COMIRB
APPROVED
For Use
19-Jun-2024
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**Principal Investigator:** **Laura Scherer, PhD**
**COMIRB No:** **22-0957**
**Version Date:** **6/6/24**

**Study Title:** **Promoting Informed Choice for Breast Cancer Screening: A Longitudinal Study**

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

## Why is this study being done?

This study plans to learn more about *individuals' reactions to evidence about breast cancer screening with mammography, including benefits and harms. In addition, we hope to identify how this information informs conversations with a health care provider about deciding when to receive mammography.*

*You are being asked to be in this research study because you*

- *Identify as female at birth and are not currently pregnant*
- *Are between the ages of 39-49 years old at the time of enrollment*
- *Have a scheduled annual evaluation/preventative or similar appointment at UCHealth Metro or UPenn Health Systems*
- *Comprehend English writing*
- *Have Internet access*
- *Have no prior diagnosis of breast cancer, ductal carcinoma in situ (DCIS, also known as "stage zero breast cancer"), or lobular carcinoma in situ*
- *Have no known BCRA1/2 gene mutation*

Up to *500* people will participate in the study.

## What happens if I join this study?

*If you join the study, you will be sent a survey and decision aid providing a brief summary of mammography evidence. You will then complete 4 more surveys via email. You will also have the option to participate in a follow-up focus group. The four surveys will be collected 1) upon enrollment and prior to the health care*

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*appointment; 2) following the health care appointment; 3) 3 months after enrollment; 4) 1 year after enrollment; 5) after the United States Preventive Services Task Force (USPSTF) guideline is finalized. Optional focus-groups will also be conducted after the USPSTF guidelines are finalized.*

*Participation ends after completing the final survey approximately one year after enrollment.*

**What are the possible discomforts or risks?**

Discomforts you may experience while in this study include psychological or emotional distress when reading about mammography benefits and harms.

**What are the possible benefits of the study?**

*This study may inform how to communicate more effectively about breast cancer screening to patients and the public.*

This study was not designed to treat any illness or to improve your health. Also, there could be risks to being in this study. If there are risks, these are described in the risks section of this document.

**Who is paying for this study?**

- *This research is being paid for by The National Institutes of Health*

**Will I be paid for being in the study? Will I have to pay for anything?**

*You will be paid electronically or via mail:*

| *VISIT* | *VISIT 1* | *VISIT 2* | *VISIT 3* | *VISIT 4* | *VISIT 5* | *FOCUS GROUP* |
|---|---|---|---|---|---|---|
| *AMOUNT* | *$25 Gift Card* | *$25 Gift Card* | *$49 Gift Card* | *$50 Gift Card* | *$25 Gift Card* | *$75 Gift Card* |

It will not cost you anything to be in the study.

**Is my participation voluntary?**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

## Who do I call if I have questions?

The researcher carrying out this study is Dr. Laura Scherer. You may ask any questions you have now. If you have questions later, you may call Dr. Laura Scherer at 303-724-5749

You may have questions about your rights as someone in this study. You can call Dr. Laura Scherer with questions. You can also call the Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

## Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and the health systems it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Health
- University of Pennsylvania

We cannot do this study without your permission to see and use your information, and share your de-identified data with others. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate health systems may not be covered by this promise.

We will do everything we can to keep your records and identity a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Laura Scherer
1890 N. Revere Ct.
Mailstop F443
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- *The National Institutes of Health,* who is paying for this research study.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

**I** .

**Information about you that will be seen, collected, used and disclosed in this study:**

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records

**What happens to Data that are collected in this study?**

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

**Agreement to be in this study and use my data**

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____