# Informed Consent/Authorization for Participation in Research

**Title of Research Study:** Quality of Life outcomes in Breast Cancer Survivors who were Pregnant during their Breast Cancer Treatment.

**Study Number:** 2023-0909

**Principal Investigator:** Eileen Hacker, PhD, APRN, AOCN, FAAN

Ashley Martinez, DNP, APRN, FNP-BC, AOCNP, CBCN, CPHQ, NEA-BC

_____ _____
Participant's Name Medical Record Number or Study ID

## ***Key Information***

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

### *Why am I being invited to take part in a research study?*

You are invited to take part in a research study because you were pregnant during your treatment for breast cancer.

### *What should I know about a research study?*

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

### *Why is this research being done?*

Very little is known about the quality of life of breast cancer survivors who received cancer

treatment while pregnant. It is important that we assess the quality of life for women who were pregnant during their breast cancer treatment. This unique research can potentially lead to more personalized care that will impact this special population.

## *How long will the research last and what will I need to do?*

You are expected to be in this research study for approximately 20 minutes, the time it takes to complete the questionnaires. You will complete the questionnaires via zoom or phone call with the researcher on this study. The zoom or phone call interaction will not be recorded. During this zoom or phone call the researcher will ask you questions about your quality of life and fear of cancer recurrence.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

## *Is there any way being in this study could be bad for me?*

It is unlikely that anything harmful will happen due to you answering the questions. However, you may become fatigued and/or emotional based on the series of questions about your quality of life.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

## *Will being in this study help me in any way?*

Although there are no direct benefits to you from your participation in this research, what we learn from your experience may help others who are pregnant during their breast cancer treatment.

## *What happens if I do not want to be in this research?*

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of medical care. Your alternative to participating in this research study is to not participate.

# ***Detailed Information***

The following is more detailed information about this study in addition to the information listed above.

## *Who can I talk to if I have questions or concerns?*

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 713-563-3684, Ashley Martinez.

This research has been reviewed and approved by an Institutional Review Board ("IRB" - an ethics committee that reviews research studies). You may talk to them at 713-792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

## *How many people will be in this study?*

It is expected that up to 45 people at MD Anderson will be enrolled in this research study.

## *What happens if I agree to be in this research?*

If you agree to participate in this research, you will sign a consent and then be contacted to complete the questionnaire. A member from the research team will record your responses to the questionnaire. The link will be sent via email, or MyChart message based off your preference. You may be contacted for future research.

## *What happens if I say yes, but I change my mind later?*

You can leave the research at any time; it will not be held against you.

## *Is there any way being in this study could be bad for me? (Detailed Risks)*

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

In the event that you become distressed during the questionnaire, your care team will be notified to provide you with additional resources.

## *Will it cost anything to be in this study? Will I be paid to be in this study?*

Taking part in this research study should not lead to added costs to you.

You will not receive any compensation for taking part in this study.

## *What happens to the information collected for the research?*

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

Federal law provides additional protections of your medical records and related health information. These are described below.

## Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will do its best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by federal law.
D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

## CONSENT/AUTHORIZATION
## (Adult Participants Only)

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

## PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

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PRINTED NAME OF PERSON OBTAINING CONSENT