RUTGERS Cancer Institute of New Jersey
RUTGERS HEALTH

COLORADO Department of Public Health & Environment

The GRACE Project
GENETIC RISK ASSESSMENT FOR CANCER EDUCATION AND EMPOWERMENT

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Genetic Risk Assessment for Cancer Education and Empowerment
Principal Investigator: Anita Kinney, PhD, RN

You are being asked to participate in an important research study, the "Genetic Risk Assessment for Cancer Education and Empowerment." The goal of this research study is to find better strategies to prevent and control cancer in women and their families. This study is being conducted by the Rutgers Cancer Institute of New Jersey.

This informed consent form provides information about a research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part in it, you should feel free to ask them and should expect to be given answers you completely understand. It is your choice whether to take part in the research. Your alternative to taking part is not to take part in the research.

After all of your questions have been answered and you wish to take part in the research study, a staff member will call you and record your verbal consent to participate in this study over the telephone.

Who is conducting this research study?
Dr. Anita Kinney, PhD, RN is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Anita Kinney or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

SPONSOR OF THE STUDY: National Cancer Institute

Why is this study being done?
You are being asked to participate in an important research study, the "Genetic Risk Assessment for Cancer Education and Empowerment." The goal of this research study is to find better strategies to prevent and control cancer in women and their families.

Who may take part in this study and who may not?
Individuals who have been diagnosed with breast or ovarian cancer may participate.

Why have I been asked to take part in this study?
You are being asked to participate in this study because: 1) you were identified from the New Jersey State Cancer Registry or Colorado Central Cancer Registry records as having been diagnosed with breast cancer or ovarian cancer and 2) you are age 21 or over.

How long will the study take and how many subjects will take part?
The first survey will take 45-60 minutes to complete. The surveys 1-month, 6-months, and 12-months after the initial survey will require less time, approximately 30-45 minutes each. Your meeting with a cancer education specialist over the phone will take approximately 15-45 minutes. The entire study will take place over the next twelve months.

What will I be asked to do if I take part in this study?
If you agree to participate, you can expect the following things:

- You will be called to complete a survey over the phone or online. This survey will ask questions about several different items, including your health, your thoughts, and your feelings toward genetic risk assessment.
- Following the initial survey, you may be asked to speak to a cancer education specialist over the phone. Whether you speak to a cancer education specialist or not will be determined randomly. Randomization is a method used to ensure the research study is fair. It means that participants are assigned by chance to different study groups. This study involves three different study groups: one will speak to a cancer education specialist, one will receive mailed materials about preventing and controlling cancer in families with a history of breast and/or ovarian cancer, and one will continue with their usual care.
- One month after the initial survey, you will be called to complete another survey over the phone or online. This will occur at six months and twelve months, as well. These surveys will be very similar to the initial survey, but will contain some new questions concerning genetic risk assessment and genetic testing. You will be compensated with a $50 merchandise card for each survey you complete, and an additional $50 merchandise card if you complete all 4 surveys.
- With your permission, all telephone calls with study staff and/or a cancer education specialist will be audiotaped for quality control. Your consent to participate in this research will also be audiotaped.
- You will be asked to sign the consent form and mail the signed document to the CINJ office or to a staff member's home during COVID 19 at the address included on the return envelope.

What are the risks and/or discomforts I might experience if I take part in this study?
There are no known risks in this study, but some individuals may experience discomfort or distress when answering questions about or thinking and talking about cancer or other health issues. Every effort will be made to protect the information you give us; however, there is a small risk of loss of privacy and confidentiality. The researchers are trained to protect your

information and to use procedures that reduce the possibility of loss of privacy and/or confidentiality.

Are there any benefits to me if I choose to take part in this study?
By participating in this study, you may learn more about your and your family's risk for hereditary breast and ovarian cancer and about current screening guidelines or other cancer prevention measures.

The findings from this study will also provide information on better ways to encourage cancer survivors to seek genetic risk assessment services, which can lead to increased knowledge in communities concerning hereditary cancers and cancer prevention.

What are my alternatives if I do not want to take part in this study?
Taking part in this study is voluntary, so you can choose not to participate. There will be no penalties involved if you choose not to take part in this study, and it will not change or influence your medical care.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to me to take part in this study?
There will be no cost to you to take part in this study.

Will I be paid to take part in this study?
You will be called to discuss completing an initial survey, which can be done over the phone or online. This survey will ask questions about several different items, including your health, your thoughts, your feelings, and your attitudes toward cancer genetic risk assessment. This first survey will take about 45-60 minutes, and you will receive a $50 gift card for your time.

One month after the initial survey, you will be called to complete another survey over the phone or online. This survey will take about 30-45 minutes to complete. This will occur again at six months and twelve months, as well. You will be compensated with a $50 gift card for each survey you complete, and you will receive an additional $50 gift card if you complete all 4 surveys. Total compensation for participation is up to $250.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. All information you share in this study will be kept confidential. Your name and other identifying information will be maintained in locked paper files and secure computer files on a secure computer server, available only to authorized

members of the research team, for the duration of the study. Data will be stored separately from your name and other identifiable information. Your personal identifiable data will only be identified by a unique number (study ID) and it will be password-protected. We will use those numbers instead of your name on files and (including audio files of telephone surveys and educational sessions) whenever possible. Paper files will be kept in locked rooms when not being used. Only people who need to use the files will have access to them. The results of the study may be published in scientific papers. People who are in the study will not be identified in those papers. Audio files will be used only to confirm information from the telephone calls or to better understand the effects of health information provided to you as part of the GRACE Project. They will be destroyed at the end of the project. We will protect your privacy at all times to the extent mandated by law. The project has a Certificate of Confidentiality from the Federal government. This certificate helps make sure we can protect your privacy. Unless you give written permission, project staff cannot be forced to tell people who are not part of this study about you being in it. Any personal identifying information, audio files, and any record linking that information to study ID numbers will be destroyed within 10 years of the end of the study.

Information contained in your study records is used by study staff, and, in some cases, it will be shared with the sponsor of the study: the National Cancer Institute. This information does not contain personal identifiers and in no way could the information be linked to you.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.
During COVID 19, the signed consents will be collected off-site and stored in a locked safe and transferred to Rutgers CINJ following the COVID 19 pandemic.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Anita Kinney195 Little Albany Street, New Brunswick, NJ 08903-1384.

Who can I call if I have questions?
If you have any questions, concerns or complaints at any time about the research study, Julianne Ani, the Program Development Specialist will be glad to address them at (732) 235-8979.

If you have questions about your rights as a research subject, you can call the IRB Director at: (732) 235-9806 or the Rutgers Human Subjects Protection Program at (973) 972-1149 in Newark or (732) 235-8578 in New Brunswick.

Consent
You are making a decision whether to participate in this study. You can ask any questions and provide verbal consent to participate in this study when you are contacted by a study team member.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What is the purpose of the research and how will my information be used?
You have been asked to take part in a research study. The consent for this study describes your participation, and that information still applies. This extra form is required by the federal Health Insurance Portability and Accountability Act (HIPAA). The purpose of this form is to get your permission (authorization) to use health information about you that is created by or used in connection with this research. This form gives permission to study investigators to view your medical records to confirm medical referrals and procedures related to this study including the dates of genetic counseling/risk assessment and genetic testing services and the results of genetic counseling/risk assessment and genetic testing.

What information about me will be used?
The information that may be used includes:

- Diagnoses
- Medical tests and procedures
- Dates of medical procedures (such as for genetic counseling/risk assessment and testing)
- Reasons for procedures
- Results of genetic testing.

Who may use, share or receive my information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study;
- Non-Rutgers researchers on the study team: University of New Mexico and Colorado
- The Rutgers University Institutional Review Board and Compliance Boards

- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- National Institute of Health

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision:

Anita Y. Kinney, PhD, RN
Rutgers Cancer Institute of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903-1384

How long will my permission last?
If you decide to be in this research study, your permission to access and use your health information in this study may not expire, unless you revoke or cancel it. Otherwise, we will use your information as long as it is needed for the duration of the study.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name:_____

Subject Signature:_____Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____Date: _____

Audio/Visual Addendum to Consent Form

You have already agreed to participate in a research study entitled: Genetic Risk Assessment for Cancer Education and Empowerment conducted by Dr. Anita Kinney, PhD, RN. We are asking for your permission to allow us to include optional procedure such as audiotape (sound) as part of that research study. You do not have to agree to be recorded in order to participate in the main part of the study.

The recording(s) will be used for quality assurance, analysis by the research team and possible use as a teaching tool to those who are not members of the research staff (i.e. for educational purposes).

The recording(s) will include your name. If you say anything that you believe at a later point may be hurtful and/or damage your reputation, then you can ask the interviewer to rewind the recording and record over such information OR you can ask that certain text be removed from the dataset/transcripts. At any time you can ask that the recording be stopped .

The recording(s) will be stored in a locked file cabinet and linked with a code to subjects' identity. The recordings will be kept until the end of the study and then destroyed.

Your signature on this form grants the investigator named above permission to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

Subject (Print) _____

Subject Signature_____Date _____

Principal Investigator Signature_____Date _____