with a pathogenic or likely pathogenic variant in the BRCA1 or BRCA2 genes also have an increased risk for prostate cancer (in males) and pancreatic cancers

- **Lynch Syndrome (LS)**: The most common cause of hereditary colorectal (colon) cancer - people with Lynch Syndrome are more likely to get colorectal cancer and at a younger age; females also have an increased risk for endometrial cancer

Please refer to the gene guides (you may access them here) for a comprehensive explanation of the increased risk of diseases associated with each gene, and appropriate medical management guidelines.

The CDC's Office of Public Health Genomics defines Tier 1 genetic conditions as those having significant potential for positive impact on public health based on available evidence-based guidelines and recommendations. These three conditions are considered to be highly actionable, in that there are clear clinical follow-ups to be taken. These results will be returned to the patient's medical record.

Participants will also receive access to non-clinical genetic insights about their ancestry and traits if they choose to create an optional Helix account to access the Helix.com online portal. These results are not expected to be supported in clinical practice and will not be included in their medical record.

How common are the CDCT1 conditions?

1-2% of all patients have one of these conditions. Studies have shown that up to 90% of patients with one of these hereditary risks are not identified through guideline-based ascertainment.

Why is **In Our DNA SC** focusing on these three conditions?

The CDC recommends screening for these three Tier 1 conditions because:

- They are highly actionable with evidence-based guidelines
- They affect 1-2% of the general population
- They are under-ascertained by current clinical practice and guidelines
- They have the potential to identify at-risk patients early in order to positively impact morbidity and mortality through early identification, screening and intervention
- Identifying at-risk patients can lead to detection of at-risk relatives
- Earlier and more frequent screenings can help mitigate the risk or catch the disease early.

What does a negative result mean?

A negative result means that no pathogenic or likely pathogenic variants were identified in the 11 genes screened for the CDCT1 conditions. While this result is reassuring, there are other genes and variants that cause cancer and cardiovascular disease that are not included in this test. If your patient has a personal or a family history of a disease that you are concerned about, please refer them to a high risk genetics clinic. Additionally, if your patient has had previous diagnostic genetic testing, it is likely that test was more comprehensive than this screening test and should not be disregarded based on the findings from this program.

Will participants receive more results over time as part of this study?

Currently, through this study, patients will only get results for the three CDCT1 conditions. However, over time, since the Exome+ genetic data is captured and stored securely, we may offer additional clinical-grade tests that may be appropriate for your patient. Any additional tests offered will require the patient to provide consent so that the patients are informed about the implications of the results. We will keep providers informed when MUSC is ready to offer additional genetic test results.

Return of Results Process

How long will it take for participants to receive results and how will they view them?

After the Helix clinical laboratory receives your patient's saliva sample, it will take about 8-12 weeks before their health results are returned to their medical record and ready to view. Patients will receive a MyChart message notifying them of new test results that are available.

Helix will also email your patient when their results are ready to view in the Helix online portal on Helix.com. Your patient may create an optional Helix account if they wish to view their results in the Helix online portal.

What support will be provided to participants when they receive their genetic results?

Participants who are found to have an increased risk for one of the three CDCT1 conditions will be offered genetic counseling at no cost. A study coordinator will reach out to the patient to assist them in scheduling a consult with the appropriate Genetics specialty.

All participants also have access to online, patient-friendly results through the Helix portal if they choose to create an optional Helix account. The online Helix portal provides education about the test, their personal results, disease-specific risks, medical management guidelines, how to share information with family, and what next steps they should take with the study and/or their providers.

Participants who are not found to have an increased risk for the three hereditary conditions tested but have high residual risk based on personal or family history should be referred for further evaluation with a genetic counselor. Such referrals will be billed to patients and their insurance.

What information will genetic counselors provide to participants?

Genetic counselors are trained healthcare providers who can help interpret genetic test results and can help in developing a personalized management plan based on genetic test result, personal medical history and family history.

Who will have access to my patient's genetic test results?

The Principal Investigator and research coordinators will receive notifications of pathogenic and likely pathogenic findings, so that they may assist the patient in scheduling a genetic counseling consult. Genetic counselors who support the study will have access to the results of participants with pathogenic and likely pathogenic findings. Providers can also access a patient's results in Epic.

Privacy and Data Protection

Will these genetic test results impact participants' health insurance?

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that prohibits health insurers and employers from using genetic information to set premiums or deny coverage. GINA does not cover other types of insurance, including disability, long-term care, and life insurance. For more information, see Helix's support page on GINA + Coverage.

Will these genetic test results impact participants' life insurance?

There is a chance that genetic test results may affect a patient's ability to get life insurance or increase the cost of such insurance. GINA, the federal Genetic Information Nondiscrimination Act, does not prohibit insurers from taking into account genetic test results as part of the underwriting process for life insurance. Patients should be advised that genetic testing may impact their life insurance options and may wish to obtain coverage, if they don't already have it, before proceeding with genetic testing. While it is important to apprise patients of this risk, recent studies suggest that life insurance companies are not actively using genetic information to inform underwriting and pricing decisions. Providers should discuss the potential benefits of genetic testing with patients, particularly where patients may learn of the existence of an actionable, inherited risk, and support patients in making a risk-informed decision about their future care.

How does Helix protect patient data?

Protecting patient data is Helix's utmost priority. All genetic and personal information is encrypted using strong SSL/TLS ciphers and stored in secure databases with strict access controls. Furthermore, clinico-genomic research data will only be shared with approved researchers after identifying information has been removed.

Research

How will the data from **In Our DNA SC** be used for research?

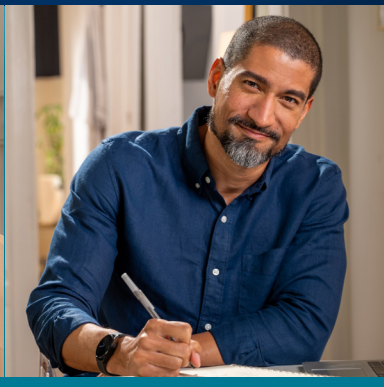
MUSC and Helix are developing a clinico-genomics dataset that will be available to local clinical and basic science researchers. This will include a database of de-identified participant phenotypic EHR data linked to a database of genomic data generated by Helix, the clinical laboratory that will sequence participants using its clinical Exome+® assay.

What type of genomic information is being generated by the study?

All samples are processed using the Exome+®, Helix's proprietary clinical assay that analyzes the entire exome (20,000+ genes) and over 300,000 highly informative non-coding regions, including GWAS findings, ancestry-informative markers, an imputation backbone, and full mitochondrial coverage. This assay is designed to enable analysis of the whole exome (WES), interpretation of targeted panels, and low coverage whole genome (lcWGS) to power current and future clinical and research applications. More technical and performance details on the assay can be found on the Helix website.

In Our DNA SC

A Community Health Research Project



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Care made just for you

Programs like In Our DNA SC help to support the future of precision medicine.

Precision medicine works to provide the right medical care to the right patient at the right time, instead of using a one-size-fits-all approach to prevention and treatment of disease.

About In Our DNA SC

In Our DNA SC is MUSC's community health research project. The goal is to learn how your DNA affects your health, how it might help improve your health care, and to support new research discoveries for our community.

We hope 100,000 South Carolinians will join the project - at no cost to you.

What will I need to do to join?

You will provide:

- Your name
- A saliva sample for DNA analysis
- Information about yourself and your health from your medical record

Precision medicine is health care based on three factors:

- **Your environment** – where you live and how it affects your health
- **Your lifestyle** – what you do every day and how it affects your health
- **Your biology** – what is special about your genes and family history

What kind of information will I get when I join?

In 8-12 weeks, you and your provider will get:

- Results about your genetic risk for certain cancers and heart disease for which actions can be taken to help prevent, delay, or reduce symptoms.
- Results about your ancestry and other traits like gluten tolerance, caffeine sensitivity, and more.

Learn more about how you can join
In Our DNA SC and discover why your DNA matters at:
web.musc.edu/InOurDNASC




Why is it important to know your genetic risk factors?

- **1 in 75 participants** in similar programs[1] learned that they are at higher risk for common cancers and heart disease.
- **90% of conditions** we test for would have been missed based on current medical practice or family history alone. Knowing if you are at higher risk can help you and your doctor personalize your health care.
- **Knowing your risk** can protect your family's health. Sharing your health information with your family members can help them take steps to prevent disease and catch it early if it develops.

Our Partner

MUSC has teamed up with Helix, a leading population genomics company, to deliver genetic information to you and your provider. This research program is part of the Helix Research Network, which is combining the genetic and health information from health partners across the country to power genetic discovery.

Why should I join?

Being part of this community health research project may help you:

- Understand your personal health risks so that you and your doctor can plan for a healthier future.
- Make a difference for generations to come by participating in research today.
- Improve your health care and could also improve health care for your family and community.

How will my information be stored?

Your information will be secure in a privacy-protected genetic and health research database. Over time, the information in this database will help researchers learn what may cause certain diseases, how to treat them more effectively, and help improve the standard of health care for all. We take great care to keep your information safe and secure and will not share personal data beyond what you have consented to.

How do I join?

Visit the website:
InOurDNASC.org

There you can:

- Learn more about the program and its potential impact on the community.
- Sign up using your MyChart account.
- Read FAQs to answer more questions you may have.
- Find contact information to get in touch with an In Our DNA SC research coordinator.

MUSC is South Carolina's only comprehensive academic health sciences center and is dedicated to changing what's possible in health care through our ongoing mission to provide excellence in patient care, education and research.

MUSC
Medical University of South Carolina

What can your genes tell you about your health?

Join MUSC's In Our DNA SC program to learn more.

In Our DNA SC is a new community health research project at MUSC. The goal of this program is to improve access to personalized health care designed for you, and to support new research discoveries. If you participate, you and your doctor will receive free, confidential results about your genetic risk for certain cancers and heart disease. This information could improve health care for you, your family, and our community.

Signing up is simple and DNA testing available at no cost to you. To get started, scan the QR code to access the website.

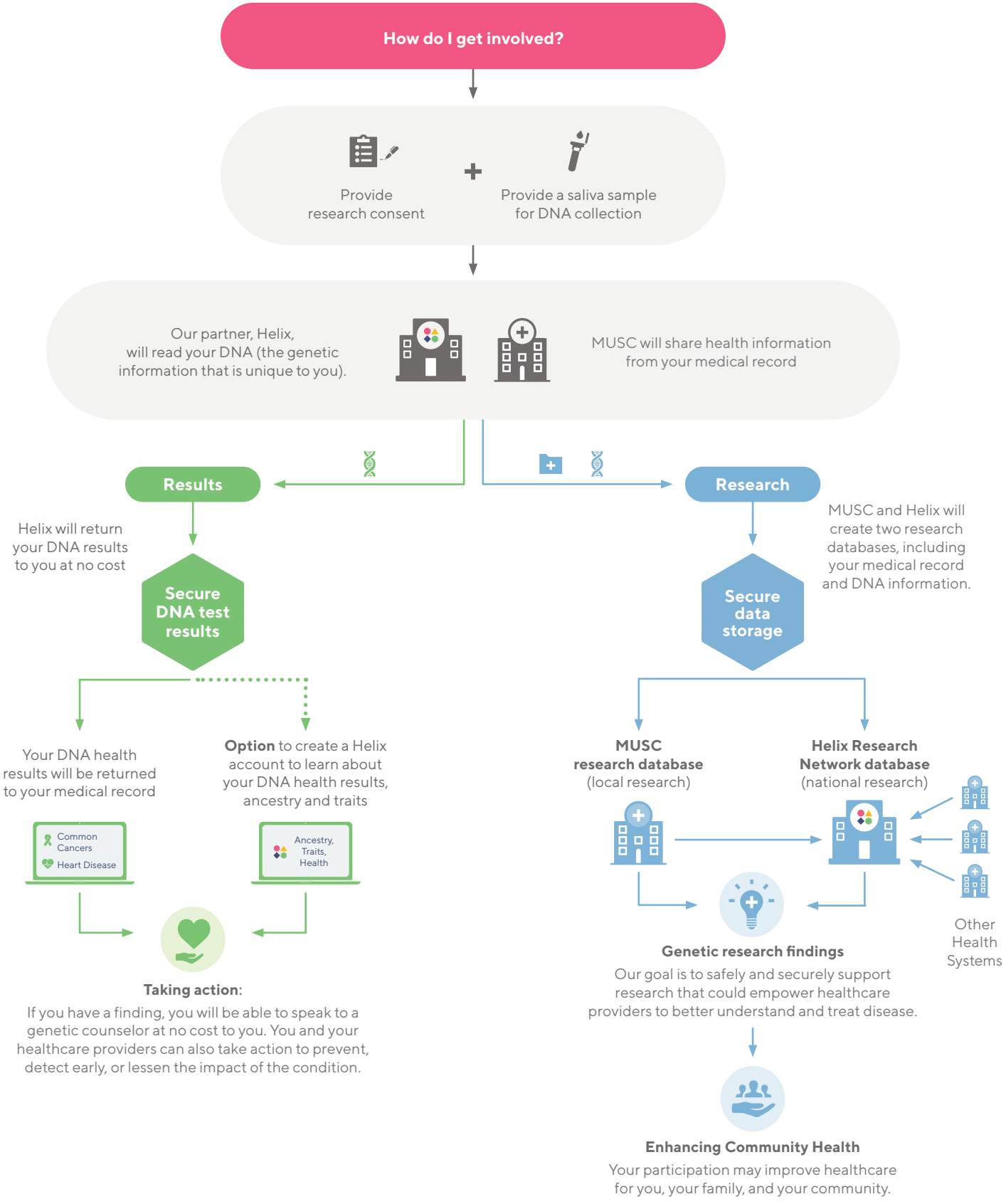
If interested in enrolling in the study, click "Sign Up Now" to review the consent form.

Questions? 843-876-0582 | InOurDNASC@musc.edu

MUSC
Medical University of South Carolina

In Our DNA SC
A Community Health Research Project

Help build a healthier future for you and your community through In Our DNA SC, a community health research program offered to you at no-cost through MUSC



Learn more about how to join In Our DNA SC at InOurDNASC.org