

## Research Consent Form

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

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**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”), 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 and to provide screening to individuals for 3 inherited genetic conditions called CDC Tier 1 conditions: Hereditary Breast and Ovarian Cancer Syndrome, Lynch Syndrome, and Familial Hypercholesterolemia. 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 securely 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. The genetic data may also be used in the future to offer new genetic interpretations to study participants. We will also be studying how genetic insights influence the health decisions made by study participants.

Your genetic information that has been interpreted will be stored in your medical record to help your providers provide personalized medicine to you according to your genetic makeup. The data in the joint genetic and health information database is meant to serve the research community at Renown Health, and the research collaboration among Renown Health, DRI, and Helix. The data will be made available to researchers from Renown, RIHI, and Helix to support

the study, as well as for future research. The stored data will be identified by your medical record number or other unique study identifiers but will have other direct identifiers like your name, address, and phone number removed. This allows researchers to update your stored health information, and it allows them to recontact you, if needed.

In addition, the data in the joint genetic and health information database may be de-identified and shared with 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 information. By signing this document, you give your permission for RIHI to contact you about future research opportunities. The information that RIHI will use to contact you is stored separately from the 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 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. 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 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.

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. Your sequenced genetic information will be securely stored at Helix and may be used in the future if your physician(s) determine that additional genetic interpretations may be important for your health and healthcare decisions.

You will have the opportunity to create or claim your online account with Helix. Through the Helix account you may also receive additional results based on your genetic information, such as inherited traits and ancestry information. The Helix account also provides access to certain test results provided through the study, such as results for inherited forms of cancer and heart disease.

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 or affiliated partners, you will be asked for authorization to share those records with RIHI.
- You will be contacted via email or web survey by RIHI and Helix from time to time 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, you may be contacted regarding future research 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. Additionally, you may request that your stored genetic information at Helix be deleted upon your withdrawal or not shared for research. However, any information already shared, such as 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 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 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.
- 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 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 specifically to impact your immediate clinical care, the practice of genomic medicine (which means medical care and healthcare decision making that is informed by genetic information) is evolving to make a positive impact on an individual level.

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 3 of the most common hereditary conditions that are frequently missed in healthcare. These CDC Tier 1 conditions include Hereditary Breast and Ovarian Cancer Syndrome, Lynch Syndrome, and Familial Hypercholesterolemia. Although only 1-2% of people will have a clinical finding for one of these conditions, if detected, these conditions are treatable and could also impact members of your family. Learning about these risks, 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.

As the study evolves, it is possible that other results 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. There is also a small chance that the genetic sequence provided to RIHI could reveal information about you that is important for your health. For example, the genetic 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.

## **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.

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 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 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 de-identified 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.

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. **You may withdraw your permission to be contacted about future research at any time by contacting the principal investigator of the study.**

## **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](http://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; 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.
9. 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: \_\_\_\_\_

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

## **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?**

If you decide to participate, you are free to withdraw your permission regarding the use and disclosure of your health information at any time, but 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, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). However, health data about you that has already been gathered 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 write to:

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

### **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?**

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.

## 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. Your information will be de-identified (removing identifying indicators) as much as possible to use as quantitative (numbers) or qualitative (descriptions) data.

## 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 Center
  - Saint Mary's Health Network
  - Western Clinical Alliance – A Clinically Integrated Network (CIN)
- The Principal Investigator and Research Staff
- Desert Research Institute (DRI)
- 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 any 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:

- (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