Informed Consent/Authorization for Participation in Research

Title of Research Study: Multi-center MRD registry for inflammatory breast cancer

Study Number: 2025-0415

Principal Investigator: Sadia Saleem, MD

Phone Number: 281-566-1900 (office)
713-792-2121 (24-hours)

_____ _____
Participant's Name Medical Record Number

Key Information

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

You are invited to take part in this research study because you have inflammatory breast cancer (IBC).

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?

The goal of this registry study is to collect data from patients with IBC who may have had MRD testing and may have surgery in the future. Researchers will use this data to study the disease response to treatment.

This study is a registry study. A registry is a collection of information about people, usually focused on a specific diagnosis or disease. This registry will help researchers learn more about the monitoring and treatment of IBC.

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

You are expected to be in this research study for up to 2 years or until your cancer recurs, whichever is sooner.

You will be asked to fill out questionnaires asking about how you feel, and your personal health information will be continually collected during your participation.

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?

Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including time commitment.

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?

There are no benefits to you from your taking part in this research. It cannot be promised that there will be any benefits to others from your taking part in this research. However, future patients may benefit from what is learned.

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 your regular benefits.

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 281-566-1900.

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 about 200 people will be enrolled in this research study.

What happens if I agree to be in this research?

Screening
Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will be performed to help the doctor decide if you are eligible:

- Your demographic information will be collected, such as your age, sex, and race/ethnicity.
- Your clinical history of IBC will be reviewed.
- Your schedule of pre-surgical MRD test will be reviewed, and you may or may not be included on this study if you pre-surgical MRD testing has been planned or completed.
- Your personal health information will be collected.

At Enrollment
At enrollment, your personal health information will be collected.

Post-therapy/Pre-surgery
Within six weeks before you have surgery, the following will be done:

- You will be asked to fill out a quality-of-life questionnaire. The questionnaire is estimated to take about 10-15 minutes to complete.

- Your study team will make sure your pre-surgical MRD test has been planned or completed.
- Your personal health information will be collected.

Follow-up Visits

When the study doctor thinks it is in your best interest, you may come back in for optional follow-up visits, in which you will perform the following:

- You will be asked to fill out a quality-of-life questionnaire, which will take about 10-15 minutes to complete.
- Your study team will make sure your pre-surgical MRD test has been planned or completed and collect any further MRD test results that your doctor has ordered for you.
- Your personal health information will be collected.
- Your doctor will discuss the results of the MRD testing with you and incorporate these results into how you will be monitored. The study is not defining these plans.

Data Collection

Your personal health information will be continually collected from your medical records during your participation in this study. This includes, but is not limited to, information about your demographics (such as your age, sex, and race/ethnicity), underlying malignancy, other underlying conditions, lab results, medications, imaging scans, and/or treatment outcome. The research team may call or email you to gather needed information.

Schedule of Activities

Study Calendar				
	Study Timepoints			
	Screening	**At Enrollment***	**Post-therapy/pre-surgery**	**Subsequent timepoint(s) (optional)**
Window			*Within 6 weeks before surgery*	
Informed Consent	X			
Demographics	X			
Clinical history of IBC	X			
Quality of Life questionnaire**			X	X
Pre-surgical MRD	X		X	X

test planned or completed				
Data collection	X	X	X	X

*Will not be duplicated if enrollment is within the timeframe of the post-therapy/pre-surgery timepoint.

**Optimally completed after the pre-surgery MRD testing result is available.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for the following:

- Tell the study team about any symptoms or side effects you have,
- Follow study directions, and
- Come to all study appointments (or contact the study team to reschedule).

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.

You may withdraw from participation in this study without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson. If you decide you want to stop taking part in the study, tell the research team either verbally or via email at IBCClear@mdanderson.org.

If you stop being in the research, already collected data may not be removed from the study database.

The study staff may ask if they can continue collecting the results of routine care from your medical record, but your direct participation (such as questionnaire completion) will cease.

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

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the questionnaire, you should tell the study doctor.

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.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

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

There are no costs for being on this study.

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.

Will my data or samples be used for future research?

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

If identifiers are removed from your identifiable private information that is collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Some of your health information might also be placed into one or more external publicly-accessible scientific databases. Your name and other information that could directly identify you (such as your address or social security number) will never be placed into these external databases. A researcher who wants to study information

from these databases must have an approved study and work with the group overseeing the database to obtain the information.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if you are unable to follow study directions or if the study is stopped.

What else do I need to know?

MD Anderson may benefit from your participation and/or what is learned in this study.

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:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and 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

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

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

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

_____
PRINTED NAME OF PERSON OBTAINING CONSENT