

The Ohio State University Consent to Participate in Research

Study Title: ImproviNg The BrEast CaNcer Care DelivEry MoDel for Sex and Gender Minority Survivors (INTENDED for SGM)

Researcher: Elizabeth K. Arthur, PhD, APRN-CNP, AOCNP

Sponsor: The Ohio State University James Cancer Hospital

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

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

Purpose:

The long-term goal of this study is to improve the quality of care and health-related outcomes for sexual and gender minority (SGM) breast/chest cancer survivors. The objective of this study is to detail the patient, support person, and provider barriers to quality care in SGM breast/chest cancer survivors.

Aim 1: With input from SGM cancer survivors, we will identify the most critical shortcomings of the breast cancer care delivery model and will identify potential solutions to improving more inclusive care. Using a community-engaged approach, we will conduct three focus groups of 5-7 SGM breast/chest cancer survivors (n=20 survivors) to obtain suggested culturally relevant changes to treatment decision-

making, provider communication, sources of information for decision-making, and other aspects of care delivery for SGM people diagnosed with breast cancer.

Aim 2: Determine necessary revisions and optimal workflow integration of culturally relevant breast cancer care model for SGM people. We will conduct individual interviews with breast cancer clinicians (n=10) to obtain feedback and recommendations to integrate culturally relevant tool, processes, and policies into clinical workflow.

1. Why is this study being done?

The objective of this study is to detail the patient, support person, and provider difficulties to quality care in SGM breast/chest cancer survivors.

2. How many people will take part in this study?

We anticipate that a maximum of 30 participants total will take part in this study: 20 SGM breast/chest cancer survivors and 10 clinicians (all clinically trained professionals).

3. What will happen if I take part in this study?

A 30-minute semi-structured interviews will be conducted one-on-one, either in-person at a location of the participant's choice (e.g., clinic, office) or virtually by Zoom call. All semi-structured interviews will be performed by a PhD prepared advanced practice nurse, who has prior training and experience in conducting semi-structured interviews, or a trained health sciences student who is knowledgeable about the SGM community.

Clinicians participants who choose to participate will be asked a series of open-ended questions regarding their personal perceptions of the survivors' needs and preferences for breast/chest cancer care, how important their needs and preferences are to health outcomes and quality care, and how well they feel those needs and preferences are being met. During the interview, you will be asked to leave the camera on during the interview and will be recorded. Your name will also be displayed throughout the interview, which will be recorded as well. All interviews will be recorded and transcribed verbatim.

All interviews will be scheduled to accommodate the clinicians' schedule. The research team will discuss with you in a screening zoom call with times that work best fit for you, such as morning, afternoon, or evenings that are adjusted around clinic schedules. Additionally, all participants clinicians will be asked to complete a brief sociodemographic survey in REDCap

4. How long will I be in the study?

Participation in this study will take no more than 30 minutes. You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

5. Can I stop being in the study?

Yes, you may leave the study at any time. If you wish to withdraw from the study, you may contact the principal investigator at any time by using the principal investigator's contact information listed at the end of the consent form. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

This study involves no more risk than that expected in daily life. However, you may become uncomfortable when answering certain questions related to your clinical experience in providing care to SGM breast/chest cancer survivors. If you are not comfortable answering certain questions, you may decline to answer.

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality. At the time of participation, each participant will be assigned a study identification number. This number will be used on data collection forms and in the database instead of names and other private information. A separate list will be maintained that will link each participant's name to the study identification number for future reference and communication.

7. What benefits can I expect from being in the study?

There may be no direct benefit to you as a participant in this study, however, this research is designed to provide benefit to society by gaining knowledge about the quality of care in the treatment of patients and their health-related outcomes for SGM breast/chest cancer survivors.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

9. What are the costs of taking part in this study?

There is no cost to participants in order to take part in this study.

10. Will I be paid for taking part in this study?

Participants will receive a giftcard to compensate them for their time. Amazon.com gift codes (to be redeemed on Amazon.com) in the amount of \$25 will be sent to each participant by email within 72 hours of completion of the interview and survey about yourself. By law, payments to subjects are considered taxable income.

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

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information be used or shared for future research?

Yes, your responses (with no personally identifying information) may be used for future research or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices; and
- The sponsor supporting the study, their agents or study monitors.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records

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(medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact Elizabeth K. Arthur at 614-293-0811.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

_____ Printed name of participant	_____ Signature of participant
	_____ Date and time
	AM/PM
_____ Printed name of person authorized to consent for participant (when applicable)	_____ Signature of person authorized to consent for participant (when applicable)
	_____ Date and time
	AM/PM
_____ Relationship to the participant	

Future Contact for Study Participation

Do you agree to be contacted in the future by the study team with opportunities to participate in additional research studies. [Circle one]

YES NO

_____ Printed name of participant	_____ Signature of participant
	_____ Date and time
	AM/PM

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

_____ Printed name of person obtaining consent	_____ Signature of person obtaining consent
	_____ Date and time
	AM/PM