



Name and Clinic Number

Approval Date: January 27, 2021
Not to be used after: December 9, 2021

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Mayo Clinic Health Tapestry: Genomic Sequencing in Clinical Practice

IRB#: 19-000001

Principal Investigator: Konstantinos Lazaridis, M.D. and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. Please take the time to read the entire consent form carefully before making your decision. You should not sign this form if you have any questions that have not been answered.

Table with 2 columns: Section Header (e.g., It's Your Choice, Research Purpose) and Description of the section content.



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<b>What's Involved</b>	<p>Study participation involves</p> <ul style="list-style-type: none"><li>• Registering online with <i>Helix</i></li><li>• Providing a Saliva (spit) sample</li><li>• <i>Helix</i> will perform DNA sequencing</li><li>• You will be offered ancestry/trait information via your <i>Helix</i> account, more details on this below.</li><li>• You will receive screening results for an inherited form of high cholesterol called familial hypercholesterolemia (FH).</li><li>• You will receive screening results for hereditary breast and ovarian cancers (HBOC).</li><li>• You will receive screening results for certain hereditary colorectal cancers, referred to as Lynch syndrome.</li><li>• You will receive additional research results such as; genetic risk for certain hereditary cancers, hereditary heart conditions and severe responses to certain medications. Your genetic and health information will be placed in a registry (or database) for future research purposes as described below.</li></ul>
<b>Key Information</b>	<p><b>If you do not want your genetic information placed in your medical record, you should not participate in this study.</b></p> <p>There is no cost for any of the activities performed as part of this research study, but there could be costs for clinical follow-up care.</p> <p>The risks of learning genetic test results may include emotional upset or insurance or job discrimination. Please see additional information about Genetic Information Nondiscrimination Act (GINA) below.</p> <p>Please note: genetic testing done in this study does not test for all causes of the conditions listed and is not comprehensive. If you have questions or concerns about your personal or family history, you should speak with your doctor. Testing done in this study is not a substitute for genetic testing that may be ordered by your doctor.</p>
<b>Learn More</b>	<p>If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will be available to talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.</p>



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### Making Your Decision

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Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about ...	You can contact ...
<ul style="list-style-type: none"> <li>▪ Study tests and procedures</li> <li>▪ Materials you receive</li> <li>▪ Research-related appointments</li> <li>▪ Research-related concern or complaint</li> <li>▪ Research-related injuries or emergencies</li> <li>▪ Withdrawing from the research study</li> </ul>	<p><b>Study Team Contact:</b> CIM CRC Team  Email: <a href="mailto:Tapestry@mayo.edu">Tapestry@mayo.edu</a>  <b>Phone:</b> (507) 422-6373</p> <p><b>Principal Investigator(s):</b>  Konstantinos Lazaridis, M.D.  <b>Phone:</b> (507) 538-4877</p> <p><b>Institutional Name and Address:</b>  Mayo Clinic  200 1st Street SW  Rochester, MN 55905</p> <p><b>Co-Principal Investigators</b></p> <p><i>Arizona Campus</i>  Aleksander Sekulic, M.D.  <b>Phone:</b> (480) 301-8330</p> <p><b>Institutional Name and Address:</b>  Mayo Clinic Arizona  13400 E. Shea Blvd  Scottsdale, AZ 85259</p> <p><i>Florida Campus</i>  Sanjay Bagaria, M.D.  <b>Phone:</b> 904-953-2523</p> <p>Richard (John) J. Presutti, D.O.  <b>Phone:</b> (904) 953-6722</p>



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Table with 2 columns: 'If you have questions about ...' and 'You can contact ...'. Rows include contact info for IRB, RSA, and Patient Account Services.

Other Information:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you use Mayo Clinic for your healthcare.

Why is this research study being done?

We are doing this study to better learn how sequencing a patient's DNA (i.e., the genetic material) could impact his/her health care.



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better therapy of disease. Through this study we are also working on developing and improving ways to include genomic information from DNA sequencing into the electronic health record (EHR), to create a more complete “Health Tapestry” for each participant.

*Helix OpCo, LLC (“Helix”)*, is a genetics company that performs the sequencing of DNA and operates an online marketplace for DNA-powered products. As part of your participation in this study, you will receive a Helix account.

As part of your *Helix* account, *Helix* will sequence your DNA and perform a genetic test called “Exome+ sequencing™”, which looks at most of the medically relevant parts of your DNA (an exome includes about 20,000 genes) that predict risk to disease development and can be helpful for insights related to ancestry, wellness, and other traits. In this study, *Helix* will initially share with Mayo Clinic approximately 60 genes, which are actionable. This means that if an individual has actionable gene(s) then medical action is required for follow up medical care. In the future, as part of this study, Mayo Clinic may obtain additional genetic information, up to and including the full Exome+ data that *Helix* sequences.

As part of this study, you will receive your results for an inherited form of high cholesterol called familial hypercholesterolemia (FH), and learn about your risks for certain hereditary cancers such as: breast, ovarian (HBOC) and colorectal cancer syndromes (Lynch syndrome) through *Helix*. When you create your Helix account, you will give Helix permission to share your genetic information with a third party laboratory for the purposes of conducting some or all of this analysis. By signing this form, you consent to Mayo Clinic receiving the results of your analysis from Helix. For those at-risk for any of these conditions Mayo Clinic will make genetic counseling available. As part of your *Helix* account, you will be offered the option to receive some genetic information about your ancestry and some inherited non-medical traits such as, how you process coffee, what type of ear wax you have.

Mayo Clinic is developing a scientific process to analyze some of the data from your exome. You may receive research results for a subset of genetic findings, which could include genetic variants that indicate you have an increased risk for certain types of hereditary cancers, hereditary heart conditions and severe responses to certain medications through a Mayo Clinic research report.

The tests performed as part of this study are to be used to help guide discussion and potential follow-up with your health care provider and not for those who are looking for genetic testing for a specific disease.

*If you or your partner are pregnant, or planning to become pregnant, you can take part in this study. Keep in mind, this study does not replace prenatal genetic testing. It is strongly recommended that you receive genetic counseling prior to participating in this study to fully*

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*discuss the possible implications of a positive result. Speaking to a genetic counselor is available to you as part of this study. If you would like to speak with a genetic counselor prior to participating, please contact the study team at: [tapestry@mayo.edu](mailto:tapestry@mayo.edu)*

As a sub-study, we are also sending questionnaires to participants in this study to learn more about the COVID-19 pandemic, how it has affected different individuals and how genetics may contribute to patient outcomes. This study will not require any additional testing for or reporting from participants about COVID-19/SARS-CoV2.

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### Information you should know

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#### **Who is Funding the Study?**

The study is funded by the Mayo Clinic Center for Individualized Medicine and is conducted in collaboration with a private company, *Helix*.

#### **Information Regarding Conflict of Interest:**

This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies. Mayo Clinic has a financial interest in *Helix*, who is a collaborator in this study. Mayo Clinic may stand to gain financially from the successful outcome of the research.

Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the significant financial interest for one or more of the investigators and/or Mayo Clinic related to this research and they have determined that this significant financial interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research.

Additional information is available to any interested study participant regarding the details of this significant financial interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at 507-284-0075.

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### How long will you be in this research study?

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Your direct participation in this study will be complete after you receive your research results. However, your genetic information may continue to be used for research indefinitely.

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## What will happen to you while you are in this research study?

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If you agree to be in the study and provide consent you will be asked to participate in the following:

- You will receive a Saliva (spit) Kit
- You will create a *Helix* account and register your kit online.
- You will collect your sample and send it back in the provided box. *Helix* will perform DNA sequencing

### Family History

As part of this study we will ask that you provide us some information about your family's health history. You will receive a link to the Mayo Clinic About Me family history tool. You will build your family tree through this application. This information will be available for future clinical use.

### What will you receive?

You will receive the following screening results from *Helix*

- Familial hypercholesterolemia (FH)
- Hereditary breast and ovarian cancers (HBOC)
- Lynch syndrome, a hereditary form of colon cancer
- As part of your *Helix* account, you will have the ability to make future purchases on *Helix's* marketplace, which in most cases will not require you to provide a second saliva sample. As part of this account, you will also have the option to access an ancestry and non-medical traits analysis. If you would like the ability to make future purchases and access ancestry and non-medical traits, you will sign a HIPAA authorization during the *Helix* account registration process. *Deciding to not sign the Helix HIPAA authorization form will also not harm your relationship with your doctors or Mayo Clinic and you will still be a full participant in the Mayo Clinic Tapestry study.*
- Results related to other health conditions may also be returned to you. This could include your risks for certain types of hereditary cancers, hereditary heart conditions, and severe responses to certain medications

***Positive Results:*** If your testing shows you have a genetic variant, this information will be made available to you through a test report, or an electronic application. For example, your FH, HBOC, and Lynch syndrome results will be available to you through the *Helix* web application. If an important genetic variant is identified, the Tapestry study team will reach out to you to schedule an appointment with a genetic counselor. If you have a Mayo Clinic primary care



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provider, your results will be shared with them. All FH, HBOC, and Lynch syndrome results will be placed in your medical record.

Negative Results: If your FH, HBOC, and Lynch syndrome testing does not identify a genetic variant, this information will be available to you through the *Helix* web application. A copy of your result will be placed in your medical record. Negative genetic results obtained from other testing performed throughout this study may be placed in your medical record if the testing is performed in a clinical laboratory.

#### Additional Questionnaires and Samples

During this study we may ask you to fill out questionnaires about your experience, which may include health care questionnaires. To learn more about genetics and its relationship to the COVID-19 disease, you may be sent a questionnaire asking general questions related to your health and the related recent coronavirus pandemic, regardless if you have developed COVID-19 disease or not. We may also ask you to submit additional samples, which could include, blood, urine or stool collections. You can always say no to these additional requests.

#### Future Research (Tapestry Genomic Registry)

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. Confirmation of future research results in a clinical laboratory will be required prior to changing your medical care. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

Please keep in mind that the registry could make it possible to do more genetic research for many years and a result related to your health could be discovered very far in your future when you are not expecting it.

#### **Where will your data be stored?**

Mayo Clinic will store your genetic and health information and in the Tapestry Genomic Registry, for future research and commercial use.

*Helix* will keep your sequencing file for you, ready for analysis. *Helix* securely stores your genetic information and will only share your information with your permission. If you wish to learn more, you can arrange for additional genetic results from your DNA sequencing to be returned to you through additional *Helix* apps, if you sign the HIPAA authorization form. If you choose to purchase any additional tests from *Helix*, the results of such additional tests will not be shared with Mayo Clinic. Please refer to [Helix's Privacy Policy](#) for additional details.



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### What are the possible risks or discomforts from being in this research study?

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Confidentiality Risk: As with all research, there is a chance that the confidentiality of your medical information could be compromised; however, we take precautions to decrease this risk.

Genetic Testing: The risks of learning genetic test results may include emotional upset or insurance or job discrimination.

#### Genetic Information Nondiscrimination Act (GINA)

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), 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 this information if it is in the electronic medical record (EMR) i.e. FH results.
- 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.

This law doesn't protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

*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](http://www.ginahelp.org) or you can ask a member of the research team to give you additional details about GINA.



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### Are there reasons you might leave this research study early?

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**If you do not want your genetic information put in your medical record, you should not participate in this study.**

If you choose to withdraw from this study before your saliva sample is sent to *Helix*:

- Your testing will not be performed and a report will not be put in your medical record.
- You will not be contacted to provide new information.
- You will have an account with *Helix* but it will not have any genetic information so you will not be able to purchase or access products from *Helix*.

If you withdraw from this study after your saliva sample is sent to *Helix*:

- FH, HBOC, and Lynch syndrome results will be put in your medical record.
- You will be contacted with the opportunity to discuss any clinically important findings.
- You will not be contacted again to provide new information for the study.
- You will continue to have a *Helix* account, unless you separately close your *Helix* account in accordance with the [Helix Terms of Use](#).

If you want to withdraw, contact the Center for Individualized Medicine at [Tapestry@mayo.edu](mailto:Tapestry@mayo.edu).

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### What if you are injured from your participation in this research study?

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#### Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

#### Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.



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**What are the possible benefits from being in this research study?**

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This study may not make your health better. However, information/results obtained from the study may be of benefit to you and/or your family in the future. Other people may benefit in the future from what we learn in this research study.

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**What alternative do you have if you choose not to participate in this research study?**

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This study is only being done to gather information. You may choose not to take part in this study.

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**What tests or procedures will you need to pay for if you take part in this research study?**

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You will not need to pay for the following tests and procedures:

- Pre-test Genetic Counseling
- Saliva (Spit) Kit Collection/ Shipping
- DNA sequencing
- FH screening test
- Hereditary breast and ovarian cancer screening test
- Lynch syndrome screening test
- Helix account which includes the option to receive ancestry and traits
- Return of results that may impact your health (phone call with a Genetic Counselor)
- Additional research testing

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles. This includes the recommended confirmatory testing that is estimated to be needed in around 2%-3% of all patients who enroll in the study, as well as any future research results considered medically actionable.



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\*\*There may be a sub-set of inconclusive results that require confirmatory testing prior to finalizing the test result. In these rare finding, expenses associated with the re-testing will be covered by the research study. You will be notified by the study team if this scenario applies to you\*\*

*Please note that Medicaid, Medicare and some insurance companies may not cover all of the cost, and this testing cost, in whole or in part, may become your responsibility. Positive testing results from Helix should not be used for clinical decision without confirmation.*

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**Will you be paid for taking part in this research study?**

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You won't be paid for taking part in this study.

There is a very small chance that some commercial value may result from the use of your sample and information. This could include new products like a drug or a test to diagnose a disease. If that happens, you will not be offered a share in any profits.

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**Will your information or samples be used for future research?**

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Tapestry is a resource meant to serve the research community at Mayo Clinic, and at other institutions, indefinitely. There are no plans for it to end. By participating in this study, you are agreeing to be a part of ongoing health research. Your participation will enable researchers to examine the roots of disease and novel treatments for many years to come.

Mayo Clinic Researchers

Researchers at Mayo Clinic who aren't involved with this study may ask to use your information and/or samples for future research. These researchers may receive identifiable information to further their research.

Researchers outside of Mayo Clinic

Researchers outside of Mayo Clinic may also ask for a part of your information and/or samples for future studies or commercial use. Mayo may send the information and/or Mayo Clinic collected samples to researchers who request them, but Mayo will not send your name, address, phone number, social security number, or any other identifying information with the information and/or samples. Your information and/or samples may be sent with a code, and only the researchers for this study at Mayo Clinic would be able to link the code to you.



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### Research Databases

It is helpful for researchers to share information they get from studying samples and information. They do this by putting it into scientific databases. Researchers can study the shared information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information may be placed into one of more scientific database. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database.

Even though information traditionally used to identify you will not be shared, people may develop ways in the future to allow someone to link your genetic information back to you. For this reason, confidentiality cannot be guaranteed. It is also possible that identified information could be used in discriminating ways, and there could be additional unknown risks. This risk of this happening is very small, but may grow in the future. We will make every effort to protect your confidentiality.

**You may withdraw your consent for future use of your information and/or samples at any time, by writing to the Principal Investigator at the address provided in the "Contact Information" section of this consent form.**

Your information and/or samples would be removed from any repository where they are stored, if possible. Information and/or samples already distributed for research use will not be retrieved.

*You would retain your Helix account, and Helix would continue to store and use your information and/or samples in accordance with the [Helix Terms of Use](#) and [Privacy Policy](#), unless you separately close your Helix account in accordance with those terms. However, Helix will not share any further genetic data for this study.*

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### **How will your privacy and the confidentiality of your records be protected?**

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Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. All research data related to this study will be assigned a code number and used in place of your name and Mayo Clinic number. The data will be stored in locked files and/or in password-protected files on Mayo Clinic secure, firewall protected servers. Your questionnaire responses and relevant clinical data will be entered in a secure password-protected database accessible only to the study team.



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When you register with *Helix*, as per *Helix's* Terms of Service, *Helix* will collect your name, date of birth, biological sex, street address, city, state, and zip code for the purpose of establishing and maintaining your account.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or “authorization”) to Mayo Clinic.

**Health information may be collected about you from:**

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

**Why will this information be used and/or given to others?**

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

**Who may use or share your health information?**

- Mayo Clinic research staff involved in this study.
- *Helix* and a third party laboratory that may perform genetic analysis

**With whom may your health information be shared?**

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site



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location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Family Access to Medically Actionable Results:

This study involves genetic testing. Your genetic information is unique to you, but you share some genetic similarities with your blood relatives, including your children, parents, brothers, and sisters (when they are biologically related to you). You may wish to consider whether you want to share your genetic results with family members, so they can decide whether to be tested to find out if they have the same result.

Please note that there is no guarantee that your family members will get any benefit from receiving the results. There is a risk that they may feel distress from learning the result. There is also a risk that our understanding of the result might change as we learn more. You are free to tell your family members about your results at any time. If you share your results with family members, there is a risk that they will share your results with other people. If your family members decide to ask the research team about your genetic results, we will ask them to talk to you so you can decide whether they should get your result.

If you can no longer decide for yourself (for example, because you are too sick to decide or are deceased), we would like to provide these results to someone you trust (your representative). This person can then share your results with other family members according to your wishes. These genetic results are those that could impact your family members and sharing this information could reduce the risk of harm to their health.

The Tapestry Genomic Registry could support research for decades into the future.

Please read the following statement and mark your choice

If I can no longer decide for myself because I am too sick to decide or have passed away, I would like the Tapestry Study team to contact my representative with genetic results arising from my participation in this study that could prevent harm to the health of my family members.

[ ] Yes [ ] No Please initial here: \_\_\_\_\_ Date: \_\_\_\_\_





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If you select Yes, we will send you a form to name your representative.

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## Your Rights and Permissions

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Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

**Deciding to not sign the *Helix* HIPAA authorization form will also not harm your relationship with your doctors or Mayo Clinic and you will still be a full participant in the Mayo Clinic Tapestry study.**

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic  
Office for Human Research Protection  
ATTN: Notice of Revocation of Authorization  
201 Building 4-60  
200 1st Street SW  
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: [researchsubjectadvocate@mayo.edu](mailto:researchsubjectadvocate@mayo.edu).

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.



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Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

FOR REVIEW ONLY