PRINCIPAL INVESTIGATOR: Christine Alewine, M.D., Ph.D.

STUDY TITLE: Phase II Study of Olaparib in Subjects with Advanced Pancreatic Acinar Cell Carcinoma

STUDY SITE: NIH Clinical Center

Cohort: *Affected Participant*

Consent Version: *1/14/2025*

WHO DO YOU CONTACT ABOUT THIS STUDY?

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KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research at the NIH is your choice.

You are being asked to take part in this study because you have Pancreatic Acinar Cell Carcinoma (PACC).

The purpose of this study is to is see if using olaparib may be a better way to treat your cancer. Olaparib has been tested in humans with several different types of cancers and is FDA approved for the treatment of metastatic prostate, breast, and pancreatic cancers and advanced ovarian cancer.

The use of olaparib in this study is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA) to treat PACC. However, the use of olaparib is approved to treat other cancers (breast, ovaries, pancreas, and prostate).

There may be other drugs that may be used to treat your disease, and these can be prescribed/given by your regular cancer doctor, even if you are not in this study. The way in which the study drug is given in this study and the side effects are not significantly different than if you were to receive standard care therapy.

If you decide to join this study, here are some of the most important things that you should know that will happen:

- We will first do some basic tests to make sure you qualify for the trial. This is called "screening." The tests that we will do include: physical exams, blood and urine tests, imaging, and tests to look at your heart function. We will also confirm your diagnosis. If you do not qualify, we will remove you from the study.

- If eligible to take part, you will take olaparib by mouth twice a day for 28 consecutive days each cycle. Each cycle is 28 days. There is no interruption between cycles. You may continue receiving the study drug for two years or as long as your disease does not get worse or you do not have serious side effects.
- You may experience side effects from taking part in this study. Some can be mild or very serious, temporary, long-lasting, or permanent, and may include death. Examples of some of the side effects that you may have include low blood counts which could affect your ability to fight infection, diarrhea, fatigue, and nausea. Other side effects are described further on in this consent form. It is important that you read these.
- We will see you during the study. You will have clinical, laboratory, and imaging tests to see how you are doing and to assess your disease. We will also collect required samples from you (such as blood and tissue) for both clinical and research purposes.
- If you can become pregnant or you are a sexually active person with a partner capable of becoming pregnant, you and your partner must agree to use birth control before initiating the study, during the study. If you can become pregnant, you must continue this birth control for 6 months after the last dose of study drug. If you are an individual able to father a child, you must continue this birth control for 3 months after the last dose of study drug.
- After you finish taking the study drug, we will contact you every 90 days by phone or email for up to one year to collect clinical data and ask about any other cancer therapies you may have started and about your survival status.

Just as we do not know what side effects you might have, we cannot know if you may benefit from taking part in this study. If you do not benefit, this study and the results from our research may help others in the future.

You are free to stop participating in the trial at any time. If you decide to stop, the study doctor may ask you to agree to certain tests to make sure it is safe for you to stop.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to see if olaparib is an effective treatment for PACC.

We are asking you to join this research study because you have been diagnosed with PACC and your cancer did not respond to previous therapies or is ineligible for surgery.

Olaparib is a tablet taken by mouth (orally). It belongs to a group of medicines called PARP inhibitors. The effects of drugs in this class include preventing cancer cell growth. The effects of olaparib on cancer cells may also be beneficial in PACC, as it acts against some of the factors that are thought to be important in the development and growth of PACC.

The use of olaparib in this study is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA) to treat PACC. However, the use of olaparib is approved to treat other cancers (breast, ovaries, pancreas, and prostate).

WHAT WILL HAPPEN DURING THE STUDY?

Before you begin the study – Screening

Before you begin the study, you will have several tests performed to check whether the study is suitable for you. This is called screening. Your doctor will review your medical history and the drugs that you are currently taking as well as the previous treatments you received for your disease to determine whether you can participate in this study.

Some of these tests or procedures are part of regular care and may be done even if you are not being considered to join the study. Most tests must be performed within 28 days before the start of treatment. If you have had some of these tests or procedures recently, they may or may not have to be repeated. Briefly, these tests include:

- Confirmation of diagnosis (You must provide a sample tumor tissue for formal evaluation by the NCI Laboratory of Pathology. The tissue may be from a previous surgery or biopsy. If none is available, we will ask you to have a biopsy to provide a fresh sample).
- Medical history and physical examination including weight and height and vital signs. If you have medical records from another clinic or hospital, we will ask you to get copies of these records, or your study doctor may be able to request them on your behalf.
- Performance status: an evaluation of your ability to perform everyday activities
- Routine blood and urine tests to check for blood counts, organ function, and for signs of infection.
- Pregnancy test if you can become pregnant. Pregnant participants will not be allowed on study.
- Computerized Tomography (CT) Scans
- Electrocardiogram (ECG) to check your heart function.
- As part of this study, we will test you for infection with HIV, the virus that causes AIDS. If you are infected with HIV, you will not be able to take part in this study. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report HIV infections, and the importance of informing your partners at possible risk because of your HIV infection.

During the study - Study Drug

If the screening process showed that you are eligible to participate in the study, and if you choose to join, you may need to have a few additional standard tests completed if not done recently. You will also have additional samples collected for research tests. If any of the screening tests need to be repeated, and show that you have become ineligible, you will not be able to continue with this study.

If you decide to take part in the study, we will ask you to:

- Receive study drug at the NIH Clinical Center and be seen regularly in the clinic, to have tests and procedures during and after the study drug in follow-up to see how you are doing and to assess your disease.
- Provide specimens (such as blood, tumor, and normal tissue) for research studies.

Once it is decided that you are eligible to participate for this study, you will begin taking the study drug. The study is divided up into segments of time called "cycles". For this study, a cycle will be 28 days. You will take olaparib by mouth twice daily for 28 consecutive days for each cycle. There is no interruption between cycles. The capsule must be swallowed whole with one cup of water and should not be chewed. You should take olaparib at approximately the same time every day. You can have a light meal/snack with your dose. If you forget to take olaparib, you will not take the missed dose if it is more than 2 hours late.

Before you start taking any new medicines, including medicines you can buy 'over-the-counter', please talk to the study doctor to make sure they are allowed on this study. In addition, while you take olaparib, you cannot drink grapefruit juice or eat grapefruit. We may ask you to keep a diary of the medicine that you are taking during the study. We may be reviewing this diary with you during your visits to the clinic, so, if you have it, please bring it to every visit.

At each clinic visit at the NIH Clinical Center, please bring your completed medication diary (if you have it) and all of your capsule containers (whether they are empty or not) as we will be counting the capsules and reviewing your diary pages as part of the safety evaluation for this study.

If you have certain side effects, we may reduce the dose of olaparib to prevent return of the side effect. If the side effect(s) is/are too severe, you may need to stop taking olaparib.

You may continue receiving olaparib for up to 2 years or as long as your disease does not get worse and you do not have serious side effects, or you decide to stop receiving the study drug.

While you are taking study medication, we will perform some tests and examinations for safety and to test the effect of the study drug. We will also collect samples from you for purposes of research only. We will see you in clinic at the NIH Clinical Center at least once during the first cycle, then at the beginning of each cycle after. If needed, we may ask you to come to clinic more often. If you are unable to travel to the NIH Clinical Center, you can complete the required evaluations with your local medical provider.

The assessments and tests to be done at every visit include:

- Physical exams and measures of your vital signs. Also, we will ask you about any changes in medications that you are taking and changes in how you are feeling to check for potential side effects.
- Pregnancy test if you can become pregnant.
- Routine blood and urine tests
- Blood for tumor markers
- Imaging with CT scans every 8 weeks beginning from cycle 2. The study team will use these scans to see if the study drug is helping your cancer. Your doctor will discuss other imaging to be done if felt to be better to assess your disease.

ADDITIONAL RESEARCH TESTING

In addition to the tests that we will conduct to determine whether you are having side effects or if you are responding to the study drug, during the course of the study we will also collect samples from you for purposes of research only. The samples are being collected to look at the effects of the study drug on markers of tumor activity.

The samples included for these studies include:

- Blood (before you start the first cycle of study drug)
- Tumor tissue collection – optional:
    - Archival tumor sample: This may be tissue from a prior biopsy or procedure within the last 90 days, after any prior treatment. The study team will contact the facility where the procedure was done to request the tumor tissue if not done at the NIH.
    - Core needle biopsy: A piece of your tumor (biopsy) is obtained using a needle through the skin into your tumor. A CT scan may be used to assist the biopsy tumor tissue collection. We will give you a sedative prior to the biopsy. Conscious sedation is usually given to help someone relax and minimize discomfort. It can be given as a pill, a shot, an IV or even inhaled. You may have to wait up to an hour to start feel the effects depending on how it is given. Once it takes effect, you will be mostly awake, though relaxed or drowsy. We will monitor you throughout the procedure. Also, you may receive a local anesthesia before undergoing a biopsy, if needed. Local anesthesia is given to minimize discomfort. We will inform you of the additional risks prior to undergoing the procedure. We will ask you to sign a separate procedure consent form prior to each biopsy. We may collect your tumor biopsy before you start taking the study drug, once while you are taking the study drug and when you finish taking the study drug. You can refuse to have these biopsies performed for research purposes only and be in this study anyway.

We also plan to grow your cells from the tissue biopsy in the lab and in mice. Establishing laboratory cell lines allows your cells to be studied without needing to collect new samples. There are no plans to provide financial compensation to you should research using samples you provided lead to a patented or licensed product.

The tissue samples collected for research purposes on this study (such as the tumor and normal tissue) may be used to look for specific changes in the DNA in tumors that could be used to develop new ways of diagnosing and treating cancer. DNA (also called deoxyribonucleic acid) in the cells carries genetic information and passes it from one generation of cells to the next – like an instruction manual. Normal tissue contains the DNA (instructions) that you were born with, DNA in tumor cells has changed – or mutated – and we think that change in the DNA is what causes tumors to form and to grow.

To look at your DNA, we may use do what is called "whole genome sequencing." This where we will do special tests in the lab to look at the entire sequence, or order, of how your DNA is put together. This is what makes you unique.

To determine which parts of the DNA have mutated, we will compare the DNA in your tumor cells to DNA from your normal cells. We will then analyze the results from similar tumors to see if there are any changes in the DNA that are common to a particular type of tumor. To examine the tumor and normal tissue we may use several different techniques depending on the type of tissue we collect. These could include growing cell lines (cells which keep dividing and growing in the laboratory, sometimes for years allowing us to continually study those cells), xenograft studies (placing or growing cells in another animal, such as mice), and looking in detail at the parts of the genes that produce specific proteins.

However, you should know that the analyses that we perform in our laboratory are for research purposes only; they are not nearly as sensitive as the tests that are performed in a clinical laboratory that is certified to perform genetic testing or testing for routine patient care. For these reasons, we will not give you the results of the research tests done on your research samples in most cases. There may be exceptions to what we share with you and this is described later in this consent form in the section for "Return of research results."

WHEN YOU ARE FINISHED TAKING THE DRUGS

End of Treatment Visit

If you need to stop taking the study drug for any reason (including that your disease has started to grow while you are receiving the study drug), then we will ask you to return to the NIH approximately 2-4 weeks after you have had last dose of study drug or before you begin a new anti-cancer treatment for an end of treatment visit.

The visit will include the following clinical tests:

- Medical history and physical exam
- Routine blood tests
- Pregnancy test if you can become pregnant
- Blood for tumor markers
- Tissue biopsy (optional)

If you are unable to return to NIH for this visit, we may contact you or your local physician to collect clinical data and ask for your symptoms.

Safety visit

We will ask you to return to the study center 30 days after you finish taking the study drug or before you begin a new anti-cancer treatment for a safety visit.

At this visit, the study doctor/study team will do the following clinical evaluations:

- Medical history
- Pregnancy test if you can become pregnant
- Review of contraception
- Review of current medications

Long Term Follow-Up

We will contact you every three months by phone for 1 year to check on your disease status and to see how you are feeling and to see if you have started any new treatments.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last up to three years or until your cancer worsens, you have unacceptable side effects, you decide to no longer take part in the study, or your study doctor decides it is no longer suitable for you to continue.

We will see you several times during the study. The outpatient visits during the study and after you finish taking the study drug usually take about 3 hours but should not take longer than 8 hours.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have about 15 people participate in this study at the NIH.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

If you choose to take part in this study, you are at risk for 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, and some may never go away. It is also possible that you may experience more than one side effect at the same time. Some side effects may be mild. Other side effects may be very serious and even result in death.

Olaparib interacts with many drugs which can cause side effects and must be used very carefully with other medicines that need certain liver enzymes and transport proteins to be effective or to be cleared from your system. Before you enroll onto the clinical trial, your study doctor will review any medicines and herbal supplements that are capable of increasing or decreasing the clearance of the study drug in your body. Over-the-counter drugs (including herbal supplements) may contain ingredients that could interact with your study drug as well.

Risks and Possible Side Effects of Olaparib

- Reduction of numbers of blood cells potentially resulting in:
    - Decreased ability of the immune system to fight infection which could lead to hospitalization for serious, life-threatening infection or death.

  - Decreased ability to clot blood
  - Anemia (decrease in the number of red blood cells)
- Changes in your digestion or activity of your stomach and/ or bowels causing:
  - Nausea or vomiting
  - Indigestion
  - Diarrhea or constipation
  - Bloating
  - Decreased appetite
- Fatigue and tiredness
- Abdominal and stomach pain
- Stomatitis (sore or inflammation inside of the mouth)
- Joint or muscular pain
- Altered sense of taste
- Headache
- Skin rash
- Skin irritation (dermatitis)
- Erythema nodosum (skin inflammation)
- Cough and upper respiratory tract infection
- Difficulty breathing
- Back pain
- Urinary tract infection
- Dizziness
- Swelling
- Kidney problems (increase in blood creatinine)
- Fever
- Cold
- Difficulty sleeping (insomnia)
- Hand or foot pain
- Muscle cramps
- Muscle pain
- Inflammation of your lung tissues (pneumonitis)
- Myelodysplastic syndrome (a type of cancer in which the bone marrow does not make enough healthy blood cells and there are abnormal cells in the blood and/or bone marrow)
- Leukemia (bone marrow cancer)
- Venous thromboembolism (blood clot in a vein with possible pain, swelling, and/or redness)

RISKS FROM STUDY RESEARCH PROCEDURES

The following study procedures may have risks and cause discomfort while you participate on this study:

Blood draws

Risks include temporary discomfort, pain, redness, bleeding, bruising, and swelling at the site where the needle is inserted, and/or very rarely inflammation/infection of the vein, which could require antibiotics. You may also experience dizziness, nausea, or rarely, fainting during blood taking. Please tell the study doctor if you do not feel well after having your blood drawn. Up to 3 ½ tablespoons of blood may be collected at any visit but no more than 8 ½ tablespoons in any 8-week period.

Urine collection

There is no risk related to urine collection.

Conscious sedation

The most common risks of conscious sedation last up to a few hours after being given can include drowsiness, feeling slow or sluggish, low blood pressure, headache, and nausea.

Local anesthesia

Biopsies may be done under local anesthesia. Potential side effects include drowsiness, headaches, blurred vision, twitching muscles or shivering, continuing numbness, weakness, or pins and needles sensation. These side effects usually go away quickly.

Tumor biopsies (optional)

There may be some temporary pain or discomfort during the procedure and afterwards in the area where the tissue was removed. You may also experience some bruising around the biopsy site over the following days. In rare cases an infection or bleeding may occur.

Imaging

In addition to the radiation risks discussed below, CT scans may include the risks of an allergic reaction to the contrast. Participants might experience hives, itching, headache, difficulty breathing, increased heartrate and swelling.

What are the risks related to pregnancy?

If you can become pregnant, we will ask you to have a pregnancy test before starting this study. You must use effective birth control methods and try not to become pregnant while participating in this study and for 6 months after you finish taking the study drug. We will provide you with a list of all acceptable forms of birth control methods. If you become pregnant, there may be unknown risks to the fetus or unborn child, or risks that we did not anticipate. There may be long-term effects of the study drug being studied that could increase the risk of harm to a fetus. You must tell the study doctor if your birth control method fails while you are in the study. If you think or know you have become pregnant while participating in this research study, please contact the study team as soon as possible. If you plan to become pregnant in the future, please discuss with the study team how long you need to wait before becoming pregnant after completing the study.

If you are a sexually active person with a partner able to become pregnant, it is important that your partner not become pregnant while you are taking the study drug, and for 3 months after you finish taking the study drug. There may be unknown risks to a fetus or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you think your partner has become pregnant during your participation in this study, please contact the study team as soon as possible. If you and your partner plan for your partner to become pregnant after your participation in this study, please discuss this with the study team.

What are the risks of radiation from being in the study?

During your participation in this research study, you may be exposed to radiation from up to 4 CT guided biopsies, and up to 8 CT scans. The amount of radiation exposure from these procedures is equal to approximately 13.6 rem. A rem is a unit of absorbed radiation.

Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. The average person in the United States receives a radiation exposure of 0.3 rem per year from these sources. This type of radiation is called "background radiation." No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The CT guided biopsies and CT scans that you get in this study will expose you to the roughly the same amount of radiation as 45.3 years' worth of background radiation. Being exposed to too much radiation can cause harmful side effects such as an increase in the risk of cancer. The risk depends on how much radiation you are exposed to. Please be aware that about 40 out of 100 people (40%) will get cancer during their lifetime, and 20 out of 100 (20%) will die from cancer. The risk of getting cancer from the radiation exposure in this study is 1.4 out of 100 (1.4%) and of getting a fatal cancer is 0.7 out of 100 (0.7%).

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study. However, the potential benefit to you might be shrinking of your tumor or lessening of your symptoms, such as pain, that are caused by the cancer.

Are there any potential benefits to others that might result from the study?

In the future, other people might benefit from this study because of the knowledge gained from this therapeutic intervention.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether or not to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could

- choose to be treated with surgery, radiation or with drugs already approved by the FDA for your disease
- choose to take part in a different study, if one is available
- choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

When we are examining your DNA, it is possible that we could identify possible changes in other parts of your DNA that are not related to this research. These are known as "incidental medical findings".

These include:

- Changes in genes that are related to diseases other than cancer
- Changes in genes that are not known to cause any disease. These are known as normal variations.
- Changes in genes that are new and of uncertain clinical importance. This means that we do not know if they could cause or contribute to a disease or if they are normal variations.

Since the analyses that we perform in our laboratory are not nearly as sensitive as the tests that are performed in a laboratory that is certified to perform genetic testing, the genetic changes that we find may or may not be valid. Therefore, we do not plan to inform you of all of the genetic results of testing on your tissue and blood that is performed in our research lab. However, in the unlikely event that we discover a finding believed to be clinically important based on medical standards at the time we first analyze your results, we will contact you. This could be many years in the future. We will ask you to have an additional sample to verify the findings we have seen in our lab. If the results are verified, we will re-contact you and we will offer you a referral to a genetic healthcare provider to discuss the results.

RISKS OF RETURNING INCIDENTAL GENETIC FINDINGS

- The evaluation for unexpected gene changes is limited. It may not be as complete as clinical genetic testing you might be able to get outside of the research study.
- If an unexpected gene change is confirmed, then that test result will go into your NIH medical record. These documents are confidential, but other NIH investigators can see them.
- Learning about the changes in your genes could mean something about your family members and might cause you or your family distress. Before joining the study, it may be helpful to talk with your family members about whether they want you to share your results with them.
- If a gene change is found, it may reveal whether a particular parent passed on the change to a biological child.

- We may tell you about an unexpected gene change that turns out not to cause the health condition we think it does. This may cause you unnecessary distress or lead to unnecessary medical testing risks and costs

EARLY WITHDRAWAL FROM THE STUDY

Your doctor may decide that you stop taking the study drug for the following reasons:

- if he/she believes that it is in your best interest
- if your disease worsens or comes back while you are taking the study drug
- if you have side effects from the study drug that your doctor thinks are too severe
- if you become pregnant
- if olaparib may become unavailable
- if new information shows that another treatment would be better for you
- if you do not follow the study rules
- if the study is stopped for any reason

In this case, we will inform you of the reasons the study drug is being stopped.

After you stop taking the study drug, we would like to see you for an end of treatment visit 14-30 days after your last dose or before the beginning of a new anti-cancer treatment.

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. However, according to FDA guidelines, information collected on you up to that point may still be provided to Astra Zeneca or designated representatives.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

Will your specimens or data be saved for use in other research studies?

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding PACC, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my coded specimens and data to be stored and used for future research as described above.

_____ Yes _____ No

Initials Initials

Will your specimens or data be shared for use in other research studies?

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas that are similar to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded specimens and data to be shared with other researchers and used by these researchers for future research as described above.

_____ Yes _____ No

Initials Initials

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. Usually, these researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

Will your genomic data be shared outside of this study?

As part of this research study, we will put your genomic data in a large database for broad sharing with the research community. These databases are commonly called data repositories. The information in this database will include but is not limited to genetic information, race and ethnicity, and sex. If your individual data are placed in one of these repositories, they will be labeled with a code and not with your name or other information that could be used to easily identify you, and only qualified researchers will be able to access them. These researchers must receive prior approval from individuals or committees with authority to determine whether these researchers can access the data.

NIH policies require that genomic data be placed in a repository for sharing. Therefore, we cannot offer you a choice of whether your data will be shared. If you do not wish to have your data placed in a repository, you should not enroll in this study.

How long will your specimens and data be stored by the NIH?

Your specimens and data may be stored by the NIH indefinitely.

Risks of storage and sharing of specimens and data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

PAYMENT

Will you receive any type of payment for taking part in this study?

You will not receive any payment for taking part in this study.

REIMBURSEMENT

Will you receive reimbursement or direct payment by NIH as part of your participation?

On this study, the NCI will reimburse the cost for some of your expenses such as those for hotel, travel, meals. Some of these costs may be paid directly by the NIH and some may be reimbursed after you have paid. The amount and form of these payments are determined by the NCI Travel and Lodging Reimbursement Policy. You will be given a summary of the policy which provides more information.

If your travel to the NIH Clinical Center (e.g., flight, hotel) is arranged and paid for by the NIH, the agency making the reservations and their representatives will have access to your identifiable information.

COSTS

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

- If some tests and procedures are performed outside the NIH Clinical Center, you may have to pay for these costs.

CONFLICT OF INTEREST (COI)

The NIH reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

The NIH and the research team for this study are using olaparib developed by Astra Zeneca through a collaboration between your study team and the company. The company also provides financial support for this study.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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 PROTECTIONS PROVIDED IN THIS STUDY

Some of your health information, and/or 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. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. Your 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. However, the researchers will do their best to make sure that any information that is released will not identify you.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- The study Sponsor, Center for Cancer Research, or their agent(s)

- Qualified representatives from Astra Zeneca, the pharmaceutical company who produces olaparib.

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain

federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Christine Alewine, christine.alewine@nih.gov at 240-276-6146. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness should sign below if either:

1. **A short form consent process has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

Signature of Witness	Print Name of Witness	Date

NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.