APPROVED BY
INTEGREVIEW IRB
FEBRUARY 14, 2020

INFORMED CONSENT DOCUMENT FOR OPSISDx™ Urine Test

NAME OF SPONSOR COMPANY:	Grace Health Technologies and Designer Genomics International
PROTOCOL NUMBER:	GH215
TITLE OF STUDY:	"Urine Analysis Using OpsisDx™"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/ INVESTIGATOR):	Marvin S. Hausman M.D.
TELEPHONE NUMBER(S), DAYTIME:	561-475-3069
AFTER HOURS:	978-590-3193

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.

The objective of this study is to develop a new diagnostic urine test to diagnose prostate cancer. Current diagnostic tests for prostate cancer, including prostate specific antigen (PSA) and prostate biopsy may have false positive or false negative results. Inconclusive results could cloud the diagnosis and not allow needed appropriate treatment.

You are being asked to take part in a study that has the potential to provide future knowledge to increase the sensitivity of prostate cancer diagnosis.

You are being asked to allow collection of a urine sample that will be used to validate the OpsisDx™ prostate test.

It is your choice if you want to be in the study. No one can force you to be in the study. Your participation is voluntary, and your refusal will have no impact on your doctor-patient relationship. 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.

PURPOSE

The purpose of this study is:

- To enhance understanding and validate the OpsisDx prostate cancer test.

The study will last about 12 months and will involve only 1 urine specimen. This study will admit 200-250 individuals with no signs of prostate cancer and 150-200 individuals with biopsy confirmed prostate cancer.

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PROCEDURE

If you agree to be in this study you or a doctor's office personnel will obtain a first morning collection of urine in a provided sterile, plastic container.

RISKS

There are no known side effects. The study is noninvasive.

BENEFITS

You will get no medical benefit from this study. You are assisting in the development of diagnostic technology that has the potential to offer patients and healthcare professionals the ability to quickly, inexpensively and easily diagnose the occurrence of prostate cancer.

BEING IN THE STUDY

It is your choice if you want to participate in this study. Once the testing procedures are finished, any unused urine will be stored at room temperature for a maximum of 1 year in case the sample needs to be retested and then destroyed. All 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.

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 urine 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
- Other state or federal regulatory agencies

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.

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There are possible non-physical risks associated with this urine study, 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, M.D.
561-475-3069 Daytime phone number
978-590-3193 After hour
or
Holly Magliochetti
978-590-3193

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

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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 that 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 first morning urine sample.
OR
☐ I **DO NOT AGREE** to give a first morning urine sample.

_____
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.

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