Boston Medical Center and the
Boston University Schools of Medicine,
Public Health and Dental Medicine

RESEARCH CONSENT FORM

Basic Information

Title of Project: Testing scalable communication modalities for returning breast cancer genetic research results to African American women

IRB Number: H-40045

NCT04407611

Sponsor: National Institutes of Health, National Institute of Minority Health and Health Disparities

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Study Phone Number: 800-786-0814

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are a participant in the Black Women's Health Study (BWHS). As part of the BWHS, you previously provided a saliva or blood sample for use in health-related research. Some of the research results related to genetic risk for cancer are now available to return to BWHS participants who may be interested in learning their results. We are doing new research to determine the best ways to communicate cancer genetic research results to participants. If you decide to participate in this new research study, you will be asked to provide a new saliva sample by mail. You will be in the study for up to 18 months if you decide to stay the whole time. You will find more information about what will happen in this study later in this form.

The main risk of being in the study is potential distress if you receive genetic research information that indicates you are at greater risk for developing breast or other cancers. You may be advised to follow up with your health care provider for further evaluation and care. You will find more information about risks and the ways we will protect your privacy and confidentiality later in this form.

You might benefit from being in the study because you may learn about your genetic risk for developing some cancers. This information may also have important implications for your health and the health of your family members. You will find more information about benefits later in this form.

You could get these benefits without being in the study by seeking genetic counseling and testing for cancer risk, without learning your BWHS research results. You will find more information about alternatives later in this form.

Purpose

The purpose of this study is to compare two different approaches to communicating cancer genetic research results to women in the Black Women's Health Study: 1) learning results from a genetic counselor over the telephone, or 2) learning results from a secure online website.

What Will Happen in This Research Study

You previously provided either a saliva or blood sample, or both, to the BWHS to be used for health-related research. DNA from your sample was tested at a research lab, along with samples from approximately 4,000 other BWHS participants and 6,000 Black women from other studies in order to understand which rare genetic variants are associated with breast cancer risk in Black women and to estimate the lifetime chances of getting breast cancer in women who carry one of those variants. Because these genetic variants are rare, most women tested did not have one. However, this information may be important for you and your family members in the context of any personal and/or family history of cancer.

BWHS participants whose samples were tested have the opportunity to receive their genetic research results, after they have been fully informed about the meaning of results. Because the testing was done in a research lab, there is a legal requirement that we first verify results in a clinical laboratory (Clinical Laboratory Improvement Amendments or CLIA) that has been certified to do this type of testing. Fortunately, this new study has funds to cover the costs of testing a new saliva sample in a CLIA certified lab. If you decide to learn your results, the CLIA lab result will be the only result that is returned to you.

The genetic testing completed as part of this research study is not necessarily the same as the testing ordered by a health care provider. You or your health care provider should not rely only on the BWHS research findings to make any diagnosis, treatment, or health planning decisions. If your health care provider decides that follow-up tests and screenings are necessary, then you or your insurance will be billed for the costs.

You will be one of approximately 2,325 women who will be asked to participate in this study.

If you decide to participate, you will be asked to complete a baseline survey that asks questions about your personal and family history of cancer, and your thoughts about genes and cancer. Once we receive your signed consent and completed baseline survey, we will mail you a kit with instructions to collect a new saliva sample. We will ask you to follow the instructions to spit into the container and mail the container to the BWHS office at Boston University. Your new sample will be tested in a CLIA certified lab for variations in 18 genes that have been linked to breast and/or other cancers. Testing your new sample may take up to 4-6 weeks. If your sample fails for any reason OR if the lab is unable to return results for your sample, BWHS will contact you about your willingness to provide a new sample. If you are willing to provide a new sample, BWHS will send you a new kit with instructions to collect a saliva sample at no extra cost to you.

Once the testing is completed, you will be randomly assigned to a study group where you will have the opportunity to learn your genetic research results either from a genetic counselor over the telephone or from a secure online website that you review on your own. Random assignment means that the group you are assigned to is by chance, like flipping a coin.

Depending on your study assignment, we will contact you to either:

- schedule a telephone call over Zoom with a genetic counselor on the study team, or
- provide you with details on how to log in to a BWHS website to learn your results.

You will be provided with background information about genes and genetic testing in the BWHS. You will then be asked whether you wish to learn your results. If you choose to learn your results, they will be disclosed by the genetic counselor or will be displayed within the website, depending on your study group.

If you are assigned to view your results online, you will have the option to speak with a genetic counselor on the BWHS study team who can answer questions before or after you view your results. If you do not have access to the internet or otherwise cannot access the material, you may request a print version of the background information and your genetic results to be sent by mail.

All telephone calls with the genetic counselor will be audio recorded using Zoom, but only the research team will have access to these recordings. Participants who schedule a session with the genetic counselor will receive scheduling and reminder emails prior to the start of the sessions.

As part of the study, you will be asked to complete follow-up surveys at 6 weeks, 6 months, and 12 months. If you choose not to learn your results, you will have up to 12 months to change your mind.

Genetic testing and return of genetic research results:

- You will provide a saliva sample.
- You will have the opportunity to receive genetic research results for 18 genes that are known to be associated with a higher risk of breast, ovarian, colorectal, or other cancers. These results will be communicated to you either by a genetic counselor over the telephone or through a secure online website that you review on your own. Please note: genetic counselors will not reveal genetic results over the phone to participants who are assigned to learn results on the secure website.
- These genetic research results are not clinical testing results ordered by a health care provider or medical health care team. Further actions may be recommended by your health care provider based on the research findings.

- The study team cannot provide clinical care to you based on these genetic research results.
- You can choose not to learn your genetic research results.
- All participants in this study will have access to genetic counselors, who are part of the BWHS team, for help answering questions about the educational material provided and/or their genetic research results.
- Any telephone calls with the genetic counselors returning results will be audio recorded using Zoom for the purpose of internal quality checks.
- BWHS will not use your saliva sample for research other than that described in this consent form.
- Your sample will be discarded upon completion of this research study.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

Risks and Discomforts

There are two primary risks to participation in this study: 1) the potential risk of breach of confidentiality or privacy and 2) the potential risk of psychological discomfort when receiving cancer genetic results. The potential breach of confidentiality of your personal information and study responses is small. For individuals who will receive results through the secure online website, results will be accessible only when you are logged on with your study ID and password. All information will be stored on secure password-protected networks and will only be accessible by approved study staff who have signed confidentiality agreements and have been trained in responsible conduct of research.

There is a potential risk for discomfort during this study, which could include worry or stress. You may feel uncomfortable answering some survey questions throughout the study. You may also experience discomfort when learning about your genetic research results. To minimize the risk of psychological discomfort, you will have access to a genetic counselor on the study team to discuss any concerns or questions that you might have.

We will not share identifiable information about you with people or organizations not involved in our research study. However, there is a potential risk that your genetic information could be used to your disadvantage if you choose to share it. For example, if genetic research findings suggest a very high risk of cancer, that could be used to make it harder for you to get or keep a job or insurance. Federal laws, particularly the federal Genetic Information Nondiscrimination Act (GINA), generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. These laws will generally protect you in the following ways:

1. Health insurance companies and group health plans cannot request your genetic information from this research.
2. Health insurance companies and group health plans cannot use your genetic information when making decisions regarding your eligibility or premiums.
3. In most states, employers with 6 or more employees (or 15 or more employees in other states, under GINA) cannot use your genetic information from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Thus, life insurance, disability insurance and long-term care insurance companies may legally questions related to genetic testing and deny coverage based on your responses or for refusal to answer the question(s).

Potential Benefits

The benefits of participating in this study may include access to previously unknown genetic risk information for breast and other cancers including ovarian and colorectal. After speaking with your own healthcare provider, you could share this information with close relatives so that they may request genetic testing from their own health care providers, if applicable. However, you may not receive any benefit. The primary goal of this research is to learn about the best approaches to communicate genetic information to Black women in particular. The results of this study may lead to improved communications about genetic risk in the future and to more opportunities for individuals who are in research studies to learn about their own genetic risks.

Alternatives

The following alternative procedures or treatments are available if you choose not to be in this study:
1) You may independently seek clinical genetic testing through your own health care provider and insurance company, or 2) you may not seek genetic testing.

Costs

There will be no costs to you associated with this study if you decide to participate. You will not be billed any cost by the BWHS for speaking with a genetic counselor who is part of the study team. The collection and testing of your new saliva sample is for research purposes only and will be provided at no cost to you.

Payment

You will be mailed a $30 check after completing the informed consent form and baseline survey and sending a saliva sample to the BWHS office at Boston University. You will be offered up to three follow-up surveys and will receive a $20 payment after completing each survey.

Confidentiality

We must use some information that shows your identity to do this research, such as your mailing address and e-mail address. Information already collected about you will remain in the study record even if you later withdraw from this study.

We will store your information in ways we think are secure. Prior to sending your saliva sample to the laboratory for genetic testing, we will temporarily store your saliva sample in a locked cabinet in our locked office at Boston University School of Medicine. The saliva samples will only be labeled with a study ID and not with your name or other personal identifiers. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

The laboratory processing the saliva samples will not be able to link your saliva results with your name or other information that could identify you. Only a few key people at the Boston University BWHS offices will have access to the link between data from the saliva sample and names or other personal identifiers.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information or biological samples are covered by a CoC. The CoC provides guidelines on how we can share research information or biological samples. Because we have a CoC, we cannot give out research information or biological samples that may identify you to anyone who is not involved in the research except as we describe below. Even if someone tries to get your information or biological sample in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

We will only share research data where we have removed anything that might show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Using research data in future studies, done by us or by other scientists.

If you agree to be in the study and sign this form, we will share information and biological samples that may show your identity only with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People who will get your biological samples for testing as we described in the section **What Will Happen in This Research Study**. These people are expected to protect your information and biological samples in the same way we protect it.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your information.

A description of this clinical trial will be available on http://www.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.

Participant's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your participation in the BWHS, your ability to get health care or payment for your health care, or your enrollment in any health plan or benefits you can get. You will only be paid for the study activities that you complete before withdrawing.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or would like to review this document with the Study Coordinator, contact **Patricia Simmons**, at **1-800-786-0814** or email **BWHS@bu.edu**.

You may also call 617-358-5372 or email medirb@bu.edu to speak to someone at the Boston Medical Center and Boston University Medical Campus Institutional Review Board (IRB). The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research participant. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Participant: ____
Printed name of participant

By signing this consent form, you are indicating that

- you have read this form
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you agree to be audio recorded if you receive results from a genetic counselor on the study team
- you permit the use and sharing of information that may identify you as described above

To be completed by participant if personally signing

____ ___________
Signature of participant Date