PRINCIPAL INVESTIGATOR:	Raffit Hassan, MD
STUDY TITLE:	Phase II Study of Olaparib in Subjects with Malignant Mesothelioma
STUDY SITE:	NIH Clinical Center
Cohort:	Standard
Consent Version:	02/24/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

Raffit Hassan, M.D. by phone at 240-760-6232 or email raffit.hassan@nih.gov

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 to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

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?

Olaparib is a drug that may stop cancer cells from repairing damage to their DNA. Olaparib has been approved by the FDA for use in certain types of ovarian cancer and breast cancer, including persons with ovarian cancers that were born with a mutation in the *BRCA* gene. While it has not been approved for use in mesothelioma, we are studying olaparib in mesothelioma as an investigational agent because we have found in our lab that some patients with mesothelioma have mutations in a gene named *BAP-1*, that is in the same family as *BRCA*. In addition, because olaparib is designed to target cancers that have mutations in genes that help to repair DNA, we

will test whether participants with mutations in such genes other than *BAP-1* might also be treated with olaparib. We will determine whether olaparib caused tumors in persons with mesothelioma to shrink. Participants will be divided into 3 different groups for comparison. These groups are:

1) Persons that have germline mutations in genes repair DNA damage. Germline means that you were born with the mutation and that it is found in most cells in your body.

2) Persons with BAP-1 mutation in the tumor. This type of mutation, called a somatic mutation, is one that was acquired after birth and is only found in the tissues where the mutation occurred.

3) Persons with mesothelioma that are in not in group 1 or group 2.

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

You are being asked to participate because you have been diagnosed with malignant mesothelioma that has previously been treated with platinum and pemetrexed.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 40 participants will be enrolled in the study.

DESCRIPTION OF RESEARCH STUDY

Before You Begin the Study

Before beginning the study, you will need to have tests and/or procedures to help your doctor verify whether you can participate. This is called screening. Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra procedures that you will need to have if you take part in this study. If you have already had some of these examinations very recently, your doctor may decide not to repeat them. Briefly, these tests, which are performed under a separate protocol, include:

- Confirmation of diagnosis - You must provide a sample tumor tissue for an evaluation from the NCI Laboratory of Pathology. The tissue may be from a previous surgery, biopsy or collection from a tumor effusion (fluid around the tumor). If none is available, we will ask you to have a biopsy or a collection of effusion material to provide a fresh sample). Please see page 7, Tumor biopsies and effusions for a description of the procedure.
- Medical history and physical examination
- Routine blood and urine tests including pregnancy test in women who can have children. Pregnant women will not be allowed on study.
- Scans and x-rays
- Electrocardiogram (ECG) – a test of your heart

During the Study

Once the doctor has decided you are eligible and you have signed the consent for this study, we will collect a blood sample for the germline genetic testing described above. We will also test the tumor tissue we collected at screening for mutations in DNA repair. If there is not enough tissue leftover to do this, we will need to collect additional tissue.

You will start the study therapy before we have the results of the genetic testing as the information is only needed to compare the 3 groups at the end. In fact, the results may not be available to use for several months. At the beginning of each 21-day cycle, you will be given a 21-day supply of olaparib tablets. Tablets should be taken twice a day every day with water. You should try to take each dose about 12 hours apart and take them at around the same time each day. You may have a meal or a light snack with each dose. You will continue to take olaparib until your disease gets worse or for any of the other reasons listed on page 9, Stopping Therapy.

There are some medications that may interact with the olaparib used on this study; therefore, please be sure to inform the study team of all the medications and supplements that you are taking while on study therapy as you may not be able to take some of these with your study medication. You may not drink grapefruit juice or eat grapefruits while you are taking the study therapy.

You will be given a pill diary to take track of when you take each dose of olaparib along with any symptoms you might experience. Please bring the diary and any remaining pills with you for each study visit.

We will perform routine tests to monitor your organ function while you are taking olaparib. During the first cycle, you will have a blood test before you start taking the olaparib and about one week after you have taken your first dose. After cycle 1, blood tests will be done once per cycle (every 3 weeks). Other tests, including urine tests and pregnancy testing if you are a woman who can have children will be done once every 3 weeks. We will perform scans every 2 cycles (every 6 weeks) to find out whether your tumors are shrinking or not.

Blood will also be collected for research studies at the beginning of each cycle.

Genetic testing

It is important to note that even though the laboratory we are using to perform genetic tests is certified, the test we are using is investigational. Investigational means that the test is not approved by the U.S. Food and Drug Administration (FDA) and is still being tested in research studies. The FDA does allow the use of such tests in clinical trials like this one.

Though we are focused on finding the mutations that are part of the research, the tests may include genes that are not related to the ones we are looking for. These are called secondary findings.

Since the analyses that we perform in our laboratory are not approved, 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 and ask you to have an additional tube of blood drawn to verify the findings we have seen in our lab. If the results are verified, you or the person you named in the form will also be offered genetic education and counseling at NIH (at our expense) to explain the results.

If you or your designee does not want to come to NIH, we will help you (or your designee) find a local genetic healthcare provider who can explain it to you or your designee (at your or your designee's expense).

This analysis may not be performed for up to several months after the samples have been collected. Because of this, you may be deceased or have diminished mental capacity at the time results are available. Therefore, we will give you the option to complete a form to name a person (a designee) that you would like to receive information about findings that may have implications for your family. If the result is in your tumor, but not in the blood test, your doctor will provide you with the results of this testing and any possible treatment options. Your doctor will also inform you if we did not find a change in the genes that might be important to your or your family's health in the germline (blood test).

Note: Not finding a variation in a gene or genes in the germ line or your cancer or pre-cancerous tumor does not necessarily mean that your genes are "normal". This can be because we are not able to detect all changes that affect the function of a gene with sequencing. This is one of the limitations of genetic testing.

When You Are Finished Taking the Drugs

Approximately 30 days after you have had your last dose of study drug, you will be asked to return to the NIH for a follow up visit to have the following tests:

- Medical history and physical exam
- Routine blood tests
- Research blood test
- Scans (unless you stopped taking olaparib because your tumors got larger)

If you cannot return to the Clinical Center for this visit, we will contact you by telephone and ask that you send us the results of the scans and blood tests needed at this timepoint.

If after this visit, your disease remains stable or improves, you will continue come back to the Clinical Center for a follow up clinic visit and be scanned every 6 weeks until your disease worsens. If you cannot come back for these visits, you may have the scans done locally and send them to us.

BIRTH CONTROL

Female Participants

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 you will need to either abstain from any form of sexual

intercourse (if this is your usual or preferred lifestyle) or use a male condom **in addition to** a highly effective form of birth control (see list below) before starting study treatment, during study treatment, and for one month after you finish study treatment.

Male Participants

Males must use a condom during treatment and for 3 months after the last dose of olaparib when having sexual intercourse with a pregnant woman or with a woman of childbearing potential. Your female partners should also use a highly effective form of birth control (**in addition to the condom**) if she can have children. You should not donate sperm throughout the period of taking olaparib and for 3 months following the last dose of olaparib.

Male and Female Participants

If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once.

Highly effective forms of birth control include:

- intrauterine device (IUD)
- intravaginal device
- hormonal [birth control pills, injections, or implants]
- tubal ligation
- vasectomy

RISKS OR DISCOMFORTS OF PARTICIPATION

The drug 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 let you know if changes occur that may affect your health.

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

Risks of Olaparib

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.

COMMON, SOME MAY BE SERIOUS In 100 people receiving olaparib, 10 or more may have:
• Loss of appetite • Dizziness • Headache • Changes in taste of food • Vomiting • Nausea • Diarrhea • Tiredness/weakness • Indigestion/heartburn • Cough • Pain in the stomach area under the ribs • Shortness of breath • Decreased number of a type of blood cell that helps to clot blood which may lead to bruising and bleeding • Anemia which may cause tiredness or may require blood transfusion • Decrease in the total number of white blood cells and in certain white blood cells (neutrophils) that protect from infection, which can be associated with fever

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving olaparib, from 1 to 9 may have:
• Rash • Sores in mouth which may cause difficulty swallowing • Decrease in the number of white blood cells that support the immune system (lymphocytes), which can be associated with higher risk of infection • Increased blood level of creatinine (a substance normally eliminated by the kidneys into the urine)

RARE, AND SERIOUS In 100 people receiving olaparib, fewer than 1 may have:

RARE, AND SERIOUS In 100 people receiving olaparib, fewer than 1 may have:
• Allergic reactions • Itchy rash on swollen, reddened skin

The study drug may affect your ability to drive or use machines. If you feel dizzy, weak or tired while taking your study treatment, take special care when driving or using tools or machines.

Other Possible Risks

Other side effects have been seen in previous studies, but it is not yet known if these were related to olaparib, or if they were unrelated events possibly due to the patient's cancer or other cause. Assessing the full range of side effects of olaparib is an important part of this study.

- Inflammation of the lungs that may cause difficulty breathing and can be life-threatening
- A pre-cancerous condition (myelodysplastic syndrome or MDS) where the bone marrow isn't as good at producing blood cells as it was before. This condition may transform into AML, a type of leukemia (bone marrow cancer) where many abnormal and immature white blood cells are made while normal functioning blood cells are not made.
- A new cancer other than AML resulting from treatment of a prior cancer

Risks Associated with Research Sampling

Blood collections:

Side effects of blood draws include pain and bruising in the area where the needle was placed, lightheadedness, and rarely, fainting. When large amounts of blood are collected, low red blood cell count (anemia) can develop.

Tumor biopsies and effusions

Tumor biopsies and tumor effusions: local anesthesia of the skin will be given prior to any tumor biopsy or effusion collection, in order to prevent painful sensations. However, you may still experience pain or discomfort at the biopsy site. Irritation, redness, swelling and/or bleeding may also occur. There is a risk of abnormal healing, fever, infection or of an allergic reaction to the anesthetic agent used to anesthetize the skin at the biopsy site. Once the sample has been obtained, a stitch may be used to close the wound and facilitate healing.

In some cases, we may use CT scans to help guide us during your biopsy. This introduces the added risk of research radiation. This research study may involve exposure to radiation from up to 1 CT guided tumor biopsy for research**.** This radiation exposure is not required for your medical care and is for research purposes only. The amount of radiation you will receive in this study is 0.80 rem which is below the guideline of 5 rem per year allowed for research subjects by the NIH Radiation Safety Committee. The average person in the United States receives a radiation exposure of 0.3 rem per year from natural sources, such as the sun, outer space, and the earth's air and soil. If you would like more information about radiation, please ask the investigator for a copy of the pamphlet, An Introduction to Radiation for NIH Research Subjects.

While there is no direct evidence that the amount of exposure received from participating in this study is harmful, there is indirect evidence it may not be completely safe. There may be a very slight increase in the risk of cancer.

Please tell your doctor if you have had any radiation exposure in the past year, either from other research studies or from medical tests or care, so we can make sure that you will not receive too much radiation. Radiation exposure includes x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine scans in which radioactive materials were injected into your body.

Psychological or Social Risks Associated with Loss of Privacy

1. Unanticipated medical information: During the course of this investigation, it is possible (although not likely) that we will obtain unanticipated information about your health or genetic background.
2. Release of genetic information:
   - Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measures that we will use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.
   - While the controlled-access databases developed for this project will not contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.
   - There also may be other privacy risks that we have not foreseen.

Since some genetic variations can help to predict future health problems for you and your relatives, this information might be of interest to health care providers, life insurance companies, and others. However, Federal and State laws provide some protections against discrimination based on genetic information. For example, the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, GINA does not prevent companies that sell life insurance, disability insurance, or long-term care insurance from using genetic information as a reason to deny coverage or set premiums. GINA also does not apply to members of the United States military, individuals covered by the Indian Health Service, or veterans obtaining health care through the Veteran's Administration. Lastly, GINA

does not forbid insurance medical underwriting based on your current health status though the Affordable Care Act limits consideration of pre-existing conditions by insurers.

POTENTIAL BENEFITS OF PARTICIPATION

The aim of this study is to see if study therapy 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 drug's 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

Instead of being in this study, you have these options:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly. Instead, it tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Please talk to your doctor about these and other options.

STOPPING THERAPY

Your doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if your disease comes back during treatment
- if you do not comply with study requirements (e.g. you miss too many doses in a cycle)
- if you have side effects from the treatment that your doctor thinks are too severe
- if you come pregnant
- if you need to take any of the medicines that are not allowed on the study
- if the investigator decides to end the study
- if new information shows that another treatment would be better for you

In this case, you will be informed of the reason therapy is being stopped.

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 AstraZeneca or designated representatives. If you withdraw your consent and leave the trial, any samples of yours that have been obtained for the study and stored at the NCI can be destroyed upon request. However, any

samples and data generated from the samples that have already been distributed to other researchers or placed in the research databases can**not** be recalled and destroyed.

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.

The National Institutes of Health and the research team for this study are using a drug developed by AstraZeneca through a joint study with your researchers and the company. The company also provides financial support for this study.

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.

We may put your research data in a large database for broad sharing with the research community. These databases are commonly called data repositories. These data repositories might or might not be located at the NIH. The information in this database could include but is not limited to genetic information, ethnicity and sex. If your individual research data is placed in one of these repositories, it will not be labeled with your name or other information that could be used to easily identify you, and only qualified researchers will be able to look at your data. These researchers must receive prior approval from individuals or committees to access the data.

Your summary genomic data is being placed *in an* unrestricted database, so researchers will be able to access summary information about all the participants included in the study (including

you), or summary information combined from multiple studies, without applying for permission. The risk of anyone identifying you with this information is very low.

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.

On this study, the NCI will cover the cost for some of your expenses. Some of these costs may be paid directly by the NIH and some may be reimbursed after you have paid. Someone will work with you to provide more information.

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 performed outside the NIH Clinical Center, you may have to pay for these costs if they are not covered by your insurance company.
- Medicines that are not part of the study treatment will not be provided or paid for by the NIH Clinical Center.
- Once you have completed taking part in the study, medical care will no longer be provided by 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 National Cancer Institute 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
- Qualified representatives from AstraZeneca, the pharmaceutical company who produces olaparib.

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

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, Raffit Hassan, M.D., Raffit.Hassan@nih.gov, 240-760-6232. 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: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

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: _____.