SUMMARY OF CHANGES -- Consent

NCI Protocol #: 10222
Local Protocol #: 2000027026
Protocol Version Date: April 4, 2025

Protocol Title: A Phase II study of olaparib and AZD6738 in isocitrate dehydrogenase (IDH) mutant solid tumors

Informed Consent Version Date: April 4, 2025

I. Revisions requested in CTEP Request for Rapid Amendment (RRA) dated April 3, 2025:

#	Section	Comments
1.	All	Updated Version Date in Footer

2.	Drug Risks	The condensed risk profile for AZD6738 (CAEPR Version 2.1, February 27, 2025) has been modified as requested in the CTEP Request for Rapid Amendment (RRA) dated April 3, 2025 as follows:
		
		• Added New Risk:
		  • Occasional: Headache
		  • Rare And Serious: Cancer of bone marrow caused by chemotherapy; Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions
		
		• Increase in Risk Attribution:
		  • Changed to Common from Occasional: Vomiting
		  • Changed to Occasional from Also Reported on AZD6738 Trials But With Insufficient Evidence for Attribution (i.e Added to the Risk Profile): Swelling of arms, legs; Flu-like symptoms including fever, chills, body aches, muscle pain; Weight loss
		
		• Decrease in Risk Attribution:
		  • Changed to Also Reported on AZD6738 Trials But With Insufficient Evidence for Attribution (i.e Removed from the Risk Profile) from Occasional: Pain; Dizziness

Research Study Informed Consent Document

Study Title for Participants: Testing olaparib and AZD6738 in IDH1 and IDH2 mutant tumors

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
NCI #10222, A Phase II study of olaparib and AZD6738 in isocitrate dehydrogenase (IDH) mutant solid tumors (NCT03878095)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have advanced cancer and because your tumor has a change in a gene called IDH1 or IDH2.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to answer the following question:

Can we lower the chance of your cancer growing or spreading by combining two drugs, olaparib and AZD6738?

We are doing this study because we want to find out if this approach is better or worse than the usual approach for your advanced cancer. The usual approach is defined as care most people get for their particular kind of advanced cancer.

Both Olaparib and AZD6738 are experimental and have not been approved by the FDA for your advanced cancer. Olaparib and AZD6738 work by making it harder for damaged DNA in cancer cells to repair itself, which can cause cancer cells to die.

What is the usual approach to my cancer?

To date, there is no standard Food and Drug Administration (FDA) approved treatment that is specific for people with this kind of abnormality in the tumor. People who are not in a study are usually treated with standard chemotherapy, immunotherapy, targeted therapies, surgery or radiation.

These treatments may reduce your symptoms and slow down the growth of your tumor, but they are not curative.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for cancer.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will receive the olaparib and AZD6738 until your cancer grows, or you develop side effects that cannot be managed with supportive care, or you withdraw your consent from the study. The study doctors will want also to follow you up for 30 days, to make sure that if you have any side effects from the drug, they can be diagnosed and treated. Unless you withdraw your consent from the study, the doctors will also follow up with you to have information about your health and the treatments you may start after the end of the study.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

If you choose to take part in this study, there is a risk that the study drugs may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer.

There is also a risk that you could have side effects from the study drugs. These side effects may be worse and may be different than you would get with the usual approach for your cancer.

Some of the most common side effects that the study doctors know about are:

- Anemia which may require blood transfusion
- Diarrhea, nausea, vomiting
- Tiredness
- Loss of appetite

Some uncommon, but serious side effects that the study doctors know about are:

- Cancer of bone marrow caused by chemotherapy
- Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions

Benefits

It is unlikely that the study treatment will work in everyone with your cancer or help you live longer. This study may help the study doctors gain information that may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study 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.
Your 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.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor. The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to test the good and bad effects of the drugs **olaparib** and **AZD6738** in patients whose tumor has an abnormal gene called IDH1 or IDH2. **Olaparib** and **AZD6738** could shrink your cancer, but they could also cause side effects, which are described in the risks section below. The study doctors hope to learn if the study drug will shrink the cancer by at least one quarter compared to its present size.

Olaparib has already been approved by the FDA to treat other cancers.

We don't know if **AZD6738** works to treat cancer in people, but it has shrunk several types of tumors in animals.

There will be about 50 people taking part in this study.

What are the study groups?

All study participants will get the same study drugs. It will only include the study drugs olaparib and AZD6738.

Olaparib is a tablet that you can take by mouth every day. You will receive a new supply on the first day of each cycle of treatment with olaparib. Every cycle will be 28 days long.
You will take olaparib by mouth twice every day. You should take these tablets at the same time each day, approximately 12 hours apart with one glass of water. The olaparib tablets should be swallowed whole and not chewed, crushed, dissolved or divided.

You will take AZD6738 by mouth once a day on days 1 through 7 of a 28-day cycle. You should take these tablets at the same time each day with one glass of water. The AZD6738 tablets should be swallowed whole and not chewed, crushed, dissolved or divided. You may take AZD6738 with your olaparib tablet. Do not eat anything 2 hours before you take your AZD6738 and 1 hour after you take your AZD6738.

If vomiting occurs shortly after the olaparib or AZD6738 tablets are swallowed, you can take another dose only if you can see and count all the intact tablets. Should you miss a scheduled dose for whatever reason (e.g., because of forgetting to take the tablets or vomiting), you can take that dose up to a maximum of 2 hours after that scheduled dose time. If greater than 2 hours after the scheduled dose time, you must not take the missed dose and you should take the drug only at the next scheduled time.

You will be given a Study Drug Diary that you will have to maintain and update during each cycle. You will have to bring it to each visit along with the tablet bottle and any remaining study

drug. You also will be given a drug information handout and wallet card for yourself, caregivers and other health care providers. This card will tell you about the drugs you should avoid and it will have the name and the contact informations of your study doctor. Also, please, avoid grapefruit juice and St. John's Wort, since they could affect the way your body handles olaparib and/or AZD6738.

What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. There is also a tumor screening step that comes first.

If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Tumor screening:
In order for you to participate to this trial, we must confirm the presence of IDH1/2 abnormality in your tumor based on testing that has already been done with small pieces of your tumors that were removed in the past with surgery or biopsies. We will use the report from this testing to make sure that you have the IDH1/2 genetic change in the tumor.

Before you begin the study:
You will need to have the following extra tests and procedures to find out if you can be in the study:

- Pregnancy test (if appropriate)
- Blood tests
- ECG (electrocardiogram) to test the electrical activity of your heart
- Urine sample
- Radiology testing to measure tumor size (for example a CT scan or MRI scan)

Extra exams, tests, and procedures on the study:
If the exams, tests, and procedures above show that you can take part in the study, and you choose to take part, then you will need the following extra exams, tests, and procedures. They are not part of the usual approach for your type of cancer.

- 2 tumor biopsies: the first prior to receiving the study drug and the second at week 4. See About Tumor Biopsies below.
- Blood samples every 8 weeks until completion of the eighth cycle and at the end of the study
- If available, we will collect some of your old tissue (called archival tissue) from the time your cancer was first diagnosed. This tissue will not be returned to you.

This study will use genetic tests that may identify changes in the genes in your DNA. Your genes carry information about you and your family, from the color of your eyes to health conditions for which you may be at risk, such as certain kinds of cancer.

Finding these changes would not affect your treatment in this study. However, they could affect your health in other ways. If the changes in your genes were inherited, the changes could also affect the health of your family members.
You and your family may want to know about any genetic test findings that may be important to your health. You may use this form to grant us permission in advance to give this information to your doctor. If a genetic test result about you seems to be medically important and you have granted us permission to contact you, the following steps will occur:
1. Researchers will study the result further to decide if it may be medically important to you or your relatives.
2. The research laboratory that performed the genetic test will contact your doctor about the finding. The research laboratory, which will not have any identifying information about you, will provide your doctor with a code number assigned to your genetic test sample.
3. Your doctor will use the code number to identify you, and will then contact you about the medically important finding. Your doctor may make try to contact you several times.
4. You will require another genetic test to confirm the results. Your insurance may pay for this test, but it is possible that you may have to pay for it.
5. If it is confirmed that there are changes found that could cause health problems, then your doctor will discuss your options with you. We strongly suggest that you also talk to a genetic counselor. Your insurance may pay for genetic counseling, but it is possible that you may have to pay for it.

It is more likely, however, that you will not be contacted by us about a medically important finding. Even if we do not contact you, it does not mean that your genes do not contain changes that are important to your health. Researchers are always learning about new and medically important changes in genes and some information may be learned in the future. Researchers will only decide to contact you about genetic test results at the time your DNA is initially sequenced. You will not be contacted or consented for any research done using your samples in the future, and you will not receive any reports or information about any medically important findings learned in the future. Also, sometimes the meaning of genetic test results can be uncertain, and we may not know for sure what the results mean for your future health. Sharing an uncertain genetic test result with you could offer little benefit, no benefit at all, or could even be harmful.

Results from genetic testing will not be a part of your medical records, unless the results are confirmed by additional testing that you agreed to. See “Who will see my medical information?” for laws and risks in protecting your genetic information.

About Tumor Biopsies

If you participate on this trial, we will ask you to have 1 biopsy of your cancer before you start treatment and another after 4 weeks of treatment. Although we encourage you to have these biopsies so we can learn more about your cancer and how it interacts with the study drugs, you may opt out by discussing your preference with your doctor. Only a limited number of patients may opt out of biopsies on this trial, so it is possible that you may not be able to participate if you do not agree to having these biopsies.

- For all biopsies your doctor will verify that your tumor is easily accessible for biopsy and will look for the safest way to have these biopsies done. Very often the biopsy is guided by imaging (e.g. CT scan, echo).
- Your doctor will explain to you the possible complications of this procedure and will answer your questions. If the tumor is no longer accessible for a biopsy while you are on the study you will be able to continue the study drug.

The first biopsy helps us learn about how your cancer repairs damaged DNA. The second biopsy performed after you have been on treatment for 1 month will give us information about whether the characteristics of your tumor have changed since the beginning of the therapy.

You will sign a separate consent form before each biopsy is taken. This will be a standard surgical consent form from the institution where the biopsy procedure takes place. If the tumor site is no longer accessible, you will be able to continue the study drug.

As we will discuss in a specific section on the optional studies, this study also involve the possibility to store any of the specimen left over for biobanking.

Extra blood tests: We will also do extra blood withdrawal at the beginning of cycles 2, 4, and 8 and at the end of treatment. These are called liquid biopsies. The researchers will use these blood tests to look for information on your tumor that may help guide therapy for future patients.

A study calendar that shows how often these exams, tests and procedures will be done is attached.

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

General Risks

If you choose to take part in this study, there is a risk that the olaparib and AZD6738 may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer.

You also may have the following inconveniences:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The olaparib and AZD6738 used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. Your study doctor will talk to you about what types of birth control or pregnancy prevention to use during the study. Women should use birth control or pregnancy prevention for 6 months after you have completed the study, and men should use pregnancy prevention (for example, condoms) for 6 months after you have completed the study.

This study will use a sample of your tissue. Generally, your hospital will keep some of your tissue. This tissue may be used to help treat your cancer in the future. Because this study will need to use some of this tissue, there is a small risk that it could be used up.

Genetic Testing Risks

As part of this study, we are also studying a genetic test. The test is designed to find out if your tumor has the genetic changes that are needed for this study. If it does, you will be allowed to participate in the study.

Because this genetic test is still being studied, there is a risk that the test results may be wrong. If the test results are wrong, you may be included in this study even though it may not offer the best treatment option for you. Or, you may not be included in this study even though it may offer a good treatment option for you.

Biopsy Risks

Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, bruising, and pain at the biopsy site. Pain can be treated with regular pain medications. Rarely, an infection can occur.

Blood Draw Risks
Common side effects of having your blood drawn include pressure or pain from the needle, soreness or tenderness at the needle insertion site, local pain, swelling, or redness, bruising, and bleeding. Rarely, an infection can occur.

Side Effect Risks

The **olaparib** and **AZD6738** 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.

There is also a risk that you could have side effects from the study procedures.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

Drug Risks

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

Possible Side Effects for Olaparib (CAEPR Version 2.6, June 5, 2023)

COMMON, SOME MAY BE SERIOUS In 100 people receiving olaparib (AZD2281), more than 20 and up to 100 may have:
• Anemia which may require blood transfusion • Pain • Diarrhea, nausea, vomiting • Tiredness • Loss of appetite

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving olaparib (AZD2281), from 4 to 20 may have:
• Bloating, constipation, heartburn • Sores in the mouth which may cause difficulty swallowing • Swelling of arms, legs • Cold symptoms such as stuffy nose, sneezing, sore throat • Infection which may cause painful and frequent urination • Infection, especially when white blood cell count is low • Dizziness, headache • Changes in taste • Cough, shortness of breath • Rash

RARE, AND SERIOUS In 100 people receiving olaparib (AZD2281), 3 or fewer may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Bruising, bleeding • Cancer of bone marrow caused by chemotherapy • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions • Damage to lungs which may cause shortness of breath • Blood clot

Possible Side Effects for AZD6738 (CAEPR Version 2.1, February 27, 2025)

COMMON, SOME MAY BE SERIOUS In 100 people receiving AZD6738 (ceralasertib), more than 20 and up to 100 may have:
• Anemia which may require blood transfusion • Nausea, vomiting • Tiredness • Bruising, bleeding • Loss of appetite

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving AZD6738 (ceralasertib), from 4 to 20 may have:
• Constipation, diarrhea, heartburn • Swelling of arms, legs • Flu-like symptoms including fever, chills, body aches, muscle pain • Infection, especially when white blood cell count is low • Weight loss • Headache • Shortness of breath • Rash

RARE, AND SERIOUS In 100 people receiving AZD6738 (ceralasertib), 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

There may be some risks that the study doctors do not yet know about.

Photosensitivity

AZD6738 may cause photosensitivity, an extreme sensitivity to ultraviolet (UV) rays from the sun and other light sources. Sun-sensitive or photosensitive drugs are drugs that cause a moderate to severe skin reaction that is similar to a bad sunburn when exposed to the sun (UV rays), usually the forehead, nose, hands, arms, and lips. Many common medications cause this reaction in some people.

Symptoms of sun sensitivity are similar to those of a sunburn and may include:

- A stinging and burning sensation
- Rash
- Redness
- Pain
- Blisters

- Inflammation and swelling
- Itching
- Darkening of the skin

Usually, the allergic reaction appears within 24 hours of sun exposure and resolves when the blisters from the rash peel and slough off.

To prevent photosensitivity reactions, you should avoid sun exposure as much as you can while on this study. If you need to go outside, wear protective clothing and apply a sunscreen with an SPF of at least 30 on all exposed skin. You should avoid tanning beds.

Additional Drug Risks

The study drugs could interact with other drugs and food, such as grapefruit juice. Your study doctor will give you a drug information handout and wallet card that lists these possible interactions. Share this information with your family members, caregivers, other health care providers, and pharmacists.

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

CT scan risks

The CT scans that you get in this study will expose you to more radiation than you get from everyday background radiation. The amount of radiation from this scan is the same as 3 years worth of background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every 1000 people who get a very large amount of extra radiation.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your doctor about:
    - all medications and supplements you are taking
    - any side effects
    - any doctors' visits or hospital stays outside of this study
    - if you have been or are currently in another research study.
- Write down in your medication diary when you take the study drug at home.

For women: Do not get pregnant or breastfeed while taking part in this study. **For men:** Do not father a baby while taking part in this study. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 1 month after your last dose of study drug.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your cancer.

This includes:

- the costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
- your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- The extra EKGs in this study done during screening and at every treatment cycle.
- The extra blood draws for testing how your cancer repairs damaged DNA at the beginning of the study, at the beginning of cycles 2, 4, and 8 of treatment, and at the end of the study.
- The biopsies for testing how your cancer repairs damaged DNA at the beginning of the study and one month after starting treatment.

You or your insurance provider will not have to pay for the olaparib or AZD6738 while you take part in this study.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-

related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors 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. 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, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor and any drug company supporting the study, including AstraZeneca.
- The NCI Central 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 FDA and the groups it works with to review research.

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.

- You will not get reports or other information about any research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

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.

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).*

For questions about your rights while in this study, call the (*insert name of organization or center*) at (*insert telephone number*)..

Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading this optional study hope the results will help other people with cancer in the future. The results will not be added to your medical records and you will not know the results.

Taking part in this optional study is your choice. You can still take part in the main study even if you say "no" to this study. There is no penalty for saying "no." You and your insurance company will not be billed for this optional study. If you sign up for, but cannot complete this study for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for the following study.

Optional sample storage for possible future studies

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Unknown future studies

If you choose to take part in this optional study, any leftover tissue from your previous biopsy/biopsies or blood collected on the study will be stored. Storing samples for future studies is called "biobanking." The biobank is being run by the Yale Cancer Center and is supported by the NCI. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use.

We don't know what research may be done in the future using your blood and tissue samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- Future research studies may include sequencing of all or part of your DNA called genomic sequencing. All your genetic information makes up your genome. Genomic sequencing is a test that records all or part of the pieces of DNA that are in your genes, piece by piece. This is usually done to look for changes in your genome that may cause health problems.
- You will not get reports or other information about any research that is done using your samples.

What is involved in this optional sample collection?

If you agree to take part, here is what will happen next:

1. A sample from the tissue and blood that was collected at the time of your biopsies or blood draws will be sent to the biobank.
2. Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.

4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

- Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample study, your tissue could be used up.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

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

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

You will not benefit from taking part.

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 to this optional sample collection?

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?

If you decide you no longer want your samples to be used, you can call the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number)*, who will let the biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

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

Please circle your answer below to show if you would or would not like to take part in each optional study:

Samples for unknown future studies:

I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES NO

My signature agreeing to take part in the 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 and dated copy of this form. I agree to take part in the main study. I also agree to take part in 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 _____

Study Calendar

You will take olaparib by mouth twice a day, every day. You will take AZD6738 once a day, days 1-7 of every 28 day cycle. You will come to the clinic once every week (7 days) for the first 8 weeks for evaluation. Then you will come into the clinic once every 4 weeks (28 days) for evaluation. This will be repeated as long as you are not experiencing any adverse events or your disease does not progress further. The calendar below briefly shows what will happen to you during the study.

	Pre-Study	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 8	Off study
Olaparib		X	X	X	X	X	X	X	
AZD6738		X				X			
Pregnancy test (if applicable)	X	X							
Physical examination	X	X	X	X	X	X	X	X	X
Blood draw	X	X	X	X	X	X	X		X
Urine test	X								
Patient Diary Given		X			X			X	
Radiological scans to measure tumor size	X							X	X
Electrocardiogram (ECG or EKG)	X	X							
Biopsy	X				X				