The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**Supporting Black breast cancer survivors: Feasibility trial of health coaching-based navigation at the conclusion of treatment**
Principal Investigator:	Bridget Oppong, MD
Sponsor:	Department of Surgery - Division of Surgical Oncology

- **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 discuss the study with your friends and family and 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 purpose of this research is to understand the needs and challenges experienced by Black breast cancer survivors through assessing completion of scheduled referrals and participation in support services such as wellness/health coaching. The study navigator will contact you within 48 hours of consent. The wellness/health coach will ask you survey questions about your quality of life, along with questions about how you are doing since your cancer treatment. The interview will last no longer than 60 minutes. After the initial call, the wellness/health coach will reach out with bi-weekly 30-minute coaching sessions for 3 months. Then, monthly sessions for an additional 3 months. Finally, there will be a post-study survey.

1. Why is this study being done?

Black/ African American women experience a 40% higher breast cancer specific mortality compared to white counterparts. Although disparities persist in outcome, breast cancer patients overall continue to benefit from advances in treatment to make breast cancer a survivable disease for most women. The increase in survival combined with the growth and aging of the US population have produced a rise in the number of cancer survivors estimated to be more than 3.8 million women. As the numbers of survivors increase, there are reported unmet supportive care needs, including psychological distress and deficits in physical functioning. To address these needs, many cancer centers offer group coaching and counseling sessions on a variety of topics including psychological services, exercise counseling, and nutrition counseling. While there are limited studies exploring the specific needs of Black breast cancer survivors, the few that exist report a lack of culturally appropriate cancer resources necessary to understand and cope with their diagnosis. **We want to evaluate the impact on health coaching on addressing the needs and challenges experienced by Black breast cancer survivors through assessing completion of scheduled referrals and participation in support services.**

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

We anticipate 40 Black women based on the number of self-identified African American women who present consultation per year.

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

Screening & Enrollment

All study procedures are designed to work around your needs and be as flexible as possible in order to best fit into your lifestyle. Breast cancer patients seen in the NP run survivorship clinic will be recruited and consented. The study navigator will contact the participant within 48 hours. A needs assessment will be performed. Based on the needs assessment and the recommendations/ referrals for supportive services from the survivorship NP (formal psycho-oncology visit or programming of the James Care for Life offerings), the navigator will facilitate scheduling, and outline an individualized plan for the patient.

Follow-up

You will be contacted by the wellness/health coach from The Ohio State University over the telephone to complete additional needs, including physical complaints will be addressed by the survivorship clinic providers (NPs) if beyond the scope or comfort of the navigator/coach. "Check in" will be performed with biweekly virtual (30 min) sessions for 3 months and will reduce to monthly sessions until the 6-month period. After the final check-in, you will receive a post-study survey.

4. How long will I be in the study?

Your participation in this research study is expected to last for 6-months. This time period will start once you consent to enroll in the study, participate in baseline interview questions and will include telephone follow-up assessments with your health coach. There will be a final, post study survey as well.

5. Can I stop being in the study?

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. If you plan to withdraw from the study, please contact **Dr. Bridget Oppong at bridget.oppong@osumc.edu.**

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

One risk to you from participating in this study is that private health information about you will be recorded by our study team. We must protect the privacy of health information about you. Health information includes all information about you that is collected during this study. This includes interview responses, medical records and other data that our study team collects. We may use or share your health information for research only if you let us.

Breach of confidentiality is a risk to being in the study if it happens that your information is taken by, given to, or seen by someone who should not be able to look at it or have it. We take all necessary precautions to prevent this, as described in the "Other Information" section below.

Other risks include feeling upset by some of the questions we ask, and being inconvenienced due to the time involved. The research associate or the study investigators will always be available during the study to discuss with you any distress you are experiencing. There is also a risk that you may find the interviews inconvenient. All efforts will be made to make the interviews as easy and short as possible. Our study staff is available in the evenings and on the weekends to complete the telephone interviews if that works best for your schedule.

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

The information we gain from this research may help us provide better support to Black breast cancer survivors where the participant can receive additional support in

survivorship in addition to the standard program. There is evidence that interview participants may experience benefits from talking to someone about their perspectives, such as improved self-understanding, a sense of helping others, or feeling they are contributing to science. It is possible that you may not receive any individual benefit from participation in this study.

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.

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

There is no cost for participating in this study.

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

The team will not remunerate participants for their time. The team anticipates that participants will not incur any expenses during this study.

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 at The Ohio State University Wexner Medical Center.

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.

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, it/they may be used 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.

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;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - Laboratory, x-ray, and other test results
  - Questionnaires
  - Diagnosis and surgical procedures

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- 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;
- 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 record;
- Others: *[include specific names of the sponsor, collaborators, study monitor (CRO, SMO), healthcare providers, persons or organizations that analyze health information for the study, data safety monitoring boards, etc..]*.

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and

disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed because of study participation, you may contact **Dr. Bridget Oppong at 614-293-6408.**

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact **HIPAA Privacy Officer in the College of Medicine Office of Health Sciences, Suite E2140, 600 Ackerman Road, Columbus, Ohio 43202 or by phone at 614-293-4477.**

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 combined consent and HIPAA research authorization 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)**
Relationship to the 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

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time