GEORGETOWN UNIVERSITY

Lombardi Comprehensive Cancer Center
Fisher Center for Hereditary Cancer & Clinical Genomics Research

Rutgers University Study Pro #: 2022001513

Principal Investigators: Marc D. Schwartz, PhD (MedStar Georgetown Lombardi Comprehensive Cancer) and Anita Y. Kinney, PhD (Rutgers Cancer Institute of NJ)

Title: Personalized Oncology Promoting Equity for Black Lives (PROPEL)

Permission to Take Part in a Human Research Study

MedStar Health Research Institute/Georgetown University Medical Center

Location: **MedStar Georgetown Lombardi Comprehensive Cancer Center, MedStar Washington Hospital Center, Rutgers Cancer Institute of New Jersey**

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Title of Study: Personalized Oncology Promoting Equity for Black Lives (PROPEL)
Principal Investigator: Marc D. Schwartz, PhD

On behalf of the Georgetown Lombardi Comprehensive Cancer Center (LCCC) and Rutgers Cancer Institute of New Jersey, we are excited to invite you to participate in the Addressing Genomic Disparities in Cancer Survivors Research Project. This research project is being conducted in collaboration with MedStar Washington Cancer Institute (MWCI). This informed consent document provides information about this research project and what will be asked of you if you choose to participate in it. If you have any questions now or during the research project, please feel free to ask them and you should expect to be given answers that you understand completely. It is your choice whether to participate and will not affect the quality of your clinical care at the Georgetown Lombardi Comprehensive Cancer Center or MedStar Washington Cancer Institute.

Who is conducting this study?

Dr. Marc D. Schwartz 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.

The Principal Investigator 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: This study is sponsored by the National Institutes of Health

Why is this study being done?

You are being invited to take part in a research project that aims to reduce racial disparities and educate, empower, and support Black cancer survivors and their families learn about and make important health care decisions about hereditary cancer risk (cancer that runs in families). The study is designed to evaluate models of health care delivery that improve awareness and access to potentially lifesaving cancer genetic services.

Who may take part in this study and who may not?

Participants must meet the following eligibility criteria:

1) Age 18-80
2) Self-identify as Black or African American
3) Diagnosed with any of the following cancers 6 or more months ago: breast, ovarian, uterine, prostate, colorectal, pancreatic
4) Meet the national criteria for genetic testing for hereditary cancer
5) Have not had genetic testing for hereditary cancer
6) Received treatment or follow-up oncology care at one of the participating study sites in the prior two years.
7) Able to read and speak in English
8) Capable of providing informed consent
9) Have Internet access (via smartphone, tablet, or computer)
10) Comfortable using a computer or mobile phone independently to access information

How long will the study take and how many subjects will take part?

The total number of participants we will recruit at the Rutgers Cancer Institute of New Jersey, Georgetown Lombardi Comprehensive Cancer Center (LCCC) and MedStar Washington Cancer Institute (MWCI) is 428 participants.

If you decide to participate in this study, you will be asked to complete a baseline, 1-month, and 6-month survey. The duration of the study is six months.

What will I be asked to do if I take part in this study?

- You will be asked to review and sign a consent form with a research staff member and answer a few questions electronically or by phone. You will also be asked to review and sign the Health Insurance Portability and Accountability (HIPAA) authorization form electronically or on paper, so that the researchers can collect data from their medical records. If you choose to sign the HIPAA authorization form by paper, you can email us a signed copy or we will mail you a paper copy of the HIPAA authorization form with a pre-stamped envelope to mail back the signed HIPAA authorization form.
- You will be asked to complete a baseline survey over the phone or online. This survey will ask you questions about several different things, including your health, your thoughts, and your preferences and opinions about genetic risk assessment.
- Following the completion of the initial survey, you will be randomized to one of two groups described below. 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 two different study groups:

- Group 1 is Enhanced Usual Care (EUC). Participants in this group receive a clinical letter containing information about you and your family's potential risk for inherited cancer, and the next steps you could take to find out more information about your potential hereditary cancer risk and cancer genetic risk assessment services, including genetic testing.
  - If you indicate that you would like to proceed with obtaining a genetic test, a Genetic Testing Kit will be mailed to you directly.
- Group 2 is Genetic Education Digital Assistant (Geda) Group. Participants in this group will be asked to login to a webpage and engage with a digital assistant online through a smart device (phone, computer, or tablet) to learn more information about their personal and their family's potential hereditary cancer risk and cancer genetic risk assessment services, including genetic testing.
  - If you indicate that you would like to proceed with obtaining a genetic test, a Genetic Testing Kit will be mailed to you directly.

- One month after the initial survey, you will be asked to complete another survey over the phone or online.
- Six months after the initial survey, you will be asked to complete another survey over the phone or online.

What are the risks of harm or discomforts I might experience if I take part in this study?

There are potentially two main risks to participants in this study.

Initial discomfort/embarrassment: Some individuals may experience discomfort or distress when answering questions about or thinking and talking about cancer or other health issues. Participants will be asked questions of a sensitive or personal nature, which could potentially cause some discomfort or embarrassment while answering. If this happens, you can skip those questions or withdraw from the study altogether. If you decide to quit the study, your responses will NOT be saved.

Privacy and loss of confidentiality: Breach of confidentiality is a risk of harm, but a data security plan is in place to minimize such a risk. Nevertheless, there is still the potential for unintentional breach of confidentiality for participants. All efforts will be made to maintain privacy and confidentiality. We are aware that data will contain demographic and personal health information, and consistent measures will be employed to protect the security and confidentiality of this data. All data will be securely stored in a study database. Participants will be assigned a study ID, and the analyses will be limited to the variables necessary for the completion of the proposed study, and results will be reported in aggregate so that individuals are not identified. Study publications or presentations resulting from this research will not identify participants by name but will present only aggregate data. Every effort will be made to protect the information you give us. The researchers are trained to protect your information and to use procedures that reduce the possibility of loss of privacy and/or confidentiality.

Psychological or Social Risks Associated with Loss of Privacy: Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. Further, patterns of genetic variation also can be used by agencies to identify a person or their blood relatives (for example, to establish relationships between parents and their children).

Economic Risks of Harm: Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Therefore, your genetic information potentially could be used in ways that could cause you or your family economic distress.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that helps protect against genetic discrimination. In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Are there any benefits to me if I choose to take part in this study?

There may or may not be direct benefits to you for taking part in this study. However, you may find satisfaction in contributing to research and you may learn new information relating to cancer education and clinical trial participation. Participation may help you communicate genetic test results with your family members and you may learn more about you and your family's risk for hereditary cancer.

There is compensation upon completion of study surveys and there will be additional compensation for participants who complete all surveys.

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 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 I receive the results of the research?

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.

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?

If you are in the Enhanced Usual Care (EUC) Group, you will receive a $50 Forte gift card after completion of each survey (initial/baseline, 1-Month, and 6-Month), and will receive an additional $30 gift card if you complete all surveys for a potential compensation of $180.

If you are in the Genetic Education Digital Assistant (Geda) Group, you will be asked to log in to the webpage at least once and you will be offered a $50 Forte gift card after completion of each survey (initial/baseline, 1-Month, and 6-Month), and will receive an additional $30 gift card if you complete all surveys for a potential compensation of $180.

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. Identifiable information will not be stored with your responses. Instead, your responses will be assigned a subject number which will be stored separately from your identifiable information so others will not know which responses are yours. These study IDs will help maintain confidentiality. A study database will be hosted at Rutgers Cancer Institute in New Brunswick, NJ on secure computing servers with secure data entry and submission for all other sites. No information that can identify you will appear in any professional presentation or publication. There may be circumstances where this information must be released.

What will happen to my information—data, recordings and/or images— collected for this research after the study is over?

All information will remain confidential and de-identified and stored in password protected and encrypted databases. Your de-identified information may be shared with other investigators in future research.

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 the Principal Investigator:

Marc D. Schwartz, PhD
Georgetown Lombardi Comprehensive Cancer Center
2115 Wisconsin Avenue, NW, Suite 300
Washington, DC 20007

Who can I contact if I have questions?

If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact Dr. Marc Schwartz at (202) 687-0185 or schwartm@georgetown.edu

This research has been reviewed and approved by an Institutional Review Board (“IRB)”. As a collaborative study between LCCC, MWCI and Rutgers Cancer Institute of New Jersey, this research has been reviewed and approved by the Rutgers IRB. If you have questions, concerns, problems,

information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email at irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

Policy/Procedures or Research Related Injuries

The Policy and Procedure for the Sponsor, the National Cancer Institute are as follows:

The sponsor will not pay for care necessitated by a research related injury.

The Policy and Procedure for Georgetown University Medical Center and MedStar Health Research Institute are as follows:

We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive necessary medical care. The costs of this care will be charged to you or your third party payor (e.g., your health insurer) in the usual manner and consistent with applicable laws. No funds have been set aside by Georgetown University, Georgetown University Hospital, MedStar Health Research Institute, or their affiliates, to repay you or compensate you for a study related injury or illness.

Risks associated with the genetic information:

If you choose to have genetic testing as part of this study, is important for you to know that there are risks. Risks of participating in research involving genetic testing include the use of personal, genetic information for unauthorized or discriminatory purposes. All research personnel who will have access to genetic information about you are ethically and legally obligated to maintain the confidence of that information. However, there can be no absolute guarantees that the genetic information will remain confidential.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally offers the following protections:

- Health insurance companies and employer-based group health plans may not request your genetic information that we get from this research.
- Health insurance companies and employer-based 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 we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this law does not protect you against discrimination on the basis of your genetic information by companies that sell life insurance, disability insurance, or long-term care insurance.

In addition, there is a risk that being in a genetics study can cause psychological distress or tension with other family members.

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

We are committed to respecting your privacy and keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information including the health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. The health information we may collect from you and use for this research includes:

- Medical record number

- Name (First and Last)
- Contact Information (phone number, address, email address)
- Demographic information (age, race, ethnicity, education)
- Cancer Diagnosis
- Medical History, Consultation or Treatment, including visit notes with clinicians/genetic counselors
- Medical Tests, Reports and Procedures (such as pathology report)
- Laboratory/Diagnostic Tests
- Dates of Medical/Laboratory tests
- Insurance Information
- Other relevant medical records as necessary

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Georgetown University, MedStar Health, etc., and its clinical partners (or affiliates):

- The Georgetown University Office for Research Integrity
- The MedStar Office for Research Integrity
- The US Office of Research Integrity
- Rutgers University researchers involved in the research project
- 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
- The sponsor of this research study, the National Institute of Health
- The developers of the digital assistant, BotsCrew
- The communications company for SMS/text messaging, Twilio

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law, Georgetown University policy, or MedStar Health policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Georgetown University and MedStar Health workforce, who may need to see your information, such as administrative staff members from the MedStar Health Research Institute-Georgetown University Institutional Review Board (IRB) Office and its agents, and members of the Institutional Review Board.
- Others*:* The following individuals or organizations may also access, receive, or use your personal health information: Authorized study collaborators at Rutgers University, such as collaborating researchers, administrative staff members from the Rutgers Institutional Review Board (IRB), and members of the IRB.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

Your de-identified information may be shared with other investigators in future research.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire two-years following the completion of the study.

After the expiration date, Georgetown University and MedStar Health may not gather new information about you or use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Georgetown University and MedStar Health obtain permission to do so from you.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Marc D. Schwartz, PhD
Georgetown Lombardi Comprehensive Cancer Center
Department of Oncology
2115 Wisconsin Avenue, NW, Suite 3000, Washington, DC 20007

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study if you do not allow this. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

What else do I need to know?

If you agree to take part in this research study, we will provide a $50 gift card upon completion of the baseline survey. After each follow-up survey, we will load another $50 onto this card and an additional $30 if you complete all three surveys for a potential compensation of $180. Please do not dispose of the gift card – as replacements cannot be sent.

Your signature documents your permission to take part in this research.	
Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date

Printed name of person obtaining consent	IRB Approval Date

Signature Block for Capable Adults