

## Research Consent Form

**Title of Study: DRI-Renown Health Population Health study**

**Principal Investigator: Joseph Grzymiski, PhD**

**Co-Investigators: Christos Galanopoulos, MD; Christopher Rowan, MD**

**Study contact: Shaun Dabe**

**Study ID Number: 7701703417**

**Sponsor: Renown Health Foundation**

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### 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”). 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 healthcare 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 doing this study to obtain de-identified genetic data from Northern Nevada residents to combine with de-identified medical data from Renown Health along with regional weather, geologic and other data from the Desert Research Institute (DRI) and other sources. The de-identified data we collect will be stored in a joint genetic and health information database that 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 Northern Nevada citizens. We will also be studying the influence on the health decisions made by study participants as a result of obtaining the genetic insights provided to participants from Helix’s Partners.

In addition, the de-identified information 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 information will be available for any research question, such as research 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.

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. If you give us permission below, RIHI will contact you about future research opportunities. You may withdraw your permission at any time by contacting the principal investigator of the study.

*May we contact you about future research and development opportunities with researchers from RIHI or other organizations? (Please check the box for your response below)*

Yes  No

### **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 Northern Nevada 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 Northern Nevada.

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

You will be asked to provide a saliva sample to be used for genetic sequencing by Helix. Helix will use your saliva sample to sequence specific portions of your genome called whole exome plus sequencing. RIHI researchers will initially be examining your genes for risks related to cardiovascular disease, cancers and other illnesses where risks are increased based on genetic profile such as age related macular degeneration. You will also be asked for authorization to share the results of your genetic sequence with RIHI. If you have any medical records with Renown Health, you will be asked for authorization to share those records with RIHI and Helix. You will be periodically contacted via email or web survey by RIHI and Helix and asked to answer questions that will provide important additional data points that will be used as part of the research.

### **How long will you 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 data. You may also be periodically contacted via email with important information, such as new research developments, insights or opportunities being offered to participants. 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 until 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 and have no obligation to answer those emails; your genetic results will be completely de-identified and we will have no way of contacting you if medical knowledge changes. However, your de-identified genetic and health information will continue to be a part of the entire study genetic and health information database and will continue to be used by the researchers and may be used for future research. Since the data is de-identified, the researchers will have no way to tie the data they are reviewing to you or any other individual study participant.

## **Is there any way being in this study could be bad for you?**

Your participation in this study is non-invasive and cannot cause any potential adverse consequences to your health. However, there are risks involved in having your genes 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.
- 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, they may be made public or released to insurance companies, which could have a negative effect on your ability to obtain insurance coverage.
- If you or a family member has genetic data linked to your name or your family member's 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 the publicly available genetic data.

Although RIHI 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.

## **Will being in this study benefit you in any way?**

This study is not intended to provide you with any direct clinical diagnostic information so there is no intended personal health benefit to you.

You will receive access to the Helix Store, where you can get products that give you genetic insights. You may benefit from sharing this report(s) with your healthcare professional who can help you better understand the genetic information contained in the report. More information about the Helix genetic test and test results will be provided to you during the registration process using Helix's website.

There is a small chance that the genetic sequence provided to IHI will reveal information about you that is important for your health. For example, the genetic sequence may reveal that you are at risk for certain cancers, genetic syndromes, and cardiac conditions about which you may want to seek immediate medical attention and care. With your permission, researchers from RIHI will contact you regarding any such findings. You may withdraw this permission at any time by contacting the principal investigator of the study.

*May we contact you about information that IHI receives from your Helix genetic report that is important for your health? (Please check the box for your response below)*

Yes

No

### **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. You also do not need to pay for Helix's genetic sequencing. You will receive one product from the Helix Store free of charge.

### **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 ancestry analysis that you will receive at no cost to you. You are not required to use any complimentary product that is offered to you in order to participate in the study. You are not required to purchase any additional services or apps. 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 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. Employees who interact with research participants have access to names and contact information of participants, but no genetic information. All employees are trained how to work with human research participants. In addition, all researchers are trained 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. This information will be used for research purposes and will be analyzed as de-identified data. We may also provide your de-identified data to other

researchers conducting research projects in the future, as described under “Why are we doing this study?”.

Your de-identified information will be re-identified by RIHI if you give us permission to contact you about future research opportunities or information that we find is important for your health, and RIHI needs to contact you for those reasons. Your identifiers will never be associated with your information 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 have strong data privacy and security policies and procedures in place to protect your information and minimize the possibility of 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 or Helix with your name or other information that could identify you. Your name will not be used in any publications or reports that result from the study.

Helix will protect your information using the methods and practices stated in Helix’s Privacy Policy, Terms of Service, and Platform Consent, which you will have an opportunity to review during the registration process using Helix’s website.

If other researchers request access to your data for use in future research, we will only provide your de-identified data.

## **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?**

At any time, if you have questions about this study, contact Joseph Grzymiski, PhD (PI) 775-673-7478; Christos Galanopoulos, MD (Co-PI) 775-982-4000, Christopher Rowan, MD (Co-PI) 775-982-2400 or Shaun Dabe (study contact) 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 your saliva to be genetically tested and the sharing of your sequenced genetic information from Helix with the researchers conducting the study.
4. You authorize that your age, ethnicity, 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 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.
7. All right 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:** \_\_\_\_\_

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

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

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

**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?:** \_\_\_\_\_