APPROVED BY
INTEGREVIEW IRB
NOVEMBER 19, 2019

INFORMED CONSENT DOCUMENT FOR GENOMICS TEST

NAME OF SPONSOR COMPANY:	Grace Health Technologies and Designer Genomics International
PROTOCOL NUMBER:	GH101
TITLE OF STUDY:	**"**Genetic Susceptibility to Chronic Disease"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/ INVESTIGATOR):	Marvin S. Hausman MD
TELEPHONE NUMBER(S), DAYTIME& AFTER HOURS:	503-327-4173

INTRODUCTION

You are being invited to participate in a research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about the study. Please ask as many questions as you need to before you decide if you want to be in the study. Do not sign this form if you have any questions that have not been answered. All testing results will be supplied to you and your doctor.

DNA is the inherited code that makes each person unique. DNA is arranged into different genes that determine things like hair color, eye color and height. Genes also control how the body breaks down drugs. For example, with some drugs, genetic differences change how long the drug stays in the body. Scientists are learning more about differences in genes that may predict whether a subject will be at risk for diseases. By learning about these differences in genes, we hope to be able to improve our understanding and treatment of different diseases.

Many patients who undergo currently used genetic testing procedures may receive inconclusive results due to limitations of DNA-only genetic testing. We propose to add to your current submitted genetic sample for DNA measurement a simultaneous RNA genetic test. You are being asked to take part in a study that has the potential to provide you and your doctor with more accurate, actionable, informed findings that can be used in your healthcare assessment.

You are being asked to allow collection of a buccal (mouth) sample of your cheek cells to look at your genes (DNA and RNA). You do not have to consent for this add-on RNA study to consent for your doctor advised regular DNA study. Your participation is voluntary and your refusal will have no impact on your doctor relationship.

PURPOSE

The purpose of this study is:

- To provide additional genetic testing to your scheduled DNA testing
- To enhance understanding of the DNA variant testing and interpretation.

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The study will last about 12 months and will involve only 2 visits. About 300 men and women with cancer, ages 21 to 85, undergoing a scheduled DNA genetic testing are expected to be in this study.

PROCEDURE

If you agree to be in the genetic research program, you or a doctor's office personnel will obtain cheek cells by using a provided applicator stick with a cotton tipped swab. The swab is placed into a tube containing preservative and the contained cells undergo DNA and RNA testing at an approved genetic testing lab.

RISKS

There are essentially no side effects except for a possible sense of irritation in the cheek area where the swab is applied.

BENEFITS

A genetic report will be provided to you and your doctor. You will get no medical benefit from this study, other than the results of the RNA genetic panel study.

BEING IN THE STUDY

It is your choice if you want to have your cells undergo RNA testing. Once the testing procedures are finished all cell samples are destroyed and you will not have to undergo any further procedures. All genetic data will undergo bioinformatic analysis and the findings will remain confidential.

The analytic results from your bio-specimens (even if identifiers are removed) when combined with analytic results from other individuals in the study may be used for commercial profit. You will not share in this commercial profit.

The individual research results will be provided to you and your doctor. Strict rules of confidentiality will be maintained.

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that is obtained from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that is obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

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Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

Since the study is for research only, the only other choice would be not to be in the study.

CONFIDENTIALITY AND OTHER RISKS

Once we have your cheek cell sample, we will give it a code. This code will contain your age, sex, race, and other information. It will not contain your name.

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The investigator
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- IntegReview IRB

The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

There are possible non-physical risks associated with this genetic research, such as the risks associated with a breach of privacy or confidentiality.

Although this testing is supposed to be private, this cannot be guaranteed. For example, it is possible for a court of law to get health or study records without your permission.

IN CASE OF STUDY RELATED INJURY

No form of compensation is offered.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

Marvin S. Hausman, MD
503-327-4173
Holly Magliochetti
978-590-3193

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

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If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please go to the nearest emergency room.

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview is a group of people that has reviewed this research study. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
Chairperson IntegReview IRB 3815 S. Capital of Texas Highway Suite 320 Austin, Texas 78704		integreview@integreview.com

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or
toll free at 1-877-562-1589
between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT

You will not be paid for being in this study.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The investigator, the sponsor company, IntegReview, or the FDA, if applicable, may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed.

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CONSENT

☐ I **AGREE** to give a cheek cell sample for genetic research.
OR
☐ I **DO NOT AGREE** to give a cheek cell sample for genetic research.

_____
Printed Name of Adult Study Subject

_____
Signature of Adult Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will receive a signed and dated copy of this consent form.