Research Study Informed Consent Document

Study Title for Participants: COVID-19 Related Financial Hardship and Distress in Women Who Decline TMIST (EA1151) Participation

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: EAQ201: COVID-19 Related Financial Hardship and Distress in Women Who Decline TMIST (EA1151) Participation (NCT 05076266)

Rev. Add2

Version Date: May 3, 2022

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this study because you are scheduled or are planning to have a mammogram for your routine breast cancer screening, were eligible for EA1151 (TMIST) but declined to participate.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to answer the following question:

Is COVID-19 related financial hardship and distress more prevalent in Women of Color who decline participation in EA1151 (TMIST) compared to non-Women of Color who decline participation.

We are doing this study because we want to find out whether factors that lead Women of Color to decline participation in the breast cancer screening trial EA1151 (TMIST) differ from non-women of color.

What are my choices if I decide not to take part in this study?

You may choose to take part in a different research study, if one is available.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will be asked to complete a survey after registration. After completion of the survey, you will have finished the study. At the time of registration, you can choose to complete the survey online using a computer or mobile device (i.e., phone, tablet), or on paper. We estimate that it will take about 15 minutes to complete. Your completed survey will not be seen by or shared with your medical team.

In addition to information about your finances and employment from the surveys, we may also obtain the following information from your medical records:

- Basic information about you, including your name, sex, ethnicity, birth date, and home address.
- Your health insurance status

You will be asked to provide your contact information to the ECOG-ACRIN Outcomes and Economics Assessment Unit (OEAU) located at Brown University. If you would like to complete the surveys online, you will need to provide an email address and date of birth in order to activate an online account for completing the survey. Once you are registered for the study, you will receive an email asking you to return to the PRIDE patient portal to complete any available surveys. We ask that you complete the survey as soon as possible after receipt. If you do not complete the survey within 3 working days, you will receive up to 3 reminders, each about 3 days apart, in the form of emails or text messages. If the survey is still not completed, you may receive up to 3 telephone calls and/or text messages, each about 3 days apart. The web site will have a toll-free number and email address to contact if you need any assistance with the online survey.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

If you choose to take part in this study, there is a risk that you may experience minimal discomfort from answering the questions.

Benefits

Taking part in this study is not likely to help you. However, the information you provide will help the study doctors learn things about the financial hardships and distress between Women of Color and non-women of color who declined participation in the EA1151 (TMIST) study.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop and you are completing the survey at the clinic, stop completing the survey and let your study team know. If you decide to stop and you are completing the survey on-line, stop completing the survey, no other action is necessary.

Are there other reasons why I might stop being in the study?

Yes. The study team staff may take you off the study if:

- You do not follow the study rules.
- The study is stopped by the Institutional Review Board (IRB) or study sponsor (National Cancer Institute). The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to determine if COVID-19 related financial hardship and distress is more prevalent in Women of Color who decline participation in EA1151 (TMIST) compared to non-Women of Color who decline participation. There will be about 1000 women taking part in this study.

What are the study groups?

All patients enrolled in the trial will be a part of the study group.

What exams, tests, and procedures are involved in this study?

If you choose to take part in this study, you will be asked to fill out a survey with questions about your demographics, income and employment, attitudes and experiences about COVID-19, and emotional well-being. You will be asked to fill out the survey once after registration and the survey is available online and paper format. There is also the option to take the survey over the phone. The survey will take about 15 minutes to complete. You do not have to answer any question that makes you feel uncomfortable.

What risks can I expect from taking part in this study?

General Risks

You also may have the following discomforts:

- Be asked sensitive or private questions about things you normally do not discuss.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Complete the survey questions.

What are the costs of taking part in this study?

If you are completing the survey on paper at home and sending it through the mail, you will be provided with a pre-addressed and stamped envelope.

Depending on your personal cellular data provider and plan, your provider may charge data and internet access fees. When you complete the survey-online using a smartphone, tablet, or other internet-enabled device, the data use will count against your allotted data and any charges for that data will apply. There may be additional costs when receiving email, text messages or phone calls.

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information and survey responses related to this study will be kept in research databases. These databases will be used by ECOG-ACRIN for data analysis. Your contact information will be kept in a secure database separate from your health information and survey responses. Every effort will be made to protect your privacy. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor, ECOG-ACRIN Cancer Research Group, supporting the study now or in the future.
- Research staff at Outcomes and Economics Assessment Unit (OEAU) at Brown University
- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research.

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we do not know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study team will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor (*insert name of study doctor[s]*) at (*insert telephone number, and email address if appropriate*) or research associate (*insert name of research associate[s]*) at (*insert telephone number, and email address if appropriate*).

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

Rev. Add2

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor (or Research Associate) and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the EAQ201 study (COVID-19 Related Financial Hardship and Distress in Women Who Decline TMIST (EA1151) Participation).

Participant's signature _____

Date of signature _____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature _____