

MARQUETTE GENERAL HEALTH SYSTEM
Regional Medical Center

ARCHIVAL TISSUE SUBSTUDY INFORMED CONSENT FORM

STUDY TITLE: Tissue - An Observational Study of Treatment Patterns and Safety Outcomes for Metastatic or Locally Recurrent Breast Cancer. AVF4349n

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SPONSOR: Genentech, Inc.

This is a research study. Your study doctor or the study staff will explain the research study to you. The research study includes only patients who choose to take part. Please take your time to make your decision about taking part in this study. You may discuss your decision with your family and friends. You can also discuss it with your healthcare team. If you have any questions, you can ask your study doctor for more explanation. In this consent form, "you" refers to the patient.

Taking part in this study is voluntary. No matter what you decide to do, it will not affect your participation in Study AVF4349n or your medical care.

Why is this study being done?

You are being asked to take part in this study because you have already agreed to take part in and have signed an Informed Consent Form for Genentech Study AVF4349n. Genentech is the sponsor of Study AVF4349n and this is a separate study. When you were first diagnosed, you may have had a biopsy or excision of tissue that contained a sample of your breast cancer. Your tissue sample may hold important clues that might help researchers to understand more about breast cancer and why people do or do not respond to treatments. Genentech would like to collect a section of your breast cancer tissue for further research.

If you decide to take part in this additional study, your samples and related medical information collected during Study AVF4349n will be used by Genentech researchers and other researchers partnering with Genentech for future research related to breast cancer and related diseases or

how breast cancer treatments work.

A sample of your tissue may be used by researchers to learn more about the development of breast cancer and predictors of breast cancer progression. Research may also be done on how current treatments work in the treatment of breast cancer and related diseases, and may help develop new treatments or diagnostic tests in the future. Information from this research will be from all of the patients who take part in this study as a group, not just from your samples.

It may take many years to complete this research, so your samples will be stored indefinitely or until they are all used up. Your tissue and related medical information will be used only for research and will not be sold. Your samples will not be used for research involving human cloning (growing human tissue from this material).

How many people will take part in the study?

Approximately 2,000 patients who are taking part in Study AVF4349n will be asked to take part in this study. In addition, many other patients who are taking part in other Genentech research studies will be asked to provide tissue samples for future research related to disease therapy and diagnostics. Your samples will be stored in the Genentech sample repository along with many other samples collected from patients taking part in Genentech research studies.

What will happen if I take part in this study?

Genentech will ask your doctor or hospital to send your tissue samples to Genentech to allow a portion to be collected for future research. Only a small section will be taken from these samples. Genentech will then return the original tissue samples to your doctor or hospital.

Can I stop being in this study?

Yes. You can decide to stop at any time. If you change your mind, tell your study doctor at 906-225-3922, that you no longer want your blood and/or tissue samples to be stored or used for additional research. Then, any blood or tissue samples that remain will be destroyed. You do not need to give a reason for changing your mind.

If you change your mind, and your samples have already been tested, those results will still remain part of the overall research data.

Even if you withdraw or discontinue treatment in Study AVF4349n, you may continue to participate in this separate research study.

What are the possible risks or discomforts of this study?

A sample of your original breast cancer tissue has already been collected; therefore, there are no additional risks to you in collecting a sample of the tissue for future research.

Are there benefits to taking part in the study?

Taking part in this study will not make your health better. The collection of your samples or any tests done will not affect your medical care. However, research using tissue and blood samples collected from patients in this study may benefit other patients with breast cancer or other related diseases in the future.

Will I be told about new information?

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. When informed of this new information, if you agree to continue in the study, you will be asked to sign an updated consent form.

Will I be paid if I take part in this study?

You will not be paid for your participation in this study.

Your samples will be owned by Genentech. If a commercial product is developed from this research study, rights to the commercial product will belong to Genentech and its collaborators (persons or companies partnering with Genentech). You and your family will not receive any financial benefits or compensation from or have rights in any developments, inventions or other discoveries that might come out of this research.

Will it cost me anything to be in this study?

There are no costs to you or to your health plan/insurance company to take part in this optional study.

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

Because this study involves only the sharing of medical information and requires no specific procedures, tests or treatments, no research-related injuries are expected.

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

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. No matter what you decide to do, it will not affect your participation in Study AVF4349n or your medical care.

If you decide to take part in this study, you may leave the study at any time.

If you change your mind, there will be no penalty to you and you will not lose any of your regular benefits or legal rights. Leaving the study will not affect your medical care.

If you are injured as a result of taking part in this study, you do not lose any of your legal rights to seek payment by signing this form.

Will my medical information be kept private?

Your medical information will be kept as confidential as possible within the limits of the law. Your medical information may be given out if required by law. Genentech may use the medical information collected during this study to describe your tissue samples; however, you will not be identified by name or picture. If information from this study is published in a medical journal or presented at scientific meetings, you will not be identified by name, picture or any other personally identifying information.

Reports about research done with your sample will not be given to you, your study doctor or any of your doctors. These reports will not be put in your medical record. These reports will not be used to provide genetic information about you or your relatives to people such as insurers and employers, unless it is required by law.

The following people and groups of people may look at and/or copy your medical records to make sure that the study is being done properly and to check the quality of the data:

- Genentech study monitors and representatives
- Genentech collaborators and licensees (people and companies partnering with Genentech)
- The Institutional Review Board (IRB) responsible for protecting the rights and safety of the patients who take part in research studies
- The U.S. Food and Drug Administration (FDA) and other government agencies involved in keeping research safe for people

Review of your medical records by these people or groups of people will not violate your confidentiality.

How will my health information be used and disclosed?

If you sign this document, you give permission to Marquette General Health System to use or disclose (share) your health information that identifies you only for the purposes of the additional research described in this document.

The health information that you are giving permission to be used and shared includes all health information about you that has been and will be created or received by MGH and that is in your medical record kept by MGHS.

This health information about you may be used by and/or disclosed to representatives of the FDA, other health and regulatory authorities, the Institutional Review Board, Genentech, and Genentech's representatives, study monitors, collaborators and licensees (people and companies partnering with Genentech).

Those persons who receive your health information may not be required by federal privacy laws to protect it and may share your information with others without your permission, if permitted by laws that apply to them.

STUDY: Tissue Sub-study
PROTOCOL NO: AVF4349n

You do not have to sign this authorization, but if you do not, you may not take part in this optional research study. You are free at any time to limit MGH's use and sharing of your health information, without penalty or other consequence. However, you may not be allowed to take part, or continue to take part, in this optional research study if at any time you choose to limit 's use and sharing of your health information that is necessary for this study.

You have the right to see and get a copy of your medical records kept by that are related to Study AVF4349n.

You may change your mind and revoke (take back) this authorization at any time. If you revoke this authorization, no new health information will be collected about you. However, Genentech will still be able to use and disclose any health information about you from this research study that has already been collected. To revoke this authorization, you must write to the study doctor at the address listed on page 1 of this consent form.

Your authorization (permission) to use and disclose (share) your health information will continue indefinitely, but that use and sharing will only be for the purposes described in this Informed Consent Form.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor at 906-225-3922 . If you think that you have been injured as a result of taking part in the study, contact your at 906-225-3922.

If you have any questions regarding your rights as a research subject, you may contact the patient advocate at 906-225-3183.

SIGNATURE

I have been given a copy of all 6 pages of this form. I have read it or it has been read to me. I have had my questions answered. I agree to take part in this research study and authorize {Site Name} to use and disclose my health information as described in this Informed Consent.

I willingly consent to allow my tissue sample and related medical information collected during Study AVF4349n to be used for research, as described in this Informed Consent Form.

Patient Name (print)

If applicable, Name of Patient's Legally Authorized Representative (print)

Relationship to Patient

Patient Signature or Patient's Legally Authorized Representative Signature

Date

I, the undersigned, have fully explained this informed consent to the patient named above and/or the patient's legally authorized representative.

Name of Person Conducting Informed Consent Discussion (print)

Signature of Person Conducting Informed Consent Discussion

Date

Witness Name (print)*

Witness Signature*

Date

IRB approved 6/11/08