

MARQUETTE GENERAL HEALTH SYSTEM
Regional Medical Center

DNA REPOSITORY SUB-STUDY INFORMED CONSENT FORM

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

INVESTIGATORS: Sheetal Acharya, MD
Mohammad Al-Nsour, MD
Daniel Arnold, MD
Jorge Frank, MD
Gustavo Morel, MD
Suresh Nukala, MD
Irina Sachelarie, MD
Aaron P. Scholnik, MD
1414 W. Fair Avenue
Marquette, MI 49855

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. 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, "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 Study AVF4349n. Genentech is the sponsor of Study AVF4349n and this is a separate study. If you decide to participate in this research study, a small sample of your blood will be drawn. DNA (genetic material) will then be removed from the cells in your blood. Your DNA sample will be stored in the Genentech DNA Repository along with many other samples collected from patients taking part in Genentech research studies. Samples in the DNA Repository may be used in research to study the links between people's DNA (genetic material), the illnesses they get, and the way they respond to medicines. Information from this research study will be from all of the patients who take part in the study as a group, not just from your sample.

The information collected by studying your DNA sample, along with many other samples, may

help researchers to:

- Better understand why certain people are more likely to respond to medicines or drugs such as those used for advanced breast cancer treatments
- Better understand how and why breast cancer and related diseases act differently in different people
- Develop new treatments for breast cancer-related diseases
- Find reasons why certain people are more likely to have side effects to advanced breast cancer treatments
- Develop better ways for preventing diseases or treating diseases earlier
- Develop diagnostic tests (tests to detect or understand disease) related to breast cancer or related diseases to help identify the right medicine for the right person

It may take many years to complete this DNA research, so your DNA sample will be stored in the Genentech DNA Repository indefinitely or until it is all used up. Your sample will be used by Genentech researchers and other researchers partnering with Genentech for future research related to breast cancer and related diseases.

Your sample will not be sold or 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 DNA samples for future research. Your samples will be stored in the Genentech DNA repository along with many other samples collected from patients taking part in Genentech research studies.

Will my medical information be kept private?

Your DNA sample will not be identified with your name or other personal information that identifies you. All information from this research study will be kept private.

Information from research on your DNA sample will not be given to you, your legal representative, the study doctor, or any of your doctors. Information from research on your DNA sample will not be part of your medical record and will not be given to your insurance company or employer.

If the information from this study is published or presented at scientific meetings, your name, picture, or any other personal identifying information will not be used.

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:

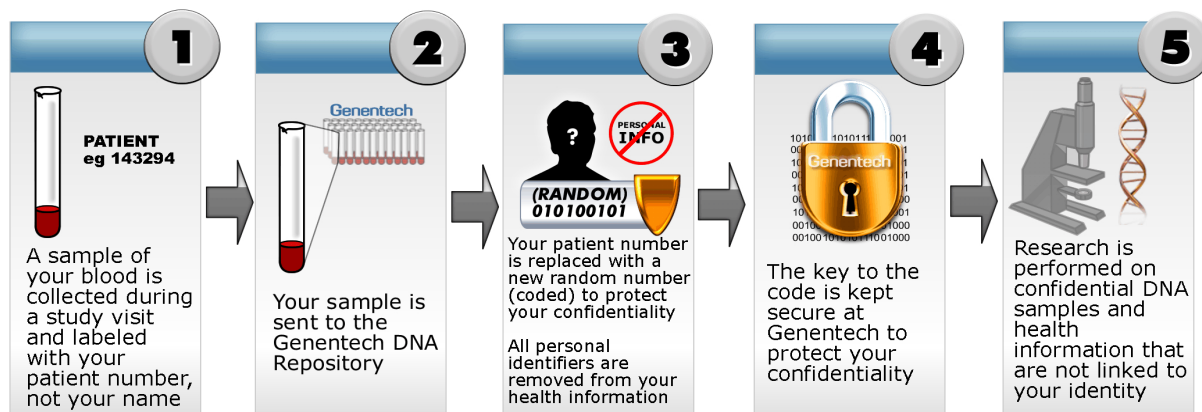
- Genentech study monitors and representatives
- Genentech collaborators and licensees (people who partner with Genentech)
- The Institutional Review Board (IRB) responsible for protecting the rights and safety of the patients who take part in research studies
- The U.S. Food and Drug Administration (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.

To help make sure that your identity is kept private, the blood sample collected in this study will be sent to the Genentech DNA Repository laboratory marked only with the date of collection of your blood sample and your patient number in Study AVF4349n, not your name. Your patient number will then be replaced with a new random number (coded) so that your sample is no longer linked to you.

The key to the code linking your sample to your patient number will be kept secure so that the risk of loss of confidentiality of any of your DNA testing results is very low. The researchers performing the DNA testing will not have the key to the code. Only a few people will be authorized to access the secure code.

Your health information used in the DNA research will be coded, so it does not contain any information that identifies you. Your health information that was collected in Study AVF4349n will also be coded with the same random number as your DNA sample to protect your privacy.



Will my DNA sample or health information ever be re-identified?

Although the DNA research in this study will be done in a manner that does not identify you, it may be necessary to link the unique random number assigned to your DNA sample back to your patient number, or go back to your health information from Study AVF4349n. This process is called “re-identification.” Your DNA sample or health information will only be linked back to your patient number, never to your name. Your DNA sample or health information will only be re-identified in order to find and destroy your sample if you change your mind about taking part in

this study or if the research results need to be part of the information sent to the FDA or other drug regulatory agency.

What will happen if I take part in this study?

The only procedure in this research study is a needle stick to draw about 1 teaspoon of blood. The blood sample may be drawn during one of your regular study visits and at the same time as one of your scheduled blood draws occurring during your participation in Study AVF4349n.

Can I stop being in the study?

Yes. You can decide to stop at any time. If you change your mind, call your study doctor at 906-225-3922 and inform him/her that you no longer want your sample to be stored or used for research. Then, any sample of your blood or your DNA that remains will be destroyed. You do not need to give a reason for changing your mind.

If you change your mind, and your sample has 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 DNA Repository study.

What are the possible risks or discomforts of being in the study?

The blood draw may cause pain where the needle is inserted and there is a small risk of bruising and/or infection at the place where the needle is inserted. Some people experience dizziness, upset stomach, or fainting when their blood is drawn.

Are there benefits to taking part in this study?

Taking part in this study will not make your health better. The collection of your blood sample or any tests done will not affect your medical care. However, your participation in this DNA Repository study may benefit other patients with advanced breast cancer 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 research study.

Your sample 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?

It is important that you tell your study doctor, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at 906-225-3922.

You will get medical treatment if you are injured as a result of taking part in this study. Your doctor will explain the treatment options to you and tell you where you can get treatment. You and/or your health plan/health insurance company will be charged for this treatment. The study doctor or study sponsor will not pay for this medical treatment and you will not receive any other kind of payment.

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.

How will my health information be used and disclosed?

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

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 records maintained 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.

You do not have to sign this authorization, but if you do not, you may not take part in this DNA Repository study. You are free at any time to limit MGHS 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 DNA Repository study if at any time you choose to limit MGHS 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 MGHS 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 your health information will continue indefinitely, but that use and sharing will only be for the purposes described in this Informed Consent and Authorization 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 the your doctor at 906-225-3922.

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

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 DNA Repository study and authorize MGHS to use and disclose my health information as described in this Informed Consent Form.

Patient Name (print)

a.m./p.m.
Time of Consent

Patient Signature

Date

Name of Person Conducting Informed Consent
Discussion (print)

Signature of Person Conducting Informed Consent
Discussion

Date

Witness Name (print)*

Witness Signature

Date

Acknowledgment of My Decision Not to Participate in the DNA Repository Study

I have read the information in this Informed Consent Form and I have decided not to take part in this DNA Repository study. I understand that my decision will not affect my participation in Study AVF4349n and that my medical care will not be affected in any way.

Patient Signature

Date

IRB approved 6/11/08