PRINCIPAL INVESTIGATOR: Alice P. Chen, M.D.

STUDY TITLE: Phase I Study of Veliparib (ABT-888), an Oral PARP Inhibitor, and M6620 (VX-970), an ATR Inhibitor, in Combination with Cisplatin in Patients with Refractory Solid Tumors

STUDY SITE: NIH Clinical Center

Cohort: Treatment

Consent Version: 1/11/2021

WHO DO YOU CONTACT ABOUT THIS STUDY?

[redacted]

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). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

If the individual being asked to participate in this research study is not able to give consent for themselves, you, as the Legally Authorized Representative, will be their decision-maker and you are being asked to give permission for this person to be in this study. For the remainder of this document, the term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research.

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 study is to test the safety of a combination of 3 drugs [**M6620 (VX-970),**

veliparib (ABT-888), and cisplatin] to find out the doses of these drugs that can be safely given to humans and to learn if these drugs have activity against tumors. Although we hope this experimental therapy will decrease the size of your tumor, we cannot promise or predict the benefits of the treatment at this time. The drugs used in this study have known side effects that will be reviewed with you by your medical team before you sign this consent form.

Cisplatin is currently approved by the US Food and Drug Administration (FDA) for the treatment of patients with bladder, ovarian, and testicular cancers in combination with other chemotherapy agents. Veliparib (ABT-888) and M6620 (VX-970) are not approved by the FDA. Combining veliparib (ABT-888) and M6620 (VX-970) with cisplatin is thought to block proteins that are known to be important for cancer cell growth.

We are also studying the genes in your tumor to help us understand how your tumor responds to these 3 drugs. Blood, tissue, and tumor cells contain genes that are made up of DNA and serve as the "instruction book" for each cell in the body. We know that variations in some tumor genes play an important role in how cancers respond to drugs. Determining whether different tumor gene variations affect how veliparib (ABT-888), M6620 (VX-970), and cisplatin work against tumors will help scientists understand why some patients might stop responding to these drugs.

WHY ARE YOU BEING ASKED TO TAKE PART IN THIS STUDY?

You are being asked to take part in this research study because you have advanced cancer that has progressed after receiving standard treatment, or for which no effective therapy exists. We hope that this combination of study drugs will slow down the growth of your cancer.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 60 patients will take part in this study at multiple sites around the US.

Description of Research Study

WHAT WILL HAPPEN IF YOU TAKE PART IN THIS RESEARCH STUDY?

If you are accepted and you choose to take part, you will begin receiving **veliparib (ABT-888)** and **cisplatin** on the first day, followed by **M6620 (VX-970)** on the second day. Cisplatin and M6620 (VX-970) are given as an infusion through a vein. The drugs are given in cycles, and each cycle is 21 days (3 weeks) long.

- Cisplatin is given the first day of each cycle and on day 8 for some patients, for at least the first 6 cycles
- M6620 (VX-970) is given on day 2 and day 9 of each cycle (or day 1 and day 8 if no cisplatin is given during that cycle)
- Veliparib (ABT-888) is given orally twice a day on days 1 through 3 and days 8 through 10 of each cycle

Each patient may receive a different dose based on when he or she entered the study. Your dose of study drugs may be decreased by the study doctor if you are not tolerating it well, or increased if you are tolerating it well.

Most of the exams, tests, and procedures you will have are part of your regular care such as a complete medical history, blood tests, and scans to measure your tumors. We would also do a pregnancy test in women who are able to become pregnant. The team will also give you a chart describing the tests and procedures that will be done each day during the study.

While you are at the Clinical Center we will perform study tests and procedures to see how the study drugs are affecting your body. If you develop any side effects, you may be asked to visit more often. You will be asked to keep a diary to record the exact time you took veliparib (ABT-888), and to report any side effects you may have. If you miss a dose or vomit the dose, please make a note of this in your diary and contact your team immediately to receive further instructions. Please bring the study diary with you to each clinic visit.

HOW LONG WILL I BE IN THIS STUDY?

You will stay in the study as long as you are tolerating the drugs and your tumors are either stable or getting better, but you can choose to leave the study at any time.

TESTS AND PROCEDURES BEING DONE TO SEE HOW THE DRUGS ARE AFFECTING YOUR BODY:

- **Imaging scans**, such as CT scans, MRI, or ultrasound (an examination using sound waves), that detect your tumor will be done before the study and every 6 weeks (or 9 or 12 weeks if you have been on study more than 1 or 3 years, respectively) while you are receiving study drugs. This is done so that any benefit of the treatment can be determined, and if your cancer is not responding to the treatment, the study team can tell you and discuss other treatment options (discussed further below).
    - **Computed Tomography (CT) scan**: The CT scanner is a doughnut-shaped machine that uses x-rays to create computer pictures showing the inside of your body. During the procedure, you will need to lie still on a table inside the CT machine. The table will move you in and out of the machine during the scan and you will be instructed to hold your breath. The scan itself will only take a few minutes to complete, the entire visit will take about 30 minutes
    - **Magnetic resonance imaging (MRI)**: An MRI creates pictures of the inside of your body using strong magnets instead of x-ray energy. At the time of each scan you will be asked to fill out a screening form to verify that it is safe for you to have the scan. You will also be asked to remove any metallic objects you may be wearing (for example, watches, earrings or piercings) and possibly to change into a hospital gown. Then you'll be asked to lie on a narrow bed that will move into the MRI scanner. Once you are comfortable, the table will be moved into the scanner (the scanner is a long, narrow tube that is open at each end). You will need to lie still on

the table during the scan which will take about 60 minutes to complete. You will hear normal "hammering" or clicking and squealing noises during the scan. While in the scanner you will be fitted with earplugs or earmuffs to muffle the sound. You will be able to communicate with the technician running the scan the entire time and will be provided an emergency button to squeeze at any time if you decide you want the scan to stop.

During part of the MRI you will receive gadolinium, a contrast agent, through an intravenous (IV) catheter. It will be done for both research and medical purposes.

It is not known if MRI with contrast is completely safe for a developing fetus. Therefore, all women of childbearing potential will have a pregnancy test performed no more than 24 hours before each MRI scan with contrast. The scan will not be done if the pregnancy test is positive.

- **Research blood tests:** We will also be collecting blood samples from some patients to find out the effects of the drug on any tumor cells in the blood. Blood samples will be collected from patients at the beginning of the study, and prior to receiving study drugs on days 1, 2, and 9 of cycle 1, days 1 and 2 of cycle 2, and on day 1 of cycle 3 and every subsequent cycle. The total blood for all these tests will be up to 2 tablespoons (about 30 mL).

- **Electrocardiogram:** An electrocardiogram (ECG) is a test that is performed while you lie still for about 5 minutes. It involves placing electrodes (small stickers that are attached to wires that go to the machine) on the chest and arms/legs and recording the electrical activity of your heart. If you have a lot of hair on your chest, it may hurt a little bit when they remove these stickers

- **Tumor Biopsy:** You may be asked to undergo imaging-directed biopsy of your tumor (removal of a small bit of tissue for microscopic examination) once on day 1 and again on day 9 in the first cycle only. We are collecting biopsy samples to study the effects of study drugs on your tumor and to search for any gene variations in your tumor that may help us understand how it responds to these drugs. Biopsies are an important part of this trial and are done for research purposes. Biopsies are optional in the early part of this study (called the dose escalation phase) but mandatory at a certain point in the study called the expansion phase.

  If you decide not to have biopsies collected, you will still receive study drugs and other tests that are part of the study and detailed above. **However, at the expansion phase, willingness to undergo tumor biopsies will be required for taking part in this study.** We will tell you if biopsies are required before you decide to take part in the study.

  No more than three biopsy procedures will be performed during the study. After the first biopsy, if you decide not to have further biopsies, you will still receive study drugs and have other tests that are part of the study. You will be asked to sign a separate consent form for each biopsy procedure.

  Tumor biopsies are only collected by trained personnel. Biopsies are collected using a small needle under imaging guidance (CT, MRI, or ultrasound as deemed appropriate by the

interventional radiologist performing the biopsy). Imaging helps the specialized radiologist know that the needle has been placed into the tumor mass.

Typical risks of biopsy collection include, but are not limited to, bleeding, infection, pain, and scarring. If you experience any complications from the biopsy, medical care will be offered to you. You will be counseled in more detail about biopsies, and you will be asked to sign a separate consent form that will describe the procedures and risks at that time. Your safety is the most important thing at all times. If upon attempting the first biopsy, no tissue can be obtained or it has caused you harm, further biopsies will not be done. After you are enrolled in this study, if for any reason the biopsies cannot be done safely, you may still receive the study drugs but the biopsies will not be done.

The biopsies are for research purposes and will not benefit you. They might help other people in the future. Even if you sign "yes" to have biopsies, you can change your mind at any time. Please read each sentence below and think about your choice. After reading the sentence, circle the initial answer that is right for you:

Have you been informed regarding what phase of the study you will be in?

Escalation phase_____ Expansion phase_____ Initials _____

I agree to have the tumor biopsies for the escalation phase of the research study (optional).

Yes ____ No ____ Initials_____

I agree to have the tumor biopsies for the expansion phase of the research study (mandatory).

Yes ____ No ____ N/A _____ Initials_____

OPTIONAL TUMOR GENOMIC SEQUENCING

Targeted Sequencing—If your cancer looks like it is getting worse, you may choose to have another, optional tumor biopsy before leaving the study and have a targeted genomic sequencing test done on this tumor tissue in a clinically approved laboratory. You and your doctor will receive the results of this test, and the results will be in your electronic medical record. Your doctor will discuss these results with you and tell you about any gene variations that might make you able to take part in targeted therapy clinical trials in the future, such as the NCI MATCH (NCT02465060) and MPACT (NCT01827384) trials.

Exome Sequencing—If you choose to have the optional, third tumor biopsy, we are also requesting your permission to perform exome sequencing on your tumor biopsies and link this information to information from your medical history. You are not required to agree to exome sequencing to take part in this trial. Your tumor tissue contains genes, which are made up of DNA (**d**eoxyribo**n**ucleic **a**cid) and serve as the "instruction book" for the cells that make up our bodies. Exome sequencing will determine the exact order of the base pairs (DNA building blocks) in your tumor. We know that variations in the base pairs of some tumor genes play an important role in how cancers respond to drugs. Information about your gene variations combined with information from your medical history may help us understand how your tumor responds to the study drugs and why it has stopped responding.

If you agree, we will identify gene variants in your tumor biopsy samples collected at the beginning and end of treatment with exome sequencing, but this information will be for research purposes only and we will not give you any individual results from this sequencing or add this information to your medical records. This is because it will probably take a long time for this project to produce health-related information that we will know how to interpret accurately. However, we will tell you if we find that you have a communicable disease that we are required by law to report.

I agree to allow genomic sequencing for research purposes:

Yes ____ No ____ Initials_____

RISKS OR DISCOMFORTS OF PARTICIPATION

What side effects or risks can I expect from being in the study?

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

You also may have the following discomforts:

- 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 agents 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 test 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 drug(s)/study approach.

Here are important things to know about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may make it hard for you to have children.
- 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.
- Your study doctor will give you a drug interactions handout and wallet card that lists possible interactions.

The tables below show the most common and the 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.

- Some patients on this study have had low platelet counts and low red and white blood cell counts in their blood, possibly due to this drug combination. These conditions can cause bruising, bleeding, slow blood clotting after an injury, tiredness, weakness, shortness of breath, and can keep your body from fighting off infections.

Risks and side effects related to veliparib (ABT-888) may include:

COMMON, SOME MAY BE SERIOUS

In 100 people receiving ABT-888 (veliparib), more than 20 and up to 100 may have:

- Nausea
- Tiredness
- Bruising, bleeding

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving ABT-888 (veliparib), from 4 to 20 may have:

- Anemia which may require blood transfusion
- Infection, especially when white blood cell count is low
- Belly pain
- Constipation, diarrhea, vomiting
- Weight loss, loss of appetite
- Dehydration
- Dizziness, headache
- Changes in taste
- Rash

RARE, AND SERIOUS

In 100 people receiving ABT-888 (veliparib), 3 or fewer may have:

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

Risks and side effects related to M6620 (VX-970) may include:

POSSIBLE, SOME MAY BE SERIOUS

- Anemia which may require blood transfusion
- Diarrhea, nausea, vomiting
- Tiredness
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Infection, especially when white blood cell count is low which may cause painful and frequent urination
- Bruising, bleeding
- Pain in tumor
- Dizziness, headache
- Itching, rash
- Flushing

While taking M6620 (VX-970), you should take protective measures to minimize sun exposure.

Risks and side effects related to cisplatin may include:

COMMON, SOME MAY BE SERIOUS

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

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

OCCASIONAL, SOME MAY BE SERIOUS

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

- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Confusion
- Difficulty with balance

RARE, AND SERIOUS

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

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

Risks associated with genomic sequencing:

Privacy Risks

Your privacy is very important to us and we will use many safety measures to protect your privacy. Your research samples will be stored with a coded identifier, not your name. Any personal data about you will also be stored in a sequence computer database with that code identifier. All information that can directly link you to the tissue or personal information will not be shared with investigators using your specimens for research. This includes information that contains your name, medical record number, date of birth, or address.

There are protections in place that restrict who can see the results of your genetic tests. However, there remains a risk someone could get unauthorized access or break into the system that stores information about you. Every precaution will be taken to minimize this risk. There also may be other privacy risks that we have not foreseen.

Genetic variant results that we return to you will become part of your medical record at the NIH. In spite of all of the safety measures that we will use, we cannot guarantee that your identity will ever become known. For instance, if you or a family member releases information about you or your involvement in this study, or an insurer, employer, or other person obtains your written consent to receive information from your NIH medical record, your identity, information about your enrollment in this study and genetic variant results may be included in a release of your medical records.

Protections against misuse of genetic information

This study involves genetic testing on samples. Some genetic information can help predict future health problems of you and your family and this information might be of interest to your employers or insurers. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits plans and health insurers from requesting genetic information or using genetic information. It also prohibits employment discrimination based on your health information. However, GINA does not address discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed condition or disease that has a genetic component.

Emotional and psychological risks

As part of the research study, it is possible that you could learn that you have genetic risks for another disease or disability. This may be upsetting and, depending on what you learn, might create a need to make challenging decisions about how to respond. Although your genomic information is unique to you, you share some genomic similarities with your

children, parents, brothers, sisters, and other blood relatives. Therefore, learning your testing results could mean something about your family members and might cause you or your family distress. Before joining the study, it may be beneficial to talk with your family members about whether and how they want you to share your results with them.

Reproductive Risks:

If you are a woman who is breast feeding or pregnant, you may not take part in the study because we don't know how this medicine would affect your baby or your unborn child. If you are a woman who can become pregnant, or are the partner of a woman who can become pregnant, you and your partner will need to practice an effective form of birth control before starting study treatment, during study treatment, and for 6 months after you finish study treatment. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once.

Effective forms of birth control include using at least two of the following:

- abstinence
- tubal ligation
- barrier methods (condoms)
- hormonal (birth control pills, injections, or implants)
- intrauterine device (IUD)
- vasectomy

Also, if you are a woman taking hormonal birth control, please tell your study doctor or nurse. Some patients on this study may be given medication to control the side effects of nausea and vomiting that can make some forms of hormonal birth control stop working or work less well. You may need to use an alternative form of birth control during this time.

Radiation Risks

During your participation in this research study, you will be exposed to radiation from CT scans and CT-guided tumor biopsies. The amount of radiation exposure you will receive from these procedures is equal to approximately 13.4 rem per year. 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." This study will expose you to more radiation than you get from everyday background radiation. No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The CT scans that you get in this study will expose you to the roughly the same amount of radiation as 45 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 1.34 out of 100 (1.34%) and of getting a fatal cancer is 0.67 out of 100 (0.67%).

Risks for MRI

People are at risk for injury from the MRI magnet if they have some kinds of metal in their body. It may be unsafe for you to have an MRI scan if you have pacemakers or other implanted electrical devices, brain stimulators, some types of dental implants, aneurysm clips (metal clips on the wall of a large artery), metal prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, tattoos, an implanted delivery pump, or shrapnel fragments. Welders and metal workers may have small metal fragments in the eye. You will be screened for these conditions before having any MRI scan. If you have a question about metal in your body, you should inform the staff. You will be asked to complete an MRI screening form before each MRI scan you have.

In addition, all magnetic objects (like watches, coins, jewelry, and credit cards) must be removed before entering the MRI scan room.

People with fear of confined spaces may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. The noise from the scanner is loud enough to damage hearing, especially in people who already have hearing loss. Everyone having a research MRI scan will be fitted with hearing protection. If the hearing protection comes loose during the scan, you should let us know right away.

There are no known long-term risks of MRI scans.

Risks for Gadolinium-Enhanced MRI

The risks of an IV catheter include bleeding, infection, or inflammation of the skin and vein with pain and swelling.

Mild symptoms from gadolinium infusion occur in fewer than 1% of those who receive it and usually go away quickly. Mild symptoms may include coldness in the arm during the injection, a metallic taste, headache, and nausea. In an extremely small number, fewer than one in 300,000 people, more severe symptoms have been reported including shortness of breath, wheezing, hives, and lowering of blood pressure. You should not receive gadolinium if you previously had an allergic reaction to it. You will be asked about such allergic reactions before gadolinium is given.

People with kidney disease are at risk for a serious reaction to gadolinium contrast called "nephrogenic systemic fibrosis (NSF)". This condition always involves the skin and can also involve the muscles, joints and internal organs. NSF has resulted in a very small number of deaths. A blood test of your kidney function may be done within the month before an MRI scan with gadolinium contrast. You will not receive gadolinium for a research MRI scan if your kidney function is below the safe level.

Most of the gadolinium contrast leaves the body in the urine. However, the FDA recently issued a safety alert that indicates small amounts of gadolinium may remain in the body for months to years. The effects of the retained gadolinium are not clear. At this time, retained gadolinium has not been linked to health risks in people whose kidneys work well. Some types of gadolinium

contrast drugs are less likely to remain than others. In this study, we will use the gadolinium contrast drugs that are less likely to remain.

Electrocardiogram Risks

Other than possibly experiencing some minor skin irritation from the electrodes there are no anticipated risks related to complete the electrocardiogram and/or the echocardiogram.

Blood Draw Risks

Blood draws may cause pain, redness, bruising or infection at the site of the needle stick. Rarely some people faint. The study team member may apply numbing cream to the area so that the needle stick won't hurt as much.

POTENTIAL BENEFITS OF PARTICIPATION

Are there benefits to taking part in this study?

The aim of this study is to see if this experimental treatment will cause your tumors to shrink. We do not know if you will receive personal, medical benefit from taking part in this study. These potential benefits could include shrinking of your tumor or lessening of your symptoms, such as pain, that are caused by the cancer. Because there is not much information about the drugs' effect on your cancer, we do not know if you will benefit from taking part in this study, although the knowledge gained from this study may help others in the future who have cancer.

ALTERNATIVE APPROACHES OR TREATMENTS

What other choices do I have if I do not take part in this study?
Instead of being in this study, you have these options**:**

- you may choose to have the usual approaches described above
- you may choose to take part in a different study, if one is available
- you may continue your standard care as usual, and not take part in this study
- or you may choose not to be treated, but you may want to receive comfort care to relieve symptoms

Please talk to your doctor about these and other options. Your doctor may decide that it is not safe for you to receive a particular treatment or you have the right to refuse a treatment, but before you decide to take part in this study you should discuss all available treatment options with your local doctor.

-

STOPPING THERAPY

You can decide to stop at any time. If you decide to stop for any reason, it is important to let your 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 include your medical information in 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.

Your study doctor may take you out of the study:

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

CONFLICT OF INTEREST

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

Members of the research team working on this study may have up to $15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

USE OF SPECIMENS AND DATA FOR FUTURE RESEARCH

To advance science, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. A researcher who wants to study the information must apply to the database and be approved. Researchers use specimens and data stored in scientific databases to advance science and learn about health and disease.

We plan to keep some of your specimens and data that we collect and use them for future research and share them with other researchers. We will not contact you to ask about each of these future uses. These specimens and data will be stripped of identifiers such as name, address or account number, so that they may be used for future research on any topic and shared broadly for research purposes. Your specimens and data will be used for research purposes only and will not benefit you. It is also possible that the stored specimens and data may never be used. Results of research done on your specimens and data will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

If you do not want your stored specimens and data used for future research, please contact us in writing and let us know that you do not want us to use your specimens and/or data. Then any specimens that have not already been used or shared will be destroyed and your data will not be used for future research. However, it may not be possible to withdraw or delete materials or data once they have been shared with other researchers.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

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

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

The NCI Developmental Therapeutics Clinic will cover some or all of your travel expenses related to participation in this study. This may include direct payments or reimbursements for expenses related to transportation, lodging, and meals. The amount and form of these payments are determined by the NCI Travel and Lodging Reimbursement Policy. We will give you a copy of this policy.

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.

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

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, the NCI Cancer Treatment Evaluation Program, or their agent(s)
- Qualified representatives from Merck and AbbVie, the pharmaceutical companies who produce M6620 and veliparib.

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 records 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 medical 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.

POLICY REGARDING 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, [redacted]. 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

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only:

Witness:

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: _____.