SWOG CANCER RESEARCH NETWORK

Version Date: August 07, 2024

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS

FROM: SWOG Operations Office (E-mail: protocols@swog.org)

RE: S1416: "Phase II Randomized Placebo-Controlled Trial of Cisplatin with or Without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer, with or Without Brain Metastases" Study Chairs: Drs. E. Rodler, P. Sharma, J.R. Gralow, J.B. Hicks and P. Kuhn.

REVISION #8

Study Chair: Eve Rodler, M.D.
Phone number: 916/734-3772
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Action Codes
(✓) Expedited review allowed
(✓) Patients Must be Informed*
(✓) Verbal notification allowed
* See "Patient Notification" and "Regulatory Considerations" instructions below.

Key Updates
(✓) Treatment / Study Calendar changes

Sites using the CIRB as their IRB of record: The protocol and/or informed consent form changes have been approved by the CIRB and must be activated within 30 days of the CIRB posting of this notice.

Sites not using the NCI CIRB: Per CTMB Guidelines, the protocol updates and/or informed consent changes must be approved by local IRBs within 90 days of distribution of this notice.

REVISION #8

The above-referenced protocol has been revised to accommodate the discontinuation of the ABT-888 (veliparib) development program and the associated study drug supply. This amendment is in response to Dr. Ivy's April 26, 2023, request for amendment.

All participating sites, where patients are currently receiving ABT-888 (veliparib) treatment, will receive this information through both the "Investigator Letter" and the "Participant Information Letter."

Protocol Changes

The above-referenced protocol has been updated as follows:

1. Formatting, typographical errors, and section links were updated throughout the protocol.

2. The version date and table of contents has been updated.

3. **Section 3.0:** A note has been included specifying the expiration dates for the existing unblinded ABT-888 (veliparib) supplies and the end of treatment date.

4. **Section 3.1d and 7.2:** A note has been included to provide the rationale for unblinding the last

patient on treatment and to provide additional guidance.

5. **Section 7.4c:** A subsection has been inserted to provide additional guidance for the remaining patient on treatment.

6. **Section 9.0:** Footnote "**" has been updated to reflect patient visits and scans after the five (5) year follow-up time frame is at the discretion of the physician.

Model Consent Form Changes

The Model Consent Form has been updated as follows:

1. The version date has been updated.

2. "How long will I be in this study?": A note has been inserted regarding the discontinuation of the ABT-888 (veliparib) development program.

Investigator and Patient Letter

The Investigator and Patient Letter has been included due to the following:

1. The letters have been provided to explain the rationale for unblinding the last patient on treatment and to provide additional guidance.

Patient Notification:

Please note that the information provided below regarding patient notification and amendments to local consent forms reflects SWOG's minimum requirements. Sites should refer to the policies/procedures of the IRB of record to determine whether they have any more stringent requirements.

SWOG has determined that the changes above may affect a patient's willingness to participate in the study; therefore, SWOG requires that patients be notified of these changes.

Who must be informed?
- All patients currently on study treatment with ABT-888 (veliparib).

How must patients be notified?
- For patients currently receiving ABT-888 (veliparib): Notification must take place via distribution of the patient letter or verbally by the next study visit.

What is the notification deadline and process?
- For patients currently receiving treatment with ABT-888 (veliparib): It is recommended that the patient be notified as soon as possible to make the determination of whether to continue treatment.

Regulatory Considerations:

Do local consent forms need to be updated?
- It depends. If your site will utilize the updated consent form for notification and formal reconsent then local consent forms must be updated. If your site will not utilize updated consent form for notification and formal reconsent then local consent forms need not be updated.

The updated protocol, model informed consent form, and patient letter can be accessed from the CTSU website (www.ctsu.org). Please discard any previous versions of the documents and replace with the updated versions.

This study has been reviewed and approved by the NCI's Central Institutional Review Board (CIRB). This memorandum serves to notify the NCI, and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE
Elizabeth Swisher, M.D. – King/Swisher Laboratory
Ruu Hsu – Kuhn-Hicks Laboratory
Katie Von Derau – WPC

Informed Consent Model for S1416

Study Title for Study Participants: Testing Cisplatin Given With ABT-888 Compared to Cisplatin Alone in Metastatic TNBC and BRCA Mutation-Associated Breast Cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: S1416, "Phase II Randomized Placebo-Controlled Trial of Cisplatin with or without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer, with or Without Brain Metastases"

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

What is the usual approach to my breast cancer?

You are being asked to take part in this study because you have metastatic triple negative breast cancer or have BRCA-mutation associated metastatic HER2 negative breast cancer. People who are not in a study are usually treated with chemotherapy.

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

If you decide not to take part in this study, you have other choices. For example:

- You may choose to have the usual approach described above
- You may choose to take part in a different study, if one is available
- or you may choose not to be treated for cancer.

Why is this study being done?

The main purpose of this study is to compare any good and bad effects of using ABT-888 (Veliparib) (a "PARP" inhibitor) along with cisplatin to using cisplatin alone. The drug being tested in this study is called ABT-888. It is investigational, which means it has not been approved for use by the U.S. Food and Drug Administration (FDA). The addition of ABT-888 to cisplatin is an experimental approach. This combination could shrink your cancer but it could also cause side effects. This study will allow researchers to know whether this different approach is better, the same, or worse than the usual approach of chemotherapy. The chemotherapy drug, cisplatin, is used for the treatment of breast cancer although it is not FDA approved for this use. Cisplatin has shown treatment response with tumor

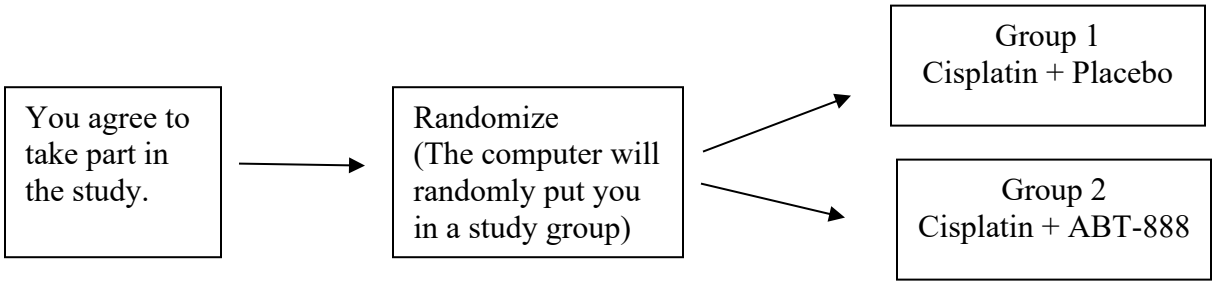
shrinkage in patients with metastatic breast cancer, including patients with the triple-negative breast cancer and BRCA mutation-associated breast cancer.

There will be about 333 people taking part in this study.

What are the study groups?

This study has two study groups. Group 1 will receive cisplatin and a placebo, a pill that looks like the study drug but contains no medication, and group 2 will receive cisplatin and the study drug, ABT-888. A computer will by chance assign you to the treatment groups in the study. This is called randomization. This is done by chance because no one knows if one study group is better, the same, or worse than the other. Once you are put in one group, you cannot switch to the other group. Neither you nor your doctor can choose or know which group you will be in.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



All patients will receive cisplatin, which will be delivered into your vein on Day 1 over 60 minutes and repeated every 21 days (Each 21-day period is called a "cycle"). On Day 1 of each cycle, you will also start ABT-888 or placebo that you will take by mouth twice a day (with or without food) for the first 14 days of each 21-day cycle. ABT-888/placebo capsules should be swallowed whole, do not crush or chew them. You will have a physical exam and blood tests done at the beginning of each cycle. A CT scan (of the chest, abdomen and pelvis) will be done after every 3 cycles of treatment. If you miss your scheduled dose of ABT-888/Placebo and less than 6 hours have passed since the scheduled dosing time, the dose should be taken immediately. If more than 6 hours have passed, wait and take the next regularly scheduled dose. If you vomit the dose, do not re-dose, wait and take the next regularly scheduled dose.

You will be provided with self-administration instructions and a medication diary to record the date and time the ABT-888/placebo was taken. You will need to bring the completed diary and any remaining pills to your study visits.

You will also be provided with an ABT-888 (veliparib)/placebo drug information handout and wallet card to carry with you and share with other providers as needed.

If your side effects from the combined drugs become too severe after receiving a minimum of 4 cycles, you and your doctor can discuss receiving the ABT-888 or placebo alone at an increased dose.

How long will I be in this study?

You will receive the two study drugs for as long as your disease does not get worse and the side effects are not too severe. After you finish the study drugs, your doctor will continue to watch you for side effects and follow your condition for up to five years.

NOTE: The ABT-888 (veliparib) development program has been stopped by the collaborator and the agent will no longer be available after December 31, 2024. Your study doctor will talk to you about your options.

What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra exams and tests that you will need to have if you take part in this study.

Before you begin the study:

You will need to have the following extra tests as part of taking part in the study:

- Patients of child-bearing potential must have a negative pregnancy test before beginning ABT-888/placebo.
- A small amount of your blood (about 3 teaspoons) will be collected (at the same time as other lab tests) for the following two tests:

  1) Genetic BRCA testing- Submission of this specimen is required even if you have had the BRCA test previously. The blood specimen will not have your name or personal information on it but will be marked with a study participant/code number. During the process of genetic testing for BRCA genes, other genes that can impact cancer risk will also be tested. The results of genetic testing (BRCA and other genes) will be given back to your doctor within 4-8 weeks. Your study doctor will discuss these results with you. The test results will not affect your treatment on this study. You may begin treatment before getting the test results.

  Genetic counseling is routinely clinically recommended for patients who are undergoing BRCA testing. You may have already received this counseling as part of your routine clinical care. Your doctor will make arrangements for you to receive this counseling if you have not already received the genetic counseling. However, genetic counseling is not required for participation in this study and you may choose to not receive genetic counseling. At the end of the consent form you can opt in or out of genetic counseling.

  2) Circulating Tumor Cell (CTC) testing- In an effort to determine if there are some patients who are more or less likely to benefit from cisplatin with or without ABT-

888 (Veliparib), one tube of your blood will be collected before you start treatment, Day 1 of Cycle 2, and whenever your cancer begins to grow. This blood will be studied for the presence of certain changes in the genes and proteins of cancer cells that have broken off the metastatic cancers in your body and are floating in your blood. This blood will also be studied for DNA not found in cells but that is also present in your blood because it has been released from the cancers in your body. You and your study doctor will not receive the results of any test done on CTC.

After the completion of the BRCA and CTC testing any remaining blood specimens will be destroyed and not retained for future research.

- A sample of your tissue will also be taken from the cancer tissue that was already removed as part of your original surgery. Any leftover tissue may be stored at the SWOG Biospecimen Bank for biobanking and used for future testing with your consent. This will be discussed in the section on optional studies.

These specimens - blood for BRCA genetic testing, blood for CTC testing and archived tissue - will be sent to a central laboratory for testing. These samples are required in order for you to take part in this study because the research on these samples will be analyzed to look for biologic markers to learn about breast cancer and also to study ways to predict who will respond to the study treatment. You and your study doctor will not receive the results of any tests done on your tissue.

Neither you nor your health care plan/insurance carrier will be billed for the collection of the samples that will be used for this study.

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- **You may lose time at work or home and spend more time in the hospital or doctor's office than usual**
- **You may be asked sensitive or private questions which you normally do not discuss**
- **The study drug/study approach may not be better, and could possibly be worse, than the usual approach for your cancer.**

The drugs used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

Over-the-counter (including herbal supplements) may contain ingredients that could interact with your study drug. Speak to your doctors to determine if there could be any side-effects.

There is also a risk that you could have side effects.

Here are important points about side effects:

- **The study doctors do not know who will or will not have side effects.**
- **Some side effects may go away soon, some may last a long time, or some may never go away.**
- **Some side effects may interfere with your ability to have children.**
- **Some side effects may be serious and may even result in death.**

Here are important points about how you and the study doctor can make side effects less of a problem:

- **Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.**
- **The study doctor may be able to treat some side effects.**
- **The study doctor may adjust the study drugs to try to reduce side effects.**
- **The study doctor may stop the study drugs due to side effects.**

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Risks and side effects related to the ABT-888 (veliparib) treatment include those that are:

COMMON, SOME MAY BE SERIOUS In 100 people receiving ABT-888, more than 20 and up to 100 may have:
• **Nausea** • **Tiredness** • **Bruising, bleeding**
OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving ABT-888, from 4 to 20 may have:
• **Anemia which may require blood transfusion** • **Infection, especially when white blood cell count is low** • **Belly pain** • **Constipation, diarrhea, vomiting** • **Weight loss, loss of appetite** • **Dehydration** • **Dizziness, Headache** • **Changes in taste** • **Rash**
RARE, AND SERIOUS In 100 people receiving ABT-888, 3 or fewer may have:

- Cancer of bone marrow caused by chemotherapy
- Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions
- A new cancer resulting from treatment of earlier cancer
- Seizure
- Blood clot which may cause swelling, pain, shortness of breath

Your study doctor will give you a medical information sheet of certain drugs to avoid during the study and a wallet card about the study.

Risks and side effects related to the cisplatin treatment include those which are:

COMMON, SOME MAY BE SERIOUS

In 100 people receiving Cisplatin, more than 20 and up to 100 may have:

- **Nausea, vomiting**
- **Infection, especially when white blood cell count is low**
- **Anemia which may cause tiredness, or may require blood transfusions**
- **Bruising, bleeding**
- **Kidney damage which may cause swelling, may require dialysis**
- **Hearing loss including ringing in ears**

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving Cisplatin, from 4 to 20 may have:

- **Hair loss**
- **Change in taste**
- **Diarrhea**
- **Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat**
- **Confusion**
- **Difficulty with balance**
- **Numbness and tingling of the arms and legs**
- **Blurred vision or changes in ability to see colors (especially blue or yellow)**

RARE, AND SERIOUS

In 100 people receiving Cisplatin, 3 or fewer may have:

- **Cancer of bone marrow caused by chemotherapy later in life**
- **Seizure**

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Reproductive risks: You must not be or get pregnant, breastfeed, or father a baby while in this study. The drugs used in this study could be very damaging to an unborn baby. Birth control measures should be continued for at least 6 months after the completion of

chemotherapy and until your study doctor indicates it is acceptable to stop. Check with your study doctor about what types of birth control or pregnancy prevention to use while in this study. If you are a woman and become pregnant while participating in this study, please inform your treating physician immediately.

Genetic Risks

Genetic research has the risk of loss of privacy. There is a small risk that if people other than the researchers were given your genetic facts, they could misuse them. If information was given to employers or insurers it could affect your ability to get a job or be insured. Misuse could cause problems for family members. In order to minimize these risks, your genetic information will be kept confidential as noted in this form.

Genetic Information Nondiscrimination Act (GINA)
A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- **Health insurance companies and group health plans may not request your genetic information that we get from this research.**
- **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 we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. The GINA protections do not help you if you work for a company with less than 15 employees.**

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

What possible benefits can I expect from taking part in this study?

It is not possible to know at this time if ABT-888 (veliparib) with cisplatin is better than the usual cisplatin approach so this study may or may not help you. This study will help researchers learn things that will help people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____ *(insert name of center)* Institutional Review Board at _____ *(insert telephone number). (Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.)*

What are the costs of taking part in this study?

The ABT-888/placebo will be supplied at no charge while you take part in this study. The cost of getting the ABT-888/placebo ready and giving it to you is not paid by the study sponsor so you or your insurance company may have to pay for this. It is possible that the ABT-888/placebo may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

The cisplatin is commercially available. The cost of getting the cisplatin ready and giving it to you is not paid by the study sponsor so you or your insurance company may have to pay for this.

Neither you nor your healthcare plan/insurance carrier will be billed for the collection of samples that will be used for this study.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

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

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

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. **The study doctors have a privacy permit to help protect your records if there is a court case.** However, some of your medical information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, and information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor (NCI Cancer Therapy Evaluation Program), SWOG, and any drug company supporting the study.
- Your local Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.
- Qualified representative(s) of the National Clinical Trial Network member with whom your institution is affiliated (ALLIANCE, ECOG-ACRIN, or NRG).

[Note to Local Investigators: The NCI has recommended that HIPAA regulations be addressed by the local institution. The regulations may or may not be included in the informed consent form depending on local institutional policy.]

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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

[Note to Informed Consent Authors: the above paragraph complies with the new FDA regulation found at 21 CFR 50.25(c) and must be included verbatim in all informed consent documents. The text in this paragraph cannot be revised.]

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

Additional Studies Section:

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading these optional studies hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you nor your study doctor will know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say 'no' to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the follow studies.

1. Optional Fresh Metastatic Tissue Biopsy

If you choose to take part in this study, the study doctor for the main study would like to collect tissue from your metastatic tumor for research on protein and genetic changes that can be linked with your clinical response to the study treatment. If there is not enough tissue from the biopsy of your previously collected metastatic tumor, you can choose to have a new metastatic tissue biopsy performed before you begin protocol treatment. Future research could include developing new treatment or drugs. You will not receive any financial benefit from the research or products, including drugs that might come from the use of your tissue. No information that could directly identify you will be available to the researchers.

The most common risks related to a biopsy are bleeding at the time of the procedure, pain at the biopsy site, infection and bruising. You will sign a separate consent form before the biopsy is taken. This will be a standard surgical consent form from the institution where the biopsy procedure takes place and will explain the specific risks related to the biopsy procedure you need.

2. Optional Sample Collections For Laboratory Studies And/Or Biobanking For Possible Future Studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part in the main study, a sample of tissue from your initial biopsy/surgery and metastatic biopsy will be collected prior to starting on protocol treatment. The researchers ask your permission to store and use your leftover samples from the planned research and health information for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking". The Biobank is being run by SWOG and supported by the National Cancer Institute.

What is Involved?

If you agree to allow your specimens to be stored and used in future research, here is what will happen next:

1) Your specimens will be collected as described above and will be sent to the Biobank.
2) Your specimens and some related information may be stored in the Biobank, along with samples and information from other people who take part. The specimens will be kept until they are used up.
3) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
4) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
5) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

What are the Possible Risks?

1) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

3)
4) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
5) In some cases, genetic information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe that the chance that these things will happen is very small, but they cannot promise that you will avoid any risk.

How will information about me be kept private?

Your privacy is very important to the researchers, and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your samples are sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and SWOG staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers that receive your sample and information from SWOG will not know who you are. Researchers must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

What are the Possible Benefits?

You will not benefit from taking part in this study. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are There any Costs or Payments?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

What if I Change my Mind?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* who will let the researchers know. Then, any samples that remain in the bank will no longer be used.

Samples or related information that have already been given to or used by researchers will not be returned.

If you decide to withdraw your specimens from a SWOG Biospecimen Bank in the future, a written withdrawal of consent should be submitted through your study doctor to the SWOG Operations Office. Please designate in the written withdrawal whether you would prefer to have the specimens destroyed or returned to the study doctor.

What If I Have More Questions?

If you have questions about the use of your samples for research, contact the study doctor, _____, *(insert name of study doctor for main trial)*, at _____ *(insert telephone number of study doctor for main trial)*.

Please circle your answer to show whether or not you would like to take part in each option (*include only applicable questions)*:

FRESH METASTATIC TISSUE BIOPSY:

I agree to have an additional metastatic tissue biopsy performed.

Yes **No**

GENETIC COUNSELING:

I agree to have genetic counseling for the BRCA testing.

Yes **No**

SAMPLES FOR FUTURE RESEARCH STUDIES:

My samples and related information may be kept in a Biobank for use in future health research.

Yes **No**

Future Contact:

I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

Yes **No**

This is the end of the section about optional studies.

My Signature Agreeing to Take Part in the Main Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study and any additional studies where I circled 'yes'.

Participant's signature_____

Date of signature_____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature_____