Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Implementing Breast Reconstruction Clinical Decision Support in Diverse Practice Settings

Principal Investigator: Mary C. Politi, PhD - (314) 747-1967

Research Team Contact: Melissa Gendron- (314) 273-8414
Krista Cooksey – (314) 747-5657

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

Key Information

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

We invite you to participate in this research study because you have recently been diagnosed with breast cancer and are considering a mastectomy as part of your treatment.

This is a research study conducted by Mary C. Politi, PhD and Clara N. Lee, MD, MPP to refine and test a tool called *BREASTChoice*. *BREASTChoice* helps women think about the pros and cons of breast reconstruction and choose an option that best matches their personal risk and preferences.

What will happen during this study?

1. If you agree to join this study, we will send you a link to view a website.
2. A computer will randomly assign you to either BREASTChoice or a standard website with information about breast reconstruction.
    a. You will be assigned by chance, like the flipping of a coin.
    b. You will have a **50/50** chance of being assigned to the BREASTChoice program or the standard website.
    c. We will send this to you through a MyChart message or through your email.
3. We will also ask some people in the study if we can audio-record their visit with their plastic surgeon when they are talking about breast reconstruction.
4. After going through the website and talking to your surgeon, we will send you a survey to fill out
5. We will review medical records for name, age, race, telephone number, mailing address, language spoken, breast cancer stage, previous breast cancer surgery, and reconstructive decision. After the study is completed, we will no longer access your medical record

What are the benefits of the study?

We don't expect you to benefit from this study. However, we hope that, in the future, other women might benefit from this study because it will help us learn about tools to help women make choices about breast reconstruction after mastectomy.

What are the risks of this study?

You could experience one or more of the risks indicated below from being in this study. In addition to

these, there may be other unknown risks, or risks that we did not anticipate.

Risks of using Tool

It is possible that you may feel uncomfortable with some of the questions or photos in the tool. You can stop using the tool at any time, and you can skip any questions or parts of the tool.

Risk of Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure and we do not expect this to happen. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

Will I be paid for being in this study?

You will be paid with a $20.00 gift card for being a volunteer participant.

The rest of this document provides more details about the study:

Will you save my research information to use in future research studies?

Your private information will NOT be used for future research studies or shared with other researchers for their studies, even if we remove identifiers.

Audio/Video Recording or Photographs

Part of this study may involve making audio recordings of you. We will randomly pick 20% of study participants who will have a visit with their plastic surgeon audio recorded. We will use this audio recording to see whether and how doctors and patients are using the information from the BREASTChoice tool as they discuss breast reconstruction.

We will create a written transcript of these recordings and will not attach your name to the transcript. The audio recordings will be saved on a password protected database and only study team members will have access to it. We will destroy the audio recordings after the study has ended and will only save the transcript without your name or other information on it. You can still be in the study even if you do not want to be recorded. Your surgeon must also agree to have the visit audio recorded. If the surgeon does not agree to have the visit audio-recorded, the visit will not be recorded. Your surgeon will also be asked to provide information about how they felt about BREASTChoice tool during your clinical discussion.

I give you permission to make audio recordings of me during this study.

_____ **Yes** _____ **No**
Initials **Initials**

How many people will participate?

About 425 total people nationally will take part in this phase of the study. About 240 total people will take part in this phase of the study at Washington University.

How long will I be in this study?
If you agree to take part in this study, your involvement will last for 25 minutes (about 15 min looking at the website and 10 min filling out the survey).

Will it cost me anything to be in this study?
You will not have any costs for being in this research study.

Will I be paid for participating?
You will receive a $20 Walgreens gift card for reviewing the website and completing the survey.

We will ask for your social security number (SSN) in order to pay you. We will ask for your address if a gift card will be mailed to you. It will take approximately 2 weeks for the gift card to be delivered.

Who is funding this study?
The Agency for Healthcare Research and Quality (AHRQ) is funding this study. This means that Washington University is receiving payments from AHRQ to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from AHRQ for conducting this study.

How will you keep my information confidential?
Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- Hospital or University representatives to complete Hospital or University responsibilities
- The National Cancer Institute
- The Siteman Cancer Center
- The Agency for Healthcare Research and Quality (AHRQ)
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality:

- We will keep the information you provide confidential by using an ID code to identify your surveys instead of your name. We will destroy the link between the code number and your name after the study is over.
- All data and the study website will be password protected. The data will be saved in a secure server and only study team members can access it.

- Study-related computers will be under firewall protection and will maintain automated virus updates.
- Hard copies of forms will be stored in locked cabinets in locked areas.
- All study staff annually sign a confidentiality statement attesting to their understanding of, and willingness to abide by, written policies on research ethics and confidentiality.
- The BREASTChoice tool passed a security review prior to use.

Are there additional protections for my health information?
Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect your treatment or the care given by your health provider, your insurance payment or enrollment in any health plans, or any benefits to which you are entitled. However, it will not be possible for you to take part in the study.

If you sign this form:
- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.

- Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
- You will not be allowed to continue to participate in the study.

Can we contact you by email?
We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Invitation with a link to BREASTChoice or a standard website
- Reminder to access BREASTChoice or a standard website assigned to you in this study
- Reminder emails about completing your survey

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer, you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

Is being in this study voluntary?
Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?
You may withdraw by calling or emailing the study team to tell them you are no longer interested in being in the study.

What if I have questions?
We encourage you to ask questions. If you have any questions about the research study itself, please contact: Melissa Gendron at (314) 273-8414 or Krista Cooksey at (314) 747-5657. If you feel that you have been harmed in any way by your participation in this study, please contact Mary Politi, PhD at (314) 747-1967.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 01/19/24.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

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(Name of Person who Obtained Consent – printed)