

**MARQUETTE GENERAL HEALTH SYSTEM
Regional Medical Center**

**OBSERVATIONAL INFORMED CONSENT FORM AND
AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION**

STUDY TITLE: VIRGO - 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 an observational study, also known as a non-experimental study or a registry study. In an observational study, the investigators look at the results of the regular medical care of patients who have the same disease or who are taking the same medication. Your study doctor will explain the study to you. You will not be asked to take an experimental drug or participate in any experimental procedures. This observational study includes only people who choose to take part. Your participation is entirely voluntary. Please take your time to make your decision about taking part. If you have any questions, you may ask your study doctor for more explanation. In this consent, "you" refers to the patient.

You are being asked to participate in this observational study because you have metastatic (spread to other parts of your body) or locally recurrent breast cancer. Participation in this study will in no way change the care you will receive from your physician. Because this is an observational study, your doctor will determine the best treatment for you.

Genentech, Inc. is the sponsor of this observational study.

Genentech, the study sponsor, will pay the study center to cover the study center's costs of conducting this observational study.

Why is this study being done?

The main purpose of this study is to gather information about various standard treatments for metastatic and locally recurrent breast cancer regarding how safe they are and how well they work.

How many people will take part in the study?

Approximately 2,000 patients will take part in this study at about 150 study centers in the United States.

What will happen if I take part in this research study?

PROCEDURES

If you choose to participate in this study, there will be no changes to the treatment you receive from your doctor. In this study, your doctor will be required to provide information to Genentech Inc., the sponsor of the study, or its agents. Your doctor will provide information about the history of your breast cancer and the past treatments you have received for it. Four times a year, your doctor will provide information about your ongoing cancer treatment, your response to treatment, and side effects of treatment that you may experience. Your doctor will continue to provide this information four times per year, for as long as you continue to participate in the study, up to a maximum of approximately 7 years (the length of the study).

OPTIONAL PROCEDURES

Participation in these optional procedures will not affect your participation in the main study.

HEALTH ECONOMIC ASSESSMENT

You can choose to participate in a Health Economic Assessment Substudy. If you choose to participate in the Health Economic Assessment Substudy, you must indicate this in this main AVF4349n Informed Consent Form (see page 7).

If you consent, your physician will collect health economic information consisting of information about your insurance coverage, income, and out-of-pocket costs. This information will be used to better understand how financial costs in general affect access to cancer treatment and the potential economic impact on treatment decisions.

Information in the form of a survey, one page in length, will be collected during two routine office visits: once when you first begin participating in this study (AVF4349n), and one more time about 3 months later. At the beginning of your participation in the study, you will be asked to complete a survey that includes questions about the details of your insurance and income. The study site will also be asked to provide information about the type of insurance coverage you have; specifically, whether you have Medicare, Medicaid, or private insurance and if private, what type, such as a PPO, HMO, point-of-service, or fee-for-service plan. The site will not be asked to report any information about which insurer covers you or your account information with that insurer. The second survey includes questions about how much you have spent out of your own pocket for your cancer treatment during the past 3 months.

The data collected from the Health Economics Survey is confidential within the limits of the law. The information will be treated the same as the medical information from the main study (AVF4349). For more details about the privacy of medical information from this study, please see page 5.

You may decide to opt out of the optional Health Economic Assessment at any time without affecting your participation in the main study or Blood DNA Repository and Archival Tissue Collection substudies.

ARCHIVAL TISSUE COLLECTION

You can choose to participate in an Archival Tissue Collection Substudy. In order to participate in this substudy, you must sign an optional Informed Consent Form. If you consent, an archival tissue sample (the sample originally removed to diagnose your cancer) will be retrieved from the pathology laboratory where your breast cancer was diagnosed.

BLOOD DNA REPOSITORY

You can choose to participate in a Blood DNA Repository Substudy. In order to participate in this substudy, you must sign an optional Informed Consent Form. If you consent, a blood sample of approximately 1 teaspoon will be collected. The DNA will be extracted from the blood sample and stored in a DNA Repository and analyzed to better understand breast cancer and the body's response to treatment.

How long will I be in the study?

If you decide to take part in the study, you will be followed for up to a maximum of approximately 7 years (the length of the study).

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop.

The study doctor may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped, even if you want to continue. Your participation in this study may be ended at any time for medical reasons or because Genentech finds it necessary to limit or stop this study.

What are the possible side effects or risks of being in the study?

Because this study is an observational study of your breast cancer care, there should be no physical risks or discomforts to you as a direct result of participation in this study.

Are there benefits to taking part in the study?

You may not receive any direct health benefit from participating in this study. However, the knowledge gained from this study may help in the advancement and understanding of metastatic or locally recurrent breast cancer and its treatment, and consequently, may help other people with metastatic or locally recurrent breast cancer.

Will I be told about new information?

Any significant new findings that become known during the course of this research study that might reasonably affect your willingness to participate in this study will be provided to you.

What other choices do I have if I do not take part in this study?

This observational study is not meant to change your medical treatment as prescribed by your physician. It is designed only to follow your breast cancer care and collect information. You are free to not participate in this study. If you decide to participate in this study, you are free to withdraw from this study at any time.

No matter what you decide to do, your decision to participate or not participate in this study will not affect your existing medical care.

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

You will not be paid for taking part in this study.

Will it cost me anything to be in this study?

There will be no additional costs to you during the course of this 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. If you decide to take part in this 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 regular benefits. Leaving the study will not affect your medical care. In the case of injury resulting from 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. 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.

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 who partner with Genentech)

- The Institutional Review Board 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 this research study and for research related to breast cancer and related diseases and/or the use of breast cancer treatments in disease therapy and diagnosis.

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 MGHS 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, MGHS 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.

You do not have to sign this consent form, but if you do not, you may not take part in the research study. You are free at any time to limit MGHS'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 research study if at any time you choose to limit MGHS's use and sharing of your health information that is necessary for the completion of this observational study.

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 to use and disclose 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 doctor at 906-225-3922

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

PARTICIPATION IN THE OPTIONAL HEALTH ECONOMIC ASSESSMENT

_____ I will participate in the Health Economic Assessment

_____ I will NOT participate in the Health Economic Assessment

SIGNATURE

I have been given a copy of all 7 pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this observational study and authorize MGHS to use and disclose my health information 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