STANFORD CONSENT FORM

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Are you participating in any other research studies? _____ Yes _____No

PURPOSE OF RESEARCH

You are invited to participate in this clinical trial (a type of research study) because you have HER2 negative breast cancer or a non-breast metastatic solid tumor that has spread outside of the breast or other part of body (metastasized) and which may be sensitive to a class of drugs called PARP inhibitors. This study is a single-arm clinical trial, which means all participants will receive the study drug.

The information in this form is part of a process called informed consent, which will allow you to make a decision about whether you want to volunteer for this clinical trial. Your study doctor will also explain the clinical trial to you. Clinical trials include only those people who choose to take part. Please take your time to make your decision and discuss it with your friends and family.

Once all of your questions have been answered, if you still wish to take part, you will be asked to sign this form. Your study doctor and/or a member of the study team will also sign the form. You will receive a copy of the form to keep. If you have any questions at any time during the research study, you should feel free to ask them. You will receive answers to your questions in a way that you will be able to understand. You are not giving up any of your legal rights by volunteering for this research study or signing this consent form.

This is an investigator-initiated led by Dr. Melinda Telli.

This research study contains two patient cohorts. Each cohort is looking for a total of 20 patients. Cohort A consists of patients with sporadic (i.e. lacking an inherited form of the BRCA1 or BRCA2 gene mutation), advanced triple-negative (estrogen receptor-/progesterone receptor-negative, and HER2-negative) breast cancer with faulty DNA repair mechanisms based on a new tumor tissue assay produced by Myriad Genetics. Cohort B consists of patients with HER2-negative breast cancer or non-breast metastatic solid tumors with either evidence of a hereditary breast cancer syndrome, excluding BRCA1 or BRCA2, or with evidence of genetic changes in the tumor tissue, making the tumor sensitive to the study agent. Enrollment will only occur at the Stanford Women's Cancer Center.

If you decide to terminate your participation in this study at any time, you should notify Dr. Melinda Telli at [redacted].

WHY IS THIS STUDY BEING DONE?

- Studies have documented tumor shrinkage when using this class of study agents called PARP inhibitors in advanced breast cancer patients who carry an inherited BRCA1 or BRCA2 mutation.
- It has been suggested that PARP inhibitors may also have a role in the treatment of triple-negative breast cancer patients, who do not have an inherited risk, but whose tumors have similar DNA repair defects.
- Likewise this study agent may have a role in the treatment of breast cancer patients with different inherited mutations affecting the same DNA repair pathway, or similar types of mutations arising in the tumor tissue itself.

The **purpose of this study** is to evaluate if treatment with the study drug, talazoparib, causes tumor shrinkage in breast cancer and non-breast cancer patients whose tumor cell's have impaired ability to repair DNA.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

HOW LONG WILL YOU BE IN THE STUDY?

Following the Pre-Study visit you will be required to visit Stanford every 28 days. Each visit will last a few hours depending on the examinations to be performed. The study doctor and research coordinator will inform you of the length of each visit.

You will receive study treatment for 12 cycles with talazoparib (first stage of treatment called the Induction Phase). Each cycle is 28 days long. The Induction Phase will be given for up to 12 cycles (or up to about 12 months), unless your disease progresses or side effects of therapy would make it unsafe for you to continue.

If after 12 cycles your disease has not progressed and you remain on treatment, you will proceed to the second stage of treatment called the Continuation Phase. You will continue to receive treatment every 28 days.

You will continue treatment until your disease progresses or side effects of therapy would make it unsafe for you to continue.

Your study doctor will keep track of your medical condition for up to 3 years from the time you enrolled on this study to look at the long-term effects of the treatment.

Your study doctor may decide to take you off this study if your disease does not improve or if side effects of treatment would make it unsafe to continue. You will be informed of new developments that may become available that might affect your participation in the study.

PROCEDURES

WHAT IS INVOLVED IN THIS STUDY?

BEFORE YOU BEGIN THE STUDY

You will need to have the following exams, tests and procedures done in order to find out if you can safely be in the study. Many of these are part of your regular care and would be done even if you were not to take part in this study. If you have had some of these recently, they may not need to be repeated. You will need to sign this consent form before any study related procedures are performed.

Within 4 weeks prior to treatment initiation, the following will be performed:

- Review of your medical history, including any medications you are currently taking. The review will also include an assessment of any history of or risk factors you may have for hepatitis B or hepatitis C.
- Complete physical examination, including an assessment of your heart rate, blood pressure, temperature, height and weight
- Evaluation of how active you are and your ability to perform every day activities (performance status)
- Radiology or Imaging scans to measure the size and location of the cancer (such as a CT or "CAT" Scan)
- Serum pregnancy test for women of childbearing potential
- Blood tests including complete blood count and metabolic chemistry panel
- Hepatitis B and/or Hepatitis C tests may be done if you have any known risk factors. If you have a positive hepatitis B or hepatitis C result, you may be required to take an antiviral medication for 1-2 weeks prior to the first dose of study drug.

The results of these tests will be reviewed by your study doctor to see if you have met all of the requirements for the study.

DURING THE INDUCTION PHASE OF THE STUDY

If the exams, tests and procedures show that you can be in the study and you choose to take part, then you will need the following exams, tests and procedures during the study:

Day 1 of Each Cycle- At least once every 28 days, the following will be performed:

- Physical examination including heart rate, blood pressure, temperature, and weight

- Review of any medications you are currently taking
- Evaluation of how active you are and your ability to perform every day activities (performance status)
- Blood tests including complete blood count and liver and kidney function tests. Additional blood may be required to perform tests for hepatitis B and/or hepatitis C if you had a positive result prior to the start of the study. Please note: You will have a complete blood count measured once every two weeks for the first two cycles.
- Check to see how you are taking the study medication at home. You will be asked to complete a Patient Pill Diary. Please bring your study medication and Patient Pill Diary to each visit.
- Monitoring of side effects – you should tell your study doctor if you have new problems at any time when they occur. Your study doctor or nurse will also ask you about new problems before the start of a new study cycle. You should also tell your study doctor if you are taking any other medications.

Once every 8 weeks (every 2 treatment cycles) the following will be performed:

- Radiology or Imaging scans to measure the size and location of the cancer (such as a CT or "CAT" Scan). You may have additional radiology tests during the study if your study doctor feels it is necessary.

DURING THE CONTINUATION PHASE (AFTER COMPLETION OF 12 CYCLES OF THERAPY IN THE INDUCTION PHASE)

You will continue to receive single-agent talazoparib. At each clinic visit, we will evaluate the following:

- Complete blood count and kidney and liver function tests.
- You will continue to complete a Patient Pill Diary. Please bring your study medication and Patient Pill Diary to each visit.
- Monitoring of any unresolved side effects – you should tell your study doctor if you have new problems at any time when they occur. Your study doctor or nurse will also ask you about any ongoing problems after you have stopped taking the study medication. You should also tell your study doctor if you are taking any other medications.

Once every 12 weeks (every 3 treatment cycles) the following will be performed:

- Radiology or Imaging scans to measure the size and location of the cancer (such as a CT or "CAT" Scan). You may have additional radiology tests during the study if your study doctor feels it is necessary.

You can discuss the details of the study calendar with your study doctor or the study staff.

AFTER END OF FIRST STAGE OR END OF ALL TREATMENT

When you go off the study you will be asked to return for a follow-up exam within 30 days after receiving your last dose of talazoparib. The following tests and procedures will be done at the off-study visit:

- Physical examination including heart rate, blood pressure, temperature, and weight
- Review of any medications you are currently taking
- Evaluation of how active you are and your ability to perform every day activities (performance status)
- Blood tests including complete blood count and kidney and liver function tests.
- Final check to see how you took the study medication at home. Please bring your study medication and completed Patient Pill Diary.
- Monitoring of side effects – you should tell your study doctor if you have new problems at any time when they occur. Your study doctor or nurse will also ask you about any ongoing problems after you have stopped talking the study medication. You should also tell your study doctor if you are taking any other medications.
- Radiology or Imaging scans to measure the size and location of the cancer (such as a CT or "CAT" Scan), if due.

Once you have come off study, you will be followed for 3 years from the date you were randomized to the study. Your doctor will ask you about problems that were ongoing at the time you came off the study. The following tests and procedures may be done approximately every 3 months:

- Complete blood count – only if there are any ongoing side effects.
- Radiology or Imaging scans to measure the size and location of the cancer (such as a CT or "CAT" Scan), if your cancer had not previously progressed (gotten worse).

WHAT IS THE STUDY TREATMENT PLAN?

After you have agreed to be in the study by signing this consent form and you have met all of the conditions for the study, you will receive the study drug, talazoparib. All study participants will receive a pill bottle containing 28 capsules of equal concentration of talazoparib to take daily. We will provide a refill every 28 days after our clinic visit with you.

You will continue to take the study drug as prescribed during the Induction Phase, for approximately 12 cycles (each cycle is 28 days long) or until the disease gets worse or the side effects are not acceptable. If your tumor grows, or if you develop new tumors, the study treatment will be stopped. Your study doctor may stop treatment if you have side effects that would make it unsafe for you to continue, or you may decide to stop participating in the study at any time for any reason. Even if you stop treatment, you will be followed by your study doctor for up to three years.

If you forget to take a pill and remember by 10 PM, you may take the dose. Otherwise just skip that dose and begin as usual the next day. Please mark dates of any missed pills on your Patient Pill Diary. Your study doctor or nurse will give you the Patient Pill Diary to write down the pills that you take.

If your disease has not progressed (gotten worse) after 12 cycles of treatment (Induction Phase), you may continue to receive treatment (Continuation Phase). You may continue to receive treatment as long as your disease is not getting worse. You will continue be followed by your study doctor on a monthly basis.

If you have serious side effects during your treatment, the dose of talazoparib may be lowered. If the serious side effects do not improve with the lowering of the dose or if the side effects are life threatening, the drug may be stopped by your study doctor.

Women of Childbearing Potential

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control such as an intrauterine device (IUD) or double barrier contraception during treatment and for 30 days after the last dose of study drug to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study.

You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

Blood and Tissue Sampling for Research

Research using blood and tissue is an important way to try to understand human disease. You have been given this information because the investigators want to include results from your blood and tumor tissue in this research project and because they want to save the samples for future research. **If you do not already have an adequate tumor tissue biopsy from a metastatic site (i.e. a site that your cancer has spread to), you are required to undergo a repeat tissue biopsy to be considered eligible for this study.** There are several things you should know before allowing your blood and tumor tissue to be studied.

Your blood and tissues will be stored using a unique identifier and not linked to your medical record number. Tissues will be sent outside of Stanford University for analysis.

Because your samples will not be linked to your name after they are stored, you cannot withdraw your consent to the use of the samples after they are taken. Following completion of all research the samples will be destroyed.

You will be told the results of tests that are part of your clinical care, but you will not be told the results of the research tests, including any future research tests.

_____ I consent to my samples being analyzed for this research study and being saved for future research
_____ I consent to my samples being analyzed for this research study *only*; I do not consent to my samples being saved for future research
_____ I do not consent to my samples being used for this research study or saved for future research (please note: you will not be eligible for the study if you select this option)

Tissue Sampling for Genetic Testing

Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to provide information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

Any tissues you have donated which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the researchers, Stanford University and/or others. However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Regarding informing you of the test results, you should understand the following:

- The information may be too limited to give you particular details or consequences;
- You may be determined to carry a gene for a particular disease that can be treated;

- You may be determined to carry a gene for a particular disease for which there is no current treatment;
- You may carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

Please circle [yes or no] as to whether you wish to be told the test results.

Please circle [yes or no] as to whether you wish your family members to be told the test results.

Birth Control

If you and your sex partner are able to have a baby, you must agree to avoid pregnancy by using highly effective birth control methods such as an intrauterine device ("IUD"), oral (birth control pills), intravaginal, transdermal (patch) or injectable contraception methods or use abstinence (not having sexual intercourse).

A woman receiving talazoparib must use the birth control from the time she signs the informed consent and for 45 days after the last dose of treatment.

Men receiving talazoparib must use a condom when having sex with a pregnant woman and when having sex with a woman who could have a baby, from the time of the first dose of study drug through 105 days after the last dose of study drug. Men should talk about the use of highly effective birth control methods with a woman partner who could have a baby.

This is important in research studies when the drugs have not been tested on pregnant women or the fetus. The only sure way to keep from getting pregnant or to make sure you do not make your partner pregnant is to not have sex. If you choose to have sex while you are in this study, you must talk about birth control and make an agreement with the study doctor. There is a risk that you could still get pregnant, even if you are using birth control. The treatment could make you lose the pregnancy (miscarry) or it might hurt the fetus. Ask your study doctor if you have questions about pregnancy or birth control during this study.

Risks associated with pregnancy and nursing:

Like any other experimental drug, talazoparib may have unknown and serious risks that could lead to death. If you are pregnant or breast feeding (nursing) a child, you cannot be in this study. Talazoparib was shown to harm the fetus of pregnant rats. Although the risk in humans of harming the fetus, nursing a baby, or losing a pregnancy (miscarriage) while taking talazoparib is unknown, you must use highly effective birth control during the study. If you think you could be pregnant you must tell your study doctor.

For male patients, if your partner becomes pregnant or for female patients, if you become pregnant, you must immediately notify the study doctor of the pregnancy. The sponsor will ask the study doctor to provide medical information on the pregnancy and the health of the baby.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Take the study drug as instructed
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Keep the study drug in a safe place, away from children and for your use only.
- Keep your diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

WHAT WILL HAPPEN IF I DO NOT WISH TO PARTICIPATE OR DECIDE NOT TO CONTINUE IN THE STUDY?

Taking part in this study is your choice (voluntary). You may choose not to take part or may leave the study at any time. Leaving the study, or choosing not to take part, will not affect further treatment options or your relationship with your doctor. If you do not wish to participate in this trial, your doctor will discuss your other treatment options with you. You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. Beginning on the date you withdraw your permission, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Telli at [redacted].

If you withdraw from the study, or the study medication is stopped for any reason, we will ask you to return all study-related supplies, including unused study drug.

The Protocol Director may also withdraw you from the study and the study medication may be stopped, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

WHAT ARE THE RISKS OF THE MEDICATION OR TREATMENTS IN THE STUDY?

While you are participating in this study, you should tell your study doctor about all medications that you are currently taking and before starting any new medications (including all herbal and over-the-counter medications). You should also tell your study doctor about any allergies to medications which you currently have or have had in the past. Severe allergic reactions, which may be life threatening, are possible with the medication prescribed in this study. For your safety, you will be monitored throughout the study for any changes that may occur because of the treatment that you receive.

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

Risks that have been associated with talazoparib are:

- Low red blood cell counts (anemia), low platelet counts (thrombocytopenia), and low neutrophil counts (neutropenia)
- Low neutrophil count (falls within subgroup of white blood cells) can weaken the immune system and increase the risk of infection, including severe infection or sepsis requiring hospitalization and IV antibiotics
- Other side effects associated with this drug include: nausea, vomiting, diarrhea, muscle cramps, fatigue, dizziness, hair loss, cough, swelling or irritation of the mucus membranes (mucus membranes form a moist lining for body parts like your mouth, lungs, and digestive tract) and flatulence

Talazoparib is considered a cytotoxic agent, subjects should be advised that oral anticancer agents are toxic substances and that (other than the subject) caregivers should always use gloves when handling the capsules.
Furthermore, this class of drugs has been associated with a small risk of secondary hematological malignancies, such as acute leukemia. As such, if you decide to enroll in this study, we will pay

very close attention to your laboratory results and will refer you to a hematologist (blood specialist) if your blood counts remain low for more than six weeks.

As this is an investigational therapy it may involves risk to the study participant that is currently be unforeseeable.

All problems need to be reported to the study doctors or study nurses looking after you either by phone or at the next visit.

For more information about risks and side effects, you should feel free to ask your study doctor. If you are concerned about your health between visits due to participating in this trial, please call your study doctor using the telephone numbers provided at the end of this document.

In rare instances where a nurse, a doctor, or a laboratory technician sustains an exposure to your blood by needle stick, cut or splash to mucosa or damaged skin, it may be necessary to test your blood for certain viral infections including Hepatitis B, Hepatitis C, and HIV on the blood sample already available. This is to enable that person to receive appropriate counseling, monitoring and treatment, if necessary. In this instance the study doctor will offer you the information relevant to your health and advise you on the next steps. Confidentiality of your data will be respected at all times.

OTHER RISKS AND DISCOMFORTS

Other Medications

Other drugs may be given to make side effects less serious and less uncomfortable including drugs for nausea, such as ondansetron or prochlorperazine. Other medications may be given to address symptoms of cancer. Please discuss the potential side effects of any new medications with your study doctor.

Blood Collection

The risks from having blood drawn and or inserting the needle in your vein when giving study drug include fainting, bleeding, bruising at the place on your arm where the blood was drawn or needle inserted, as well as pain, swelling and rarely, infection or nerve damage.

Tumor Assessments

Imaging scans such as CT, MRI, and bone scans will expose you to low doses of radiation and some may be performed with contrasting agents (dyes), which have additional side effects. If you need an MRI scans, there is a risk of heating from radiofrequency imaging coils and their cables, button response boxes and their cables, and the cables from monitoring devices that record physiologic processes such as heart beats per minute or electrical activity of the brain. Please report any heating sensation immediately. You may have the scan stopped at any time if this occurs. The risks of these procedures should be discussed with your study doctor and the person performing the exam. This research study involves exposure to radiation from a screening CT scan. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation exposure is about 20 mSv, which is approximately

equal to 40% of the limit that radiation workers (for example, a hospital x-ray technician) are allowed to receive in one year. This amount of radiation involves minimal risk and is necessary to obtain the research information desired.

Tumor Biopsy
In general, having a biopsy can cause pain, swelling, bleeding and/or infection at the site where the biopsy needle penetrates through your skin. If your doctor decides to use anesthetic, an allergic reaction may occur. With a tumor biopsy, there is a rare possibility of tumor cells spreading from the tumor into the nearby area.

POTENTIAL BENEFITS

If you agree to take part in this study, there may or may not be any direct medical benefit to you. The possible benefits to you from taking part in this study are that the drug may slow the growth or shrink your tumor. However, this cannot be guaranteed. We hope the information learned from this study will benefit other patients with cancer in the future.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

ALTERNATIVES

- Standard chemotherapy if you have triple-negative breast cancer
- Standard chemotherapy or anti-estrogen therapy if you have estrogen receptor and/or progesterone receptor-positive breast cancer
- Stanford chemotherapy if you have a non-breast metastatic cancer
- Enrollment in a different clinical trial, if you meet the eligibility criteria
- No therapy at this time, with care to help you feel more comfortable

Please talk to your doctor about these and other options available to you for your treatment.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

If new information is learned that may affect you after the study has been completed, you will be contacted by the study doctor.

ClinicalTrials.gov

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.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this study is to find out what effect single agent talazoparib will have on your cancer. This study will also look at the side effects associated with this drug. The results will be provided to the drug manufacturer, the Food and Drug Administration and other federal and regulatory agencies as required.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The purpose of this study is to find out what effect single agent talazoparib will have on your cancer. This study will also look at the side effects associated with this drug.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Melinda Telli, [redacted].

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to,

- The history and diagnosis of your disease;
- Specific information about the treatments you received, including previous and future treatment(s);
- Information about other medical conditions that may affect your treatment;
- Medical data including laboratory test results, health status (blood pressure, activity status, smoking status, etc.) tumor measurements, imaging scans (CT or Cat scan, MRI), x-rays, and pathology results;
- Information on side effects (adverse events) you may experience, and how these were treated;
- Long-term information about your general health status and the status of your disease;
- Information that will identify you for the study, such as your date of birth, sex, age, and other medical history

You may request a blank copy of the forms that will be used to collect your study data, from the study doctor or his/her research staff to learn what information will be shared.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Dr. Melinda Telli
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration

- The drug supplier, Pfizer, Inc.
- Government agencies as authorized or required by law;
- Other auditors sent for review of research at the site by any of the persons listed above.

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2025 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Print name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____ _____
Print Name of LAR Authority to Act for Participant
(e.g., parent, guardian or conservator)

FINANCIAL CONSIDERATIONS

Payment

You may be eligible for travel and meal reimbursement if you live more than 50 miles from study site. Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa.

Costs

If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the study visits.

The study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. If you would like to review the list of such covered services, supplies, procedures and care, please tell us now or at any time during the study.

Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. **You will be responsible for any co-payments and/or deductibles as required by your insurance.**

The drug company, Pfizer, Inc., which supplies the study drug, will provide the study drug free of charge to all study participants. All other drugs will not be supplied and will be billed to your insurance company. Your doctor will answer any questions you may have.

Sponsor

This is an investigator-initiated clinical trial led by Dr. Melinda Telli. The study will be conducted at the Stanford Women's Cancer Center. The study is financially supported by Pfizer, Inc., which is providing the study drug, talazoparib. The National Institutes of Health are providing some financial support for the facility and staff where part or all of the study is taking place.

Consultative or Financial Relationships

Dr Melinda Telli is a paid advisor to Pfizer, the company sponsoring this study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for

all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Melinda Telli. You may contact her now or later at [redacted].

Injury Notification: You should also contact her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

WHERE CAN I GET MORE INFORMATION?

You will get a copy of this form. You may talk to your study doctor at any time regarding your participation in the study or your treatment. More information on cancer clinical trials may be available from your study doctor, and can be found through resources like the National Cancer Institute (1-800-4-CANCER) or http://www.cancer.gov/clinicaltrials.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;

- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you? ____ Yes ____ No

Signing your name means you agree to be in this study and that you were given a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness Date

_____
Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.
- The English consent form (referred to as the "Summary Form" in the regulations):
  - Must be signed by the witness AND the Person Obtaining Consent (POC).
  - The non-English speaking participant/LAR does not sign the English consent.
  - The non-English speaking participant/LAR should not sign the HIPAA participant line
  - If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.