

## Research Consent Form

**Title of Study: Renown Health Population Health study (Healthy Nevada Project)**

**Principal Investigator: Joseph Grzymiski, PhD**

**Co-Investigators: Gai Elhanan, MD; Karen Schlauch, PhD**

**Study contacts: Alexa Anderson and Savanna Grime**

**Study ID Number: 7701703417**

**Sponsor: Renown Health**

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### STUDY SUMMARY

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You are invited to participate in a research study being conducted by Renown Institute for Health Innovation (RIHI). Please read our study summary and detailed study information to learn what will be asked of you in the event you choose to participate in this study.

**Voluntary Participation:** This research study is completely voluntary, and you may take as much time as needed in making a decision on whether to participate. Please feel free to consult with your health care providers or family before participating. You may consent to this study without the presence of our research staff, but if you have any questions or concerns while reviewing this consent form, you may talk to a member of the study team anytime during normal business hours Monday – Friday by calling 775-982-6914. You may withdraw your consent at any time during the study and declining or stopping your participation will have no negative effects on you.

**Genetic Research:** This study involves research on the DNA of many people from diverse backgrounds. DNA is found in your blood, saliva, and other tissues in your body and is often called your genetic information. Genetic information is like a special code inside our bodies, which is the unique set of instructions you are born with that tells your body how to work and may be connected to your health. Sometimes changes in your DNA can lead to an increased risk for certain conditions. By studying DNA, we may be able to learn more about your health, certain traits, genetic ancestry, and better understand the genetic factors that play a role in your risk for disease and risk factors for the general population.

**Study Purpose:** We are conducting this research study with the goal of improving the health of the Nevada population and to offer screening for three inherited genetic conditions: Hereditary Breast and Ovarian Cancer Syndrome, Lynch Syndrome, and Familial Hypercholesterolemia. This study is called the Healthy Nevada Project (HNP) and is being conducted by the Renown Institute for Health Innovation (RIHI) and genetic sequencing provided through Helix OpCo, LLC (“Helix”). There is no cost to you as a participant and your contributions may help us better understand the mechanisms of cancer and other diseases.

**Study Procedures:** This study is looking for participants within Nevada and surrounding areas to provide a saliva or blood sample after they have consented to participate in this study. Once collected, the sample is sent to our genetic testing partners at Helix. Helix has a state-of-the-art laboratory where they will sequence your DNA, like reading the words of a book, and store that information in a secure database to be used for research and for returning results. Genetic test results are generally returned within 12 weeks of sample collection and receipt at the lab. If a genetic mutation or positive test result is detected that places you at increased risk for disease, genetic counseling will be offered at no-cost to help understand the significance of any genetic findings. Throughout the duration of the study, you may receive opportunities to participate in voluntary surveys or contacted to participate in other research opportunities as they become available.

**Study Data:** The information used as part of this study, including genetic information, medical record information, and survey data, will be maintained in private databases and shared among approved researchers both internally, externally, and across the Helix Research Network (HRN) to perform many studies over time. Your personal identifying information, such as name, birthdate, or contact information, will be removed from any data that is shared with researchers to protect your information and maintain your privacy.

**Benefits of Participating:** Our study offers screening and clinical results for 3 inherited genetic conditions: Hereditary Breast and Ovarian Cancer Syndrome, Lynch Syndrome, and Familial Hypercholesterolemia. There is no cost to you as a participant and the results from the genetic testing will be returned directly to you and may also be made a part of your medical record. These results may indicate you are at increased risk for certain conditions, such as heart disease or certain cancers, that when detected early can have a positive impact on your health. You may also receive insights into your personal ancestry and other non-medical traits such as your tolerance to lactose or gluten that may be of interest to you.

**Risks of Participating:** This study is considered to be minimal risk of harm. This means the risks of your participation in the research are similar in type or intensity to what you encounter during your daily activities or routine clinical care. Potential risks include the following:

- If chosen to provide a blood sample, there are risks associated with venipuncture.
- There are potential risks to your privacy. Despite RIHI and Helix having extensive policies and procedures in place to prevent a data breach, in the event of a breach, there is a chance that research data and health information could be compromised.
- If you receive results from any voluntary tests offered by the study, and those results indicate increased risk for disease, it may be important to follow up with your healthcare providers. You would be responsible for any follow up care following these tests, including the cost of additional testing or clinical visits that may not always be covered by insurance.

### **Rights and Confidentiality:**

Your identity will be kept as confidential as possible as permitted within the law.

*Note, for example, that 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 all records regarding this study to monitor, audit, or review your identifiable record for verification of study procedures and/or data.

You may ask about your rights as a research participant. If you have questions, concerns, or complaints about this research, you may report them (anonymously if you so choose) by calling the University of Nevada, Reno Research Integrity Office at 775-327-2368.

You may also ask questions of the researchers by calling the study team at 775-982-6914 or by sending an email to [RenownIHI@renown.org](mailto:RenownIHI@renown.org).

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## DETAILED CONSENT FORM AND STUDY INFORMATION

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### Introduction

You are being invited to participate in the Healthy Nevada Project, a research study conducted by the Renown Institute for Health Innovation (RIHI) in collaboration with Helix OpCo, LLC ("Helix"), a clinical laboratory and population health company. Before you agree to be in the study, read this form carefully. It explains why we are doing the study; what you must do to participate in the study; what personal information, including genetic information and protected health information, you agree to share as a participant in the study, and other important information you need to know.

At any time, you may ask us to explain anything about the study that you do not understand.

You do not have to participate in this study; your participation is voluntary. If you agree now but change your mind, you will need to contact us to withdraw, and we can explain to you what happens with the information you agreed to share when you withdraw.

### Why are we doing this study?

We are conducting this study for multiple reasons:

- To provide no-cost screening to individuals for three inherited genetic conditions that have been proven to show significant implications for public health and where early identification and management can make a difference in health outcomes according to the Centers for Disease Control (CDC). These conditions, called CDC Tier 1 conditions, include Hereditary Breast and Ovarian Cancer Syndrome, Lynch Syndrome, and Familial Hypercholesterolemia. You will receive clinical test results for these conditions, which may be stored in your medical record, to assist your healthcare providers in delivering personalized care based on your genetic results.
- To learn more about the multiple factors that contribute to a person's overall health, including medical, social, behavioral, environmental, and genetic factors. By combining this

information, this gives researchers a greater opportunity to figure out how these factors influence health.

## **How will my data be used and shared if I participate in this study?**

For this study, our research study enrollment team is able to identify who has participated in the study. This enables us to recontact you for surveys and other study opportunities in the future. We share limited, identifiable information with our testing partners in order to connect you to your samples/tests. This enables us to return your testing results back to you and/or your healthcare providers as a clinical benefit and contact you for clinical reuse. Examples of information sent to our testing partners include:

- First name
- Last name
- Medical record number
- Date of birth
- Order date
- Other order-related information

Once your data is part of the medical record (such as results from genetic testing), it remains part of your record. It is subject to Renown's Medical Record policies and HIPAA.

If you choose to participate, your information will then be added to a private research database consisting of information from multiple sources and from thousands of participants. This data includes, but is not limited to, genetic information, medical record information, survey data, public health records, geologic data and environmental data. This research database will be protected by multiple layers of information security, including limiting who can access the data and maintaining encryption of the data. The database will be maintained indefinitely or until it no longer offers scientific value to the research community.

When a research dataset is created to be shared with researchers, we remove certain identifiable information from the set and assign your information to a random participant ID. Researchers examining the data do not have access to personally identifiable information. The study will always ensure your personal privacy.

Research data from the joint genetic and health information database, used by the research community at Renown Health, DRI and UNR, may be shared with one or more of the below entities to facilitate collaboration across a broad research network and multiple partners for the advancement of science and medicine.

- Helix Research Network (HRN) Database. This database is a collaborative genetic and health information database created by Helix that will be used by approved researchers to learn more about medical conditions and to improve human health through DNA research. No information that can identify you such as your name, date of birth, or contact information will be kept in this database. Once your data is added to the Helix Research Network

Database, future use of the data will be overseen by Helix. RIHI has approved this ongoing collaboration with Helix and the Helix Research Network.

- Researchers outside of RIHI, as approved by RIHI, including for commercial or for-profit purposes. For example, the data will be available to researchers who are seeking to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, and development of new treatments for certain diseases. No information that can identify you such as your name, date of birth, or contact information will be used or shared with researchers. RIHI will vet and approve all requests from outside researchers before providing them with access to data.

The information that RIHI uses to contact you, which is collected and validated during enrollment, is not shared with outside partners. That means that researchers outside of RIHI will **NOT** have access to your contact information and provides an added layer of protection.

If you withdraw from the study, your data used in previous datasets will remain and cannot be revoked. You will be removed from the research database, and any newly formulated datasets will not contain your data or information.

## **Why are we asking you to be in this study?**

We are asking you to consider being a part of this study because you are a resident of Nevada or surrounding areas and you indicated to us your interest and willingness to participate in research.

## **How many people will be in this study?**

We expect to enroll approximately 250,000 participants from across the geographic area of Nevada.

## **What will you be asked to do if you agree to be in the study?**

If you consent to be in this study, you will be asked to provide a saliva sample or a blood sample. Helix, the clinical laboratory that partners with the Healthy Nevada Project, will use your saliva or blood sample to analyze your DNA, the genetic code you are born with that contains the instructions for how your body functions. Helix uses a process called sequencing to read specific parts of your DNA that can provide important information about health conditions as well as insights about non-health-related traits (like hair color) and your genetic ancestry.

Helix will securely store your genetic information which can then be used for clinical interpretation and to help answer research questions for as long as the data is stored. RIHI and Helix will initially be examining your DNA and returning results for risks related to cardiovascular (heart) disease, certain types of cancer and other changes or variations in DNA that can impact a person's risk for certain health conditions. You may receive additional health-related information based on your DNA over time as the study continues, but this cannot be guaranteed.

Any clinically significant results obtained from analyzing your genetic information may be automatically uploaded and included in your medical record to help your physicians provide you with the best care possible. You will also have the opportunity to create or claim your online account with Helix. Through the Helix account you will receive access to your genetic results and may also receive additional results based on your genetic information, such as inherited traits and ancestry information.

Your sequenced genetic information will be securely stored at Helix and may be used in the future for additional clinical uses. Your family doctor or healthcare provider may be able to order additional tests, as they become available, based on your existing genetic information without having to provide a new sample. This may include testing for additional genetic conditions or for pharmacogenomic purposes to look at how your DNA affects the way you might respond to certain drugs and medications. Any additional tests ordered by your family doctor or healthcare provider for clinical re-use will require additional consent before they can be completed and may not be covered under the scope of this study. To facilitate the ability to offer clinical re-use of your genetic information in the future, your medical record may be updated to reflect that you have participated in this study and/or your genetic information is available to be re-used for future clinical tests.

From time to time, researchers from RIHI, Helix or other research partners might want to ask you to participate in additional research studies, surveys or development projects. In some cases, you might be a particularly good candidate for a particular study because of your health history or genetic information. By signing this document, you give your permission to be contacted about future research opportunities and surveys by RIHI.

In summary, if you agree to be in this study, you agree to the following:

- You agree to have a saliva or blood sample collected for genetic sequencing.
- You authorize Helix to share your genetic information with RIHI and, in some cases, with Helix's partners who perform the clinical interpretation. Clinical interpretation refers to the process of analyzing your genetic information to determine if any variations exist that can impact your risk for certain health conditions. This requires highly specialized skills and processes provided by experts who may be employed by clinical laboratories outside of Helix and RIHI.
- You permit the use of your medical record with Renown Health to be shared as part of this study
- If you have any medical records outside of Renown Health or affiliated partners, you could be asked for authorization to share those records with RIHI.
- You may be contacted via MyChart, email, or web survey by RIHI and Helix and asked to voluntarily answer questions that will provide additional important information about you that will be used as part of the research.
- You will be re-contacted by RIHI if you qualify for additional research studies. Under no circumstances are you required to participate, and the study will obtain your additional

informed consent if you decide to participate. You may withdraw your permission to be contacted about future research by sending an email to [renownIHI@renown.org](mailto:renownIHI@renown.org).

## **What do you have to do to be in the study?**

The study enrollment will take about 30 minutes of your time which includes the education and registration process as well as providing your saliva or blood sample. For the duration of this research study, you will be periodically contacted via MyChart, or email and asked to answer several questions providing additional relevant information about you. You may also be periodically contacted via MyChart or email with important information, such as new research developments, insights or opportunities being offered to participants. Any research activities following the donation of your sample are voluntary but are greatly appreciated by the study team.

## **How long will you be in the study?**

Your genetic and health information will be stored indefinitely in a database for future research use, as described under “How will my data be used and shared if I participate in this study?”. In addition, you may be contacted regarding future research opportunities unless you withdraw your permission. Researchers with access to your data are not provided information that can identify you such as your name, date of birth, or contact information.

## **What happens if you choose not to be in this research study?**

If you decide not to be in the study, you will not be asked to provide a saliva or blood sample and there is no other obligation.

## **What if you agree to be in the study now, but change your mind later?**

You may withdraw from the study at any time by notifying the Principal Investigator of the study. The result of withdrawing from the study is that you will no longer receive any emails or other communication as part of the study. Additionally, you may request that your stored genetic information at Helix be deleted upon your withdrawal or not shared for research, including removal of your information from the Helix Research Network Database. However, any information already shared and converted to a research record will continue to be a part of the joint genetic and health information database and will continue to be used by the researchers and used for future research. Likewise, your medically relevant genetic information that has been interpreted and included in your medical record will continue to be stored in your medical record for your healthcare provider to review as part of your overall healthcare.

## **What are the risks associated with being in this research study?**

Your participation in this study is voluntary and the risks are minimal. If you choose to provide a saliva sample, there is no risk to your physical health. If you choose to provide a blood sample, there are risks with venipuncture. The risks associated with drawing blood from a vein include discomfort, possible bruising and swelling, infection, or faintness. Additionally, there are risks involved in having your genetic information analyzed and in sharing your genetic and health information.



- If you receive any clinical tests offered by this study, including DNA sequencing or pharmacogenomic testing (PGx), the results of those tests will be entered into your medical record to help with your overall healthcare. Some test results may indicate you could be at higher risk for disease, and you may choose to seek additional follow up visits with your healthcare providers. Any follow up medical care resulting from tests offered by this study, but outside of the scope of the study, will be your responsibility, including the cost of additional testing or clinical visits that may not always be covered by insurance.
- Some of the test results from this study may show that you have a higher chance of developing certain diseases, like cancer or heart disease. This information may cause emotional stress for you and may mean you need to get more medical care, which could cost more money. You would be responsible for any medical expenses from any follow up care you seek, which may not always be covered by insurance.
- These results could also affect your family members who are related to you by blood. If you are found to have an increased risk for certain conditions, it might mean they could be at risk too. It is recommended that you share your results with family members so they can be tested for the same conditions, which may be stressful for you and your family.
- If you return a positive genetic risk finding as part of the study and you elect not to receive genetic counseling, you may miss out on important information pertaining to your future health. While this is voluntary, it is highly recommended to participate in a genetic counseling session, provided by the study at no-cost.
- If you have already been told that you have a hereditary risk for one of the conditions analyzed by the Healthy Nevada Project, there is a small chance that the screening test will not detect that genetic variant. Such a finding does not mean that the previous test results are incorrect. It is important to discuss this with the Healthy Nevada Project research coordinators or genetic counselors.
- Some survey questions may make you or your family members uncomfortable.
- As with any database, despite RHHI and Helix implementing privacy and security measures to protect the privacy of your information, there is always a chance that your genetic data, health information, survey responses, and/or personally identifying information may be compromised in the event of a security breach. In the event of such a breach, if your data are associated with your identity, there is a risk they could be made public or released to insurance companies. The Genetic Information Nondiscrimination Act (GINA) of 2008 is a federal law that protects individuals from genetic discrimination in health insurance and employment, but does not apply to life, disability, or long-term care insurance.
- In the event of a data breach, if you or a family member has genetic data linked to your name or your family members' name in a public database, someone who has access to your



genetic data might be able to link that data to your name or your family member's name through publicly available data.

In addition to the risks noted above, there may be additional risks to participation that are currently unforeseeable. We do not know every possible risk that might come up in the future, especially with advances in medicine and technology, but will do our part to minimize this risk once known.

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

As a population health study, the primary purpose of this research study is to help researchers and clinicians better understand how genetic information may be used to improve the health of individuals and communities.

By participating in this study, you will receive clinical grade genetic sequencing and storage of that information, performed by Helix, at no cost to you. You will receive clinical results for three of the most common hereditary conditions that are frequently missed in healthcare. These CDC Tier 1 conditions include the following:

- Hereditary Breast and Ovarian Cancer Syndrome (HBOC): An inherited genetic condition that may increase the risk of developing breast, ovarian, and other related cancers, primarily due to changes in the BRCA1 and BRCA2 genes.
- Lynch Syndrome: Also known as hereditary non-polyposis colorectal cancer (HNPCC), is an inherited genetic condition that increases the risk of developing certain types of cancer such as colorectal cancer and endometrial cancer in women.
- Familial Hypercholesterolemia: A genetic disorder that leads to high levels of LDL (bad) cholesterol in the blood, increasing the risk of heart disease, heart attacks, and strokes.

Approximately 1-2% of people will have a clinical finding for one of these conditions. If detected, steps can be taken to reduce your risks for disease through treatment and preventative medicine. If a finding is detected, you will be offered follow up genetic counseling at no cost to you to help you understand your results. Your results can also positively impact members of your family by identifying potentially unknown risks for blood relatives. Receiving genetic test results, whether positive or negative, can be valuable so you and your healthcare providers can make informed decisions about what next steps are most appropriate for you and your family.

You will also receive access to your own personal, secure Helix account through the Helix website where you may have access to various genetic insights or reports based on your genetic information, such as regional ancestry and dietary insights based on your DNA.

Genetic sequencing information may reveal that you are at risk for other hereditary conditions. These results, called incidental findings, may help you learn more about your genetic risks for disease and can be returned to you as they become available, as deemed appropriate by the study team.

As the study evolves, it is possible that other results or expanded testing will be made available to you. Your stored genetic information at Helix can continue to be used for further testing, as deemed appropriate by your providers, without having to retest. This option, referred to as clinical re-use of your genetic information, may be deemed outside the scope of this study but may nevertheless offer you future benefits by offering affordable testing for other conditions.

## **Who will pay for the costs of your participation in this research study?**

There is no cost to you associated with participation in this study, including the cost of the DNA analysis provided by Helix and RIHI. If the analysis of your genetic data reveals important health information, further testing to confirm your results may be recommended. The cost of this additional testing will be your responsibility either through your insurance provider or through personal payment. Additionally, any medical advice or treatment that you seek as a result of that information will be your responsibility. If your stored genetic data is used for any future clinical tests ordered by your provider, you or your insurance provider may be responsible for the cost of those tests that fall outside of the scope of this study.

## **Will you be paid for being in this study?**

You will not receive any cash payment for being in this study. You will be given the opportunity to receive additional insights about your ancestry and traits at no cost to you. You are not required to use any complimentary results that are offered to you in order to participate in the study.

We may offer participants incentives to complete some surveys. For example, you will be given a chance to answer a follow-up survey from the RIHI, and if you complete this survey, you will be entered to win a prize, such as a \$250 gift card, or similarly valued item. The odds of winning are approximately 1 in 2500 and dependent on the rate of enrollment into the study and how many completed surveys are received. Terms of the drawing could change at any point in the future and will be disclosed at the time of survey distribution.

If your information is used as part of or to create products or services, there are no plans to pay you or give any compensation to you and your family.

## **Who will know that you are in this study and who will have access to the information we collect about you?**

The researchers who conduct the statistical analyses do not have access to Registration Information (name, address, email address, user ID, and password) of participants. These researchers do have access to your genetic information, which is assigned a unique code in order to protect your identity. Your healthcare providers at Renown Health and its partners will have access to any genetic test results that have been included in your medical record for clinical care as well as study enrollment information (showing you are a participant in this study).

Employees who interact with research participants have access to names and contact information of participants, but no genetic information. All employees are trained on how to work with human research participants. In addition, all researchers are trained on how to conduct research responsibly. Helix will have access to the information you provide to Helix during the registration process using Helix's website, and some of your health information stored in your medical record at Renown Health. The research team at Helix may analyze your data, for research purposes. No information that can identify you such as your name, date of birth, or contact information is used for research purposes. RIHI may also provide similar data to other researchers conducting approved and vetted research projects in the future, as described under "How will my data be used and shared if I participate in this study?". Again, no information that can identify you such as your name, date of birth, or contact information will be provided to these researchers.

RIHI will use your registration information to contact you about future research opportunities or to provide you with information that we find is important for your health, and RIHI needs to contact you for those reasons. Your registration information will never be associated with the joint genetic and health information database that will be used for research purposes.

## **How will we protect your private information and the information we collect about you?**

We will treat your identity with professional standards of confidentiality and protect your private information to the extent allowed by law. RIHI and Helix have strong data privacy and security policies and procedures in place to protect your information and minimize the possibility of a data breach.

During the initial phases of the study your genetic data will be provided to researchers. In addition, if you have a medical record at Renown Health, your health information will be provided to researchers and Helix but no information that can identify you such as your name, date of birth, or contact information will be shared. If other researchers request access to your data for use in future research, we will provide no information that can identify you such as your name, date of birth, or contact information. Your name, date of birth, or any contact information will not be used in any publications or reports that result from the study.

At the end of this consent form, you will be asked to provide us with your contact information. We will share your contact information with Helix for the limited purpose of sending you a saliva collection kit, if necessary, and ensuring the kit is appropriately tracked in Helix's systems. Helix will protect your information using the methods and practices stated in [Helix's Privacy Policy](#), [Terms of Service](#), and [Platform Consent](#), which you can review by clicking the links or visiting [Helix.com](#). You will also have an opportunity to review these policies during the kit registration process using Helix's website.

## **Do the researchers have monetary interests tied to this study?**

The researchers and/or their families have no direct financial interest in the study sponsor or its outcome.

## **Who can you contact if you have questions about the study or would like to withdraw?**

At any time, if you have questions about this study, contact Joseph Grzyski, PhD (PI) 775-673-7478 (Joseph.Grzyski@renown.org); Alexa Anderson (study contact) 775-982-2797 (Alexa.Anderson@renown.org) or the study team at 775-982-6914 (RenownIHI@renown.org).

To withdraw, please email: [RenownIHI@renown.org](mailto:RenownIHI@renown.org)

## **Certificate of Confidentiality**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse or neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document: contacting you about future research and development opportunities with researchers from RIHI or other organizations and/or contacting you about information that IHI receives from your Helix genetic report that is important for your health.

## **Agreement to be in study**

We will give you an electronic copy of this form to keep, either through email or stored within the document center of your Renown MyChart.



By signing your name below, you agree to be in this study and acknowledge and agree to the following:

1. You acknowledge that you have been given the opportunity to fully read this form and ask any questions.
2. You attest to being at least 18 years old.
3. You agree to fully participate in the registration and education process to participate in the study.
4. You authorize Helix to analyze your DNA from your saliva or blood sample, securely store that information, and share your genetic information with the RIHI researchers conducting the study.
5. You authorize that your age, gender, ethnicity, address, email, phone number and genetic and health information may be used as part of the databases created for the study, which will be maintained and used for future research by RIHI and other researchers with the approval of RIHI. No information that can identify you, such as your name, date of birth, or contact information, will be used for research purposes.
6. You agree to participate in the study by reasonably responding to email requests and surveys for additional data and allow such additional data to be used in the study.
7. You agree to receive health-related insights from the study that may enable you and your healthcare providers to take action and make informed decisions.
8. You agree to have your genetic information transferred to your medical record and indicated within your record that stored genetic information may be available for future clinical re-use.
9. You agree that RIHI may contact you regarding future research opportunities and information from your genetic information that is important for your health.
10. All rights and obligations herein may be transferred by RIHI to any successor organization.

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Participant's Name Printed

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Signature of Participant

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Date

## CONTACT INFORMATION

**Email Address:** \_\_\_\_\_

# For Review Only



University of Nevada, Reno

University of Nevada, Reno  
Institutional Review Board  
Approved on: July 14, 2023

Date of Birth: \_\_\_\_\_

Home Phone: \_\_\_\_\_

Mobile Phone: \_\_\_\_\_

Address: \_\_\_\_\_

Address (cont.): \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Ethnicity: \_\_\_\_\_

Birth Gender: \_\_\_\_\_

Kit ID (use barcode scanner to enter): \_\_\_\_\_

How Did You Hear About Us?: \_\_\_\_\_

**Research Clinical Trial conducted in Reno, Nevada**  
**Permission to Use Your Health Information for Research Purposes**  
**(HIPAA Authorization)**

***This form describes what researchers will do with information about you. We are asking you to allow your health care providers to share your health information for a research study. We are also asking you to let us use and share your health information for this research study.***

***Your medical care will not change in any way if you say no.***

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written permission. If you sign this form, it will provide that permission. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this permission form, and the informed consent form, and as required or allowed by law. Please read it carefully before signing it.

### **Why is access to my health information being requested?**

Access to your health information is requested to support the clinical return of genetic results to you and your providers and to use your health and genetic data to help answer complex research questions. The investigator and research team will use and store personal health information about you in a private and secure research database as described in the studies informed consent. We are asking your permission to obtain, use and share this information with others, as explained below.

### **Do I have to sign this permission form?**

You do not have to sign this permission form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

### **If I sign, can I revoke it or withdraw from the research later?**

At any time, you can withdraw consent to use and store your samples (including requesting the samples be destroyed) as long as the link between you and the samples are unbroken. If you withdraw your consent to use and store your samples, your remaining unused research samples will be destroyed, and no further testing will be done. However, if your samples have already been tested, any information obtained prior to the withdrawal of your consent may be used by the study Sponsor.

### **When will my permission expire?**

Your authorization for the use and/or disclosure of your health information will not end unless permission to use/give out this information is withdrawn.

### **What if I want to withdraw my consent to use my data?**

If you decide to participate, you are free to withdraw your permission regarding the use and disclosure of your health information at any time, and you will also be withdrawing your participation in the study. After any revocation, your health information will no longer be used or disclosed in the study for generating new research, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). Health data that has already been gathered and used for the purposes of research may still be used and given to others as described in this form.

If you wish to revoke your permission for the research use or disclosure of your health information in this study, you must email [RenownIHI@renown.org](mailto:RenownIHI@renown.org) or write to:

Healthy Nevada Project; 850 Harvard Way; Mailstop G7; Reno NV 89502

### **What Personal Information Will Be Obtained, Used or Disclosed?**

Your health information may be used or disclosed in connection with the Renown Institute for Health Innovation, including, but not limited to, your name, address, phone number, medical history, medical



procedures, health plan number, medical record number, date of birth, and information from your study visits and/or any other identifying information. Your health data may come from your family doctor or other health care workers. Research will collect and use the minimal amount of information needed to answer study questions.

### Who May Use, Disclose, or Receive the Information?

By signing this document, you agree to allow Renown Institute for Health Innovation to obtain and share health data about you with the following entities:

- Northern Nevada Hospital Systems and Clinics as follow:
  - Renown Health, Barton Health, Carson Valley Medical Center (CVMC), Carson Tahoe Health, Northern Nevada Medical Centers, Saint Mary’s Health Network
- Western Clinical Alliance – A Clinically Integrated Network (CIN)
- Any health system participating in Epic’s CareEverywhere or Orders and Results (AURA) network
- The Principal Investigator and Research Staff
- Desert Research Institute (DRI)
- Gilead Sciences, Inc.
- The University of Nevada, Reno (UNR)
- Helix, LLC, Helix Research Network, and their clinical interpretation partners
- University of Nevada, Reno Research Integrity (Ethical Oversight) and Institutional Review Board
- Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration (FDA)

Your information may be re-disclosed without your permission by the recipients described above, if they are not required by law to protect the privacy of the information.

### Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to health information collected as part of this study until it is completed. At that point, you may have access to such health information only if it was used to make a medical or billing decision about you (e.g., if included in your official medical record). If it is necessary for your care and/or treatment, your PHI will be provided to you or your referring or primary care doctor.

### Permission

I authorize the release of my medical records and personal health information for Research purposes, evaluation by the sponsor and those working for or with the sponsor, the Institutional Review Board and other ethical oversight, the FDA or regulatory agencies as described above.

I have been told that I will receive a signed and dated copy of this Authorization for my records.

\_\_\_\_\_  
Signature of Adult Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Adult Participant

## CONSENT FOR OBTAINING, RETAINING OR DISCLOSING GENETIC INFORMATION



As used in this document, “genetic information” means any information that is obtained from a genetic test.

1. I understand that no insurer or corporation that provides health insurance, carrier serving small employers or health maintenance organization may:

- (a) Require me or any member of my family to take a genetic test;
- (b) Require me to disclose whether I or any member of my family has taken a genetic test;
- (c) Request my genetic information or the genetic information of a member of my family; or
- (d) Determine the rates or any other aspect of the coverage or benefits for health care for me or my family based on whether I or any member of my family has taken a genetic test or based on my genetic information or the genetic information of any member of my family.

2. I also understand that:

(a) I have the right to receive the results of a genetic test, in writing, within 10 working days after the person conducting the test has received the results. The written results must indicate that, except as otherwise provided in [chapter 629](#) of NRS, my genetic information may not be obtained, retained or disclosed without first obtaining my informed consent.

(b) It is unlawful for a person or entity to obtain my genetic information without my informed consent, unless the information is obtained:

- (1) By a federal, state, county or city law enforcement agency to establish the identity of a person or a dead human body;
- (2) To determine the parentage or identity of a person in certain circumstances;
- (3) To determine the paternity of a person in certain circumstances;
- (4) For use in a study where the identities of the persons from whom the genetic information is obtained are not disclosed to the person conducting the study;
- (5) To determine the presence of certain inheritable disorders in an infant in certain circumstances; or
- (6) Pursuant to an order of a court of competent jurisdiction.

(c) It is unlawful for a person to retain genetic information that identifies me without first obtaining my informed consent, unless retention of the genetic information is:

- (1) Necessary to conduct a criminal investigation, an investigation concerning the death of a person or a criminal or juvenile proceeding;
- (2) Authorized pursuant to an order of a court of competent jurisdiction; or
- (3) Necessary for certain medical facilities to maintain my medical records.

(d) If I have authorized a person to retain my genetic information, I may request that the person destroy the genetic information. Such a person shall destroy the information, unless retention of the information is:

- (1) Necessary to conduct a criminal investigation, an investigation concerning the death of a person or a criminal or juvenile proceeding;
- (2) Authorized by an order of a court of competent jurisdiction;
- (3) Necessary for certain medical facilities to maintain my medical records; or
- (4) Authorized or required by state or federal law.

(e) Except as otherwise provided by federal law or regulation, a person who obtains my genetic information for use in a study shall destroy the information upon completion of the study or my withdrawal from the study, whichever occurs first, unless I authorize the person conducting the study to retain my genetic information after the study is completed or upon my withdrawal from the study.

(f) It is unlawful for a person to disclose or to compel another person to disclose my identity if I was the subject of a genetic test or to disclose to another person genetic information that allows the other person to identify me without first obtaining my informed consent, unless the information is disclosed:

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University of Nevada, Reno

University of Nevada, Reno  
Institutional Review Board  
Approved on: July 14, 2023

- (1) To conduct a criminal investigation, an investigation concerning the death of a person or a criminal or juvenile proceeding;
- (2) To determine the parentage or identity of a person in certain circumstances;
- (3) To determine the paternity of a person in certain circumstances;
- (4) Pursuant to an order of a court of competent jurisdiction;
- (5) By a physician after I am deceased and my genetic information will assist in the medical diagnosis of persons related to me by blood;
- (6) To a federal, state, county or city law enforcement agency to establish the identity of a person or dead human body;
- (7) To determine the presence of certain inheritable preventable disorders in an infant in certain circumstances; or
- (8) By an agency of criminal justice in certain circumstances.

I, \_\_\_\_\_ (name of person giving consent), hereby give my consent to \_\_\_\_\_ (name of person or agency obtaining genetic information) to obtain my genetic information; or

I, \_\_\_\_\_ (name of person giving consent), hereby give my consent to \_\_\_\_\_ (name of person or agency retaining genetic information) to retain my genetic information; or

I, \_\_\_\_\_ (name of person giving consent), hereby give my consent to \_\_\_\_\_ (name of person or agency disclosing genetic information) to disclose my genetic information to \_\_\_\_\_ (name and address of person or agency to receive genetic information).

This consent document is valid until \_\_\_\_\_ (date of expiration).

If the person tested is unable to sign, please indicate the reason here: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Signature of consenting person  
or his or her legal representative

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date