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)

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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 decision quality and health-related outcomes for sexual gender minority (SGM) breast/chest cancer survivors. The goal is to evaluate important ways the current care model needs adjusted for SGM people, and how best to combine a culturally significant care model into clinical practice.

Aim 1: With input from SGM cancer survivors, we will identify the most important limitations 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 parts of care delivery for SGM people diagnosed with breast cancer.

Aim 2: We will conduct individual interviews with breast cancer clinicians (n=10) to obtain feedback and recommendations to incorporate 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 expect that a maximum of 30 participants total will take part in this study: 20 SGM breast/chest cancer survivors and 10 clinicians (all clinical professionals).

3. What will happen if I take part in this study?
There will be 3 focus groups consisting of 5-7 breast/chest cancer survivors that will be conducted virtually by a recorded Zoom call. All interviews will be performed by a post graduate (PhD) advanced practice nurse, who has prior training and experience in conducting interviews, or a trained health sciences student who is informed about the SGM community. Survivor participants will be asked open-ended questions about the unique health needs of SGM breast/chest cancer survivors, including challenges to breast/chest care access, provider communication, social support, and quality of life in survivorship. During the focus group, you may leave the camera on while being recorded so that the others in the group may see you; or if you feel uncomfortable, you may turn your camera off so that only your voice is being recorded. You may also choose to keep your name displayed, or the research team can show you how to change your name to your unique study number. Additionally, chat messages during the focus group sessions will also be recorded. Interviews as well as chat messages will be transcribed word for word.
All interviews will be scheduled around the participant's schedule. The research team will discuss with all participants times that work best for patients, such as morning, afternoon, evenings and even weekends. Focus groups will be organized and scheduled around the majority of the times that work for participants to avoid any missed work. Additionally, all participants will be asked to complete a brief survey about themselves in REDCap.

4. How long will I be in the study?
Participation in this study will take no more than 1 hour and 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 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. If you decide to withdraw from the study, you may contact the research coordinator or principal investigator, and 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 cancer and healthcare experience. 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 links 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 and 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 for taking part in this study.

10. Will I be paid for taking part in this study?
Participants will receive a gift card as compensation for their time. Amazon.com gift codes (to be redeemed on Amazon.com) in the amount of $50 will be sent to each participant via email within 72 hours of completion of the semi-structured 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 (medical record release for continuity of care) may result in research-related information being released.

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

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**
	AM/PM
	Date and time

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**
	AM/PM
	Date and time