Research Consent Form

Title of Study: DRI-Renown Health Population Health study
Principal Investigator: Joseph Grzymski, PhD
Co-Investigators: Christos Galanopoulos, MD; Christopher Rowan, MD
Study contact: Shaun Dabe
Study ID Number: 7701703417
Sponsor: Renown Health Foundation

Introduction

You are being invited to participate in 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?

The overall goal of this study is to improve the population health of Nevada. To do so, we are obtaining genetic data from Nevada residents to combine with medical data from Renown Health along with regional weather, geologic and other data from the Desert Research Institute (DRI) and other sources. The data we collect will be de-identified and stored in a joint genetic and health information database. The data will be used to look for patterns and other statistically relevant information that may be beneficial in predicting, planning for, and positively influencing the health, health decisions and health care needs of Nevada citizens. We will also be studying how genetic insights influence the health decisions made by study participants.

Your genetic information will be stored in your medical record to help your providers provide personalized medicine to you according to your genes. **If you do not want your genetic information in your chart, you can opt-out by contacting the study team, listed below.**

In addition, the de-identified data in the joint genetic and health information database will be made available for other research projects and to researchers outside of RIHI, as approved by RIHI, including for commercial or for-profit purposes. For example, the de-identified 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. This is just one example of

how de-identified data may be used. RIHI will vet and approve all requests from outside researchers before providing them with access to de-identified data.

From time to time, researchers from RIHI or other institutions might want to ask you to participate in additional research studies or development projects. In some cases, you might be a particularly good candidate for a particular study because of your health history or genetic report. By signing this document, you give your permission for RIHI to contact you about future research opportunities. You may withdraw your permission to be contacted about future research at any time by contacting the principal investigator of the study. The information that RIHI will use to contact you is stored separately from the de-identified joint genetic and health information database. **You may withdraw your permission to be contacted about future research at any time by contacting the principal investigator of the study**.

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.

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. Helix, the clinical laboratory that partners with the Healthy Nevada Project, will use your saliva 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 to help answer research questions for as long as the data is stored. RIHI and Helix will initially be examining your DNA 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.

Any clinically significant results obtained from analyzing your genetic information may be stored in your medical record to help your physicians provide you with the best care possible. Your genetic information may also be analyzed at the direction of your physicians for more personalized medicine based on your genes. If you do not want results based on the analysis of your genetic information in your chart, you can opt-out by contacting the study team, listed below.

If you agree to be in this study, you agree to the following:

- 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.
- If you have any medical records with Renown Health, you will be asked for authorization to share those records with RIHI.
- You will be periodically contacted via email or web survey by RIHI and Helix and asked to answer questions that will provide additional important information about you that will be used as part of the research.

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 sample. Once enrolled in this study, your participation will not take a lot of time. For the duration of this research study, you will be periodically contacted via email and asked to answer several questions providing additional relevant information about you. You may also be periodically contacted via email with important information, such as new research developments, insights or opportunities being offered to participants.

How long will you be in the study?

Your de-identified genetic and health information will be stored indefinitely in a database for future research use, as described under "Why are we doing this study?". In addition, if you agree to be contacted regarding future research opportunities, you may be contacted regarding those opportunities unless you withdraw your permission.

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 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. Your de-identified genetic and health information will continue to be a part of the joint genetic and health information database and will continue to be used by the researchers and may be used for future research. Likewise, your medically relevant genetic information will be stored in your medical chart for your healthcare provider to determine if clinically relevant.

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

Your participation in this study is non-invasive and cannot cause any potential adverse consequences to your physical health. However, there are risks involved in having your genetic information analyzed and in sharing your genetic and health information.

- Your genetic data may reveal that you are at risk of developing certain illnesses, which might also indicate that your genetic relatives are similarly at-risk.
- Some survey questions may make you or your family members uncomfortable.
- As with any database, despite RIHI and Helix implementing rigorous 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 stolen 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, which could have a negative effect on your ability to obtain certain types of insurance coverage. 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.

Although RIHI and Helix cannot provide a 100% guarantee that your data will be safe, they have strong policies and procedures in place to minimize the possibility of a breach. In addition to the risks noted above, there may be additional risks to participation that are currently unforeseeable.

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. Although the study has not been designed to impact your immediate clinical care, the practice of genomic medicine (which means medical care and clinical decision making that is informed by genetic information) is evolving to make a positive impact on an individual level. There is a small chance that the genetic sequence provided to RIHI could also reveal information about you that is important for your health. For example, the genetic information may reveal that you are at risk for certain hereditary conditions - including cancers and cardiac conditions. Learning about these risks can be valuable so you and your healthcare providers can make informed decisions about what next steps are most appropriate for you. However, only 1-2% of the population have shown to have an incidental finding, so you may not be impacted.

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 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. More information about Helix and Helix test results will be provided to you during the registration process using Helix's website. **If you do not want to receive the results, you should not participate in this study.**

This information may be shared with your healthcare professional who can help you better understand your genetic information and provide care recommendations, unless you choose to opt out.

When you enroll, the study will provide information on which insights you can expect to receive soon after providing your sample for DNA analysis. As the study evolves, it is possible that other results will be made available to you. These reports may indicate that you have inherited risk factors that you may or may not already be aware of and that could show you are at higher risk for developing certain conditions.

As with any voluntary research study, you may withdraw at any time by contacting the principal investigator of the study.

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.

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.

Some surveys offered to participants may include incentives to complete. 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 how many completed surveys are received in an approximate 6 month time frame. 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 valuable 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 but do have access to your de-identified genetic information, which is assigned a unique code in order to protect your identity. Your providers at Renown Health will also have access to your genetic information for clinical care.

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, after it has been de-identified, for research purposes. RIHI may also provide your de-identified data to other researchers conducting approved and vetted research projects in the future, as described under "Why are we doing this study?".

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 your de-identified data in 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 de-identified genetic data will be provided to researchers. In addition, if you have a medical record at Renown Health, your de-identified health information will be provided to researchers and Helix. We will not provide the researchers with your name or other information that could identify you. If other researchers request access to your data for use in future research, we will only provide your de-identified data. Your name 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 to opt-out?

At any time, if you have questions about this study, contact Joseph Grzymski, PhD (Principal Investigator) 775-673-7478; Christos Galanopoulos, MD (Co-Principal Investigator) 775-982-4000, Christopher Rowan, MD (Co-Principal Investigator) 775-982-2400 or Shaun Dabe (study coordinator) 775-982-6914.

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 a copy of this form to keep.

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 agree to fully participate in the registration and education process to participate in the study.
3. You authorize Helix to analyze your DNA from your saliva sample, securely store that information, and share your genetic information with the RIHI researchers conducting the study.
4. You authorize that your age, ethnicity, address, email, phone number and de-identified genetic and health information may be used as part of the database for the study, which will be maintained and used for future research by RIHI and other researchers with the approval of RIHI.
5. You agree to participate in the study by reasonably responding to email requests for additional data and allow such additional data to be used in the study.
6. 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.
7. You agree to have your genetic information transferred to your medical record.
8. You agree that RIHI will contact you regarding future research opportunities and information from your genetics that is important for your health according to your preferences noted above.
9. All rights and obligations herein may be transferred by RIHI to any successor organization.

Participant's Name Printed

Signature of Participant

Date

CONTACT INFORMATION

Email Address: _____

Date of Birth: _____

Home Phone: _____

Mobile Phone: _____

Address: _____

Address (cont.): _____

City:_____ State:_____ Zip Code: _____

Ethnicity: _____

Birth Gender: _____

Kit ID (use barcode scanner to enter): _____

☐ **I am at least 18 years old**

How Did You Hear About Us?: _____

Authorization to Release Health Information that Identifies You for a Research Study

If you sign this document, you give permission to researchers at RIHI to release health information that identifies you for the research study described in this consent form.

The health information that we may release for this research includes your:

- Name
- Email address
- Phone number
- Mailing address

The health information listed above may be released to **Helix** for the limited purpose of shipping a saliva collection kit to you and ensuring the saliva kit is appropriately tracked in Helix's systems.

I may revoke this Authorization at any time, in a written revocation sent to the Custodian of Records. However, I understand that my health information might have already been released.

Information released by this Authorization might be re-disclosed by the recipient and might not be protected by state and federal privacy laws. I agree to release Renown Health from liability for release and disclosure of the released information. RIHI is required by law to protect your health information. By signing this document, you authorize RIHI to release your health information for this research.

Please note that:

- You do not have to sign this Authorization, but if you do not, you may not participate in the study.
- RIHI may not condition treatment on whether you sign this Authorization.
- You may change your mind and revoke this Authorization at any time, except to the extent that RIHI has already acted based on this Authorization.
- This Authorization will expire in ten years.
- A copy of this signed Authorization will be sent to you.

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:

(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