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Institutional Review Board
Informed Consent Document for Research
MASTER CONSENT

Study Title: BRE2257; A randomized clinical trial comparing ctDNA-directed therapy change with standard of care in patients with metastatic triple negative breast cancer.
Version Date: June 16, 2023 NCT05770531

Part 1 of 2: MASTER CONSENT

Name of participant: _____ Age: _____

You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.

Key Information:

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

You are being asked to take part in this research study because you have been diagnosed with a type of breast cancer called metastatic triple negative breast cancer (TNBC). For this condition, you are scheduled to receive standard treatment with one of the following chemotherapy regimens, as determined by you and your study doctor:

- | | |
|-------------------------------|---------------|
| • Carboplatin and gemcitabine | • Paclitaxel |
| • Capecitabine | • Eribulin |
| • Nab-paclitaxel | • Carboplatin |

The main purpose of this study is to learn if small pieces of DNA associated with a tumor (called circulating tumor DNA, or ctDNA) can be detected in investigational blood tests during the course of standard chemotherapy treatment for breast cancer, and whether information from such investigational ctDNA blood testing could possibly be used as an early indication of chemotherapy treatment failure.

Investigational means the ctDNA blood tests used in this study and the application of information from these ctDNA blood tests to help manage cancer treatment are being examined in research studies and are not currently approved as standard care by regulatory health authorities, such as the U.S. Food and Drug Administration (FDA).

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In this study (as compared to monitoring disease and treatment response mainly by traditional imaging methods such as CT or MRI scans), it is hoped that additional information from investigational blood testing for ctDNA could help doctors to switch more quickly from a standard chemotherapy treatment that typically has significant side effects and which may not be working, to a different standard treatment regimen against your disease.

All patients in this study will have their response to standard treatment monitored and measured by standard imaging methods (for example, CT or MRI scans) scheduled to be performed about every 9 weeks while on treatment. Additionally, each patient in this study will have blood drawn for research on circulating tumor DNA (typically from a vein in the arm) at regularly scheduled time points.

In order to conduct this study, each patient will be randomized (assigned by a computer program, similar to an electronic flip of a coin) to be in either Group A or Group B of the study.

Each patient's randomization will be determined by the computer. Neither you nor your study doctor can choose if you will be in Group A or Group B. Each patient who is eligible for this study will be randomized before starting treatment in the study. Randomization in this study is not stratified. This means there is a 50% chance for you to be assigned to study Group A, and a 50% chance for you to be assigned to study Group B. This study is also not blinded. This means that before starting treatment in this study, you, your study team and your study doctor will all know if you have been randomized to Group A or Group B. About 60 patients are expected to be randomized to Group A, and about 60 patients are expected to be randomized to Group B.

In this study, the difference between patients in Group A, versus patients in Group B, is in WHEN will ctDNA from blood samples be analyzed by the vendor Guardant Health, and IF this ctDNA information is expected to cause a switch to a different standard treatment against metastatic triple negative breast cancer during participation in this study:

- In Group A (also called Arm A):
Each patient's blood will be stored and ultimately analyzed for ctDNA. By design (in order to facilitate a research comparison with results from Group B), ctDNA analysis of blood from patients in Group A will likely be done on samples from many patients at the same time, and not until many or most patients in Group A are no longer receiving treatment in the study.
- In Group B (also called Arm B):
Each patient's blood from Cycle 1, Day 1 and Cycle 1, Day 15 will be compared in real-time, one patient at a time, in order to determine if that patient randomized to Group B will switch treatment (when that patient reaches Cycle 2, Day 1), from one standard treatment against breast cancer, to another standard treatment against breast cancer.

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Again, if you are randomized by the computer to Group B when you start the study, and ctDNA test results from your blood collected on Days 1 and 15 of Cycle 1 indicate that you may possibly benefit from switching to a different standard treatment regimen, then your treatment in this study (like all other approximately 60 patients in Group B) is scheduled to be switched on Cycle 2, Day 1.

If you are randomized to Group B and your treatment is switched based on ctDNA blood tests, you will switch from the standard chemotherapy-based treatment that you and your study doctor chose at the beginning of the study (one of the regimens listed above in bold text), to another standard treatment against breast cancer (an antibody-based treatment called sacituzumab govitecan, also known as SG).

Note that even if you are randomized to Group B, it is possible that ctDNA test results may not support a change to your treatment. If so, then you will continue the same standard chemotherapy treatment in the study that you and your study doctor chose at the beginning of the study (similar to how all patients randomized to Group A experience the study, as no patients randomized to Group A are intended to have their standard treatment switched during the study based on results from ctDNA blood tests).

The length of time you receive standard treatment during this study will depend on the side effects you may experience, and how your disease does or does not respond to the standard treatment you receive while in this study. It is anticipated you may receive treatment during this study until you have intolerable side effects, or until your disease gets worse. You also may withdraw from the study at any time.

If you have side effects, your study doctor may require you to temporarily stop treatment. If you have serious side effects, you may be required to permanently stop treatment during the study and discontinue participation in the study.

During your participation in this study, investigational blood testing for circulating tumor DNA (ctDNA) research will be provided by the study at no cost to you. Because the treatments against breast cancer in this study are standard regimens for your disease, you and/or your insurance will be responsible for the cost of receiving the chemotherapy regimen selected by you and your study doctor at the beginning of the study (i.e. carboplatin and gemcitabine, capecitabine, nab-paclitaxel, paclitaxel, eribulin, or carboplatin) and the cost of receiving sacituzumab govitecan (if you are switched to this antibody-based treatment during your participation in the study), as well as the usual care you would receive even if you were not participating in this study. Upon expiration or termination of the study Guardant shall retain or destroy sample remnants per Guardant's Standard Operating Procedures unless otherwise specified herein.

Up to about 120 total patients are anticipated to enroll in this study at up to approximately 10 academic medical centers in the United States.

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Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Screening

You will have the following done, in order to determine if you are a good candidate for the study:

- Review of your medical history including information about your disease and any previous treatments or surgeries you may have received.
- Physical exam and vital signs (such as your blood pressure, heart rate, breathing rate, and temperature).
- You will be asked about your level of activity.
- You will be asked about and you should tell your study doctor about any problems you are having and the medicines you are taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- Collection of about ¾ teaspoon of your blood for routine laboratory testing (including blood counts and blood chemistry).
- If you are a woman capable of becoming pregnant, you will have a pregnancy test.
- Computed tomography (CT) scan or magnetic resonance imaging (MRI) scan of your chest, abdomen and pelvis (and possibly neck if your disease is also located in the neck) to check the current status of your disease.

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Cycle 1, Day 1

If you are eligible for the study, you will return to clinic to start treatment; the following things will be done:

- Questions about any changes to your health.
- Physical exam and vital signs.
- Collection of about $\frac{3}{4}$ teaspoon of your blood for routine laboratory testing (including blood counts and blood chemistry).
- Collection of about $\frac{3}{4}$ teaspoons of your blood for research testing related to breast cancer and circulating tumor DNA (ctDNA).
- You will start a standard chemotherapy treatment regimen for your disease. As determined by you and your study doctor, your treatment will be one of the below regimens. In general and as shown below, each of these standard chemotherapy regimens is typically administered on treatment cycles lasting 21 days per cycle. Your study doctor will discuss with you additional details about your standard chemotherapy regimen.
 - **Carboplatin and gemcitabine** (IV infusions into a vein: On Days 1 and 8, of 21-day cycles)
 - **Capecitabine** (oral drug by mouth, twice per day: on Days 1-14, of 21-day cycles)
 - **Nab-paclitaxel** (IV infusion into a vein: on Days 1, 8 and 15, of 21-day cycles)
 - **Paclitaxel** (IV infusion into a vein: on Days 1, 8 and 15, of 21-day cycles)
 - **Eribulin** (IV infusion into a vein: on Days 1 and 8, of 21-day cycles)
 - **Carboplatin** (IV infusion into a vein: on Day 1 of 21-day cycles).

Cycle 1, Day 15

- Collection of about $\frac{3}{4}$ teaspoons of blood for research testing related to breast cancer and circulating tumor DNA (ctDNA).

Every Additional Cycle, Day 1

- Physical exam and vital signs.
- Collection of about $\frac{3}{4}$ teaspoon of your blood for routine laboratory testing (including blood counts and blood chemistry).
- Standard treatment against your disease.
- **On Cycle 2, Day 1: Possible switch in standard therapy to sacituzumab govitecan (SG):**
 - If you are randomized by the computer to Group B when you start the study, and results from ctDNA testing of your blood collected on Days 1 and 15 of Cycle 1 indicate that you may possibly benefit from switching to a different standard treatment regimen, then your treatment in this study (like all other approximately 60 patients in Group B) is scheduled to be switched on Cycle 2, Day 1. If this happens, your treatment will switch from the standard

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chemotherapy-based treatment that you and your study doctor chose at the beginning of the study (one of the regimens listed above in bold text), to another standard treatment against breast cancer (an antibody-based treatment called **sacituzumab govitecan**, also known as SG).

- On Cycle 4, Day 1 and Cycle 7 Day 1:
 - Collection of about $\frac{3}{4}$ teaspoons of your blood for research testing related to breast cancer and circulating tumor DNA (ctDNA).

Every 9 Weeks

- Computed tomography (CT) scan or magnetic resonance imaging (MRI) scan of your chest, abdomen and pelvis (and possibly neck if your disease is also located in the neck) to check the current status of your disease.

End of Treatment

In general, you may continue treatment while in this study as long as you do not have serious side effects to your treatment, and as long as your disease does not get worse. When you stop this study, you will have the following done:

- Collection of about $\frac{3}{4}$ teaspoon of blood for research testing related to breast cancer and circulating tumor DNA (ctDNA).

Follow-Up

About every 3 months (12 weeks) at 3, 6, 9 and 12 months after you stop treatment in this study; and then every 6 months (for a total of 3 years after you stop treatment in this study):

- You and/or your doctor's office may be contacted, for example by telephone or a clinic visit, to check on how you are doing, the status of your disease, and to learn about any new anti-cancer therapy you may have started.

This long-term follow-up is intended until one of the following occurs (whichever occurs first): study ends, you withdraw your consent, your death, or until 3 years after you stop treatment in this study. Additional follow-up beyond three years may occur if deemed medically necessary by your study physician.

Side effects and risks that you can expect if you take part in this study:

Risks of blood collection include pain, a bruise at the point where blood is taken, redness and swelling of the vein, infection, and a rare risk of fainting.

This research study may involve exposure to radiation from up to 2 CT scans of the Chest, Abdomen, Pelvis (CAP) with or without contrasts. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you may receive by participating in this study

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is equal to your body receiving 98 months (8.2 years) of radiation from your natural surroundings, or about 49% of the amount allowed in a year for people who are exposed to radiation as part of their work. If you stay in the study past the first year you may have some more procedures which expose you to radiation. You should talk to the study doctor or nurse if you have questions about radiation exposure.

Risks that are not known:

Because the circulating tumor DNA (ctDNA) blood tests used in this study and the application of information from these ctDNA blood tests to help manage cancer treatment are investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study: Participating in this study may help patients with cancer get better care in the future.

The benefits you might get from being in this study: Participating in this study may or may not have direct medical benefit for you. You may or may not receive therapeutic benefit from participation in this study. Your condition may get better but it could stay the same or get worse.

Reasons why the study doctor may take you out of this study:

Your study doctor might take you out of the study for reasons such as:

- You are unable to tolerate the treatment, or you have a side effect and the study doctor feels you should end the treatment.
- Your disease spreads or gets worse (progresses).
- You have another serious illness or need major surgery.
- You do not follow the study doctor's instructions.
- Your health changes or new information becomes available and the study doctor feels it is no longer in your best interest for you to continue in the study, or decides to stop the study.

If you are removed from the study, the reason will be explained to you.

What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

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Clinical Trials Registry.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

Consent for Genetic Research

A purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

Patients with similar diseases do not always obtain the same benefit from the same treatment. Therefore, a goal is to help understand why patients respond differently to treatment, and to then develop treatment that provides maximum benefit for individual patients.

As part of the study, you are being asked to give blood samples for genetic research testing related to breast cancer and circulating tumor DNA (ctDNA). It is possible that genetic testing on these samples could help to learn more about:

- The effect of treatment on your body
- Why some people respond to treatment and others do not
- Why some people have side effects
- The causes of the disease.

With the likely exception of ctDNA test results supporting a change to the treatment that you receive while in this study (if you are randomized to study Group B and your ctDNA test results during participation in this study indicate that you might benefit from switching from one standard treatment to another standard treatment against breast cancer), what we learn about you from research on your samples is unlikely to be put in your health record. No one else (like a relative, boss, or insurance company) will be given your test results.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job. To help prevent this, these samples will be given a code. Only the study staff

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will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Dr. Abramson and her staff helping with the study will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample may be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. Samples will be destroyed when no longer needed. Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Please check Yes or No to the questions below. A question with only a 'Yes Box' indicates a required part of the study:

My blood/tissue/fluid samples may be used for current gene research in cancer related to breast cancer:

☐ Yes ☐ No

My blood/tissue/fluid samples may be stored/shared for future gene research in cancer:

☐ Yes ☐ No

My blood/tissue/fluid samples may be stored/shared for future gene research for other health problems (such as arthritis, heart disease, etc):

☐ Yes ☐ No

Signature: _____ Date: _____

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Part 2 of 2: STUDY SITE INFORMATION

Site Name:	Vanderbilt University Medical Center
Site Principal Investigator:	Vandana Abramson, M.D.
Site Principal Investigator Contact:	() () ()

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Site specific procedures and risks:

Up to about 120 total patients are anticipated to enroll in this study at up to approximately 10 academic medical centers in the United States, including Vanderbilt.

Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury. There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Date of IRB Approval: 02/16/2023
Date of Expiration: 02/14/2024

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Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Vandana Abramson at (██████-██████). If you cannot reach the research staff, please page the study doctor at (██████-██████).

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Medical Center Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Additional information about your local site:

Clinical Trials Reporting Program: Vanderbilt's NCI-Designated Cancer Center or the Sponsor registers National Cancer Institute (NCI)-supported clinical trials with NCI through their Clinical Trials Reporting Program (CTRP) to provide study related information. The data provided will include the following identifiable information that may identify you: birth month/year and five-digit zip code. NCI uses the data to manage and enhance the nation's investment in cancer research.

Confidentiality:

All efforts within reason will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your information and samples will be given a code. Dr. Abramson, her staff, and other authorized people will be the only people who know your personal information.

Study data will be recorded in a Vanderbilt electronic database which is maintained by a research coordinator and data manager at Vanderbilt. The electronic database is password protected in order to help protect your identity. Your study records will be locked up in the clinical trials office. Vanderbilt This study may have some support from the National Institutes of Health (NIH). If so, your study information is

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protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

At any time, you may ask to have your sample destroyed. You should contact Dr. Abramson to have your sample destroyed and no longer used for research. Her mailing address is:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

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Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include Vanderbilt University Medical Center and its agents or contractors, study safety monitors and auditors, data managers and other agents and contractors used by the study team, researchers and study team members. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. Also, your records may be seen by people from regulatory authorities (such as the U.S. Food and Drug Administration [FDA]), auditors, and the Institutional Review Board [IRB]). By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include any funders of the study and their agents or contractors, outside providers, study safety monitors, government agencies, and other sites in the study. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

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What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let her know by using the contact information provided in this consent form. Dr. Abramson's mailing address is:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date

Signature of patient/volunteer

Consent obtained by:

Date

Signature

Printed Name and Title

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