

SUMMARY OF CHANGES -- Consent

NCI Protocol #: 10066

Local Protocol #: 2000021407

Protocol Version Date: 6/2/22

Protocol Title for LOI 10066: A Phase 1 / 2 Study of Olaparib in Combination with Ramucirumab in Metastatic Gastric and Gastroesophageal Junction Adenocarcinoma

Informed Consent Version Date: 6/2/22

L. Consent Changes by the Principal Investigator:

#	Section	Comments
1.	Page 3	Reinserted sentence regarding potential change in timing of scans for patients on treatment for more than 6 months.
2.	<u>All</u>	The informed consent version date was updated in the header.

CONSENT FORM

Study Title for Study Participants: Testing the Addition of the Medication “Olaparib” to Standard Chemotherapy in Advanced Stomach Cancer

Official Study Title for Internet Search: A Phase 1 / 2 Study of Olaparib in Combination with Ramucirumab in Metastatic Gastric and Gastroesophageal Junction Adenocarcinoma

What is the usual approach to my stomach cancer?

You are being asked to take part in this study because you have advanced stomach cancer. You have already been treated with one or more types of chemotherapy and your disease is now growing. People who are not in a study are usually treated with either 1) ramucirumab plus paclitaxel or 2) ramucirumab alone. Both of them are approved by the FDA.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- You may choose to have the usual approach described above
- You may choose to take part in a different study, if one is available
- Or you may choose not to be treated for cancer, but you may want to receive comfort care to relieve symptoms

Why is this study being done?

This clinical trial will take part in 2 separate phases as described below.

Phase 1:

The purpose of this portion of the study is to test the safety of the combination of olaparib and ramucirumab at different doses of olaparib to find out what side effects, if any, it has on patients. There will be about 9 patients taking part in the phase 1 portion of the study. This will be conducted before phase 2 begins, which is described below.

Phase 2:

The purpose of this study is to test any good and bad effects of the combination of olaparib and ramucirumab. The combination of olaparib and ramucirumab could shrink your cancer, but it could also cause side effects. Researchers hope to learn if the study drug will shrink the cancer compared to its present size. Ramucirumab has already been FDA-approved to treat gastric cancer, and olaparib has been approved for the treatment of other cancers. Ramucirumab decreases the oxygen delivery to tumor cells, which inhibits tumor growth and has also been shown to decrease the ability of tumors to repair DNA effectively. Olaparib also inhibits the ability for tumors to repair DNA and is most effective in tumors that already have impaired DNA repair. It is hoped that combining olaparib with ramucirumab will improve getting rid of tumors better than just the ramucirumab used alone. There will be 40 patients taking part in the phase 2 portion of the study. You will only be enrolled in one phase of the study, phase 1 or 2. Your study doctor will tell you in which study phase you will be enrolled.

What are the study groups?

Phase 1 (Part 1):

In this clinical trial all patients will receive olaparib and ramucirumab. The standard dose of ramucirumab will be used with different doses of olaparib for all patients to find out the ideal olaparib dose to use with ramucirumab. The first several study participants will receive the starting dose of olaparib. If the drug does not cause serious side effects, it will be given to other study participants at a higher dose. However if olaparib does cause serious side effects, additional patients will be enrolled at a lower dose. After the ideal dose of olaparib is determined, the study will transition to phase 2. In phase 1, between 9 and 18 patients will be enrolled depending on the side effects that are observed.

Phase 2 (Part 2):

In phase 2, all participants will receive the same treatment. Patients will receive ramucirumab in combination with the ideal dose of olaparib that was determined in phase 1. In phase 2 a total of 40 patients will be enrolled.

Your doctor will tell you what dose and how many pills of olaparib to take. Olaparib is a tablet and the pills are meant to be swallowed. Do not chew, dissolve, or crush the medications. DO NOT make up vomited doses. You should take each dose of olaparib 12 hours apart and if you miss a dose, you have up to 2 hours to make this dose up. You should avoid grapefruit, grapefruit juice, and Seville oranges while on study because of their affects on the metabolism of olaparib. You will be given a pill diary each 14 day cycle, please record the date, the number of tablets you took, and the time you took them as instructed on the diary. The other medication, ramucirumab, is an infusion given through a vein over one hour every 2 weeks at your doctors visit.

How long will I be in this study?

You will receive the olaparib and ramucirumab until disease progression or unacceptable side effects. Disease progression is defined as a 20% or more growth of your tumor masses, or any new tumor masses seen on your scans. After you finish the drugs, your doctor will continue to watch you for side effects and follow your condition with one clinic visit at 4 weeks from finishing study medication, or more often at the discretion of the treating physician.

What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra blood tests, imaging studies, and biopsies that you will need to have if you take part in this study.

Before you begin the study:

You will need to have the following extra blood tests and imaging:

- Echocardiogram (if your doctor thinks it is necessary)
- Urine pregnancy test (if you are female)

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

During the study:

Before taking the study drug:

- Mandatory blood tests to assess organ function (approximately 1 ½ teaspoons)
- Optional research blood (approximately 1 ½ teaspoons)
- CT scan of chest, abdomen, and pelvis
- Cheek swab (to obtain DNA from non-cancerous cells)
- Mandatory tumor biopsy (tumor biopsy description and risks are described on page 6)

After taking the study drug:

- Mandatory blood tests to assess organ function every week for the first 3 weeks (approximately 1 ½ teaspoons)
- After the first 3 weeks of treatment the mandatory blood tests will be done every 2 weeks to assess organ function prior to each cycle.
- Optional research blood tests every week for the first 3 weeks (approximately 1 ½ teaspoons). Note: this is mandatory for the first 20 patients in phase 2.
- Optional research blood tests every 2 weeks after the first 3 weeks of treatment (approximately 1 ½ teaspoons).
- A second optional tumor biopsy will be obtained after 16 weeks. The second biopsy will be offered to all participants as an optional procedure.
- CT scan of the chest, abdomen, and pelvis every 6 weeks. If you are receiving study drugs for more than 6 months, the scans may be done every 12 weeks if your doctor decides to do so.

You will receive the olaparib tablets to take home, and you will take the prescribed dose twice a day while you are enrolled on the clinical trial. For the participants in phase 2, they will receive the dose of olaparib that is determined in phase 1. In both phases of the study, the ramucirumab will be given intravenously at the same dose every 2 weeks, and each cycle consists of 14 days of therapy.

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

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive for private questions which you normally do not discuss
- There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with 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. There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

- There can also be a risk in finding out new genetic information about you. New health information about inherited traits that might affect you or your blood relatives could be found during a study. These results will be made available to you and your family by your treating physician.

If you choose to take part in this study, there is a risk that the olaparib (AZD2281) and ramucirumab 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 olaparib (AZD2281) and ramucirumab 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.

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.

Possible Side Effects of Olaparib

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 the lungs which may cause shortness of breath

Additional Information about Important Risks in Olaparib

- **Damage to the bone marrow (irreversible), which may cause infection, bleeding, and may require blood transfusions.**

In clinical trials using olaparib, 22 of 2,618 (<1%) of patients that received olaparib have been diagnosed with bone marrow damage diseases called myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML). The majority of MDS/AML cases were fatal, and the duration of therapy with olaparib in patients who developed MDS/AML varied between less than 6 months to more than 2 years. All patients who developed MDS/AML also had previous exposure to platinum chemotherapy, which is associated with this same risk. The study physicians will monitor your blood counts at baseline and routinely during therapy. If at any point MDS/AML develops and is confirmed, the olaparib will be stopped immediately.

- **Damage to the lungs which may cause shortness of breath (Pneumonitis).**

The damage is due to inflammation of the lungs, which occurs in less than 1% of patients who have been treated with olaparib. If you develop new or worsening respiratory issues including shortness of breath, cough or wheezing or you have abnormal results on CT scan, your therapy will likely be interrupted and additional workup will be done.

Possible Side Effects of ramucirumab:

COMMON, SOME MAY BE SERIOUS

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

- Fatigue
- Belly pain
- Decreased appetite
- Nausea, vomiting, diarrhea

OCCASIONAL, SOME MAY BE SERIOUS

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

- Constipation
- Anemia, which may require a blood transfusion
- High Blood pressure which may cause headache, dizziness, blurred vision
- Shortness of breath

RARE, AND SERIOUS

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

- Bleeding
- Blood clots
- Kidney Injury
- Tear or blockage the stomach or intestine
- Reaction during or following infusion of the drug which may cause fever, chills, rash, low blood pressure
- Heart failure

Additional Information About Important Risks for the Combination of Olaparib and Ramucirumab

- **The risk for diarrhea may be increased with the combination of both ramucirumab and olaparib and may require immediate and aggressive treatment.**

Your study doctor may recommend specific medications, such as loperamide (Imodium) to manage diarrhea. Specific dosing of loperamide will be outlined in an additional handout provided by your study physician.

Risks associated with tumor biopsy: Your study doctor will inform you in further detail about the risks associated with the biopsy. There are many different ways to obtain tumor tissue for a biopsy, the most common is a needle biopsy guided by a CT scan. Other options include small surgical procedures or an endoscopy (going into the stomach with a camera). Small pieces of cancer tissue removed by obtaining a biopsy that will be taken for the study prior to the first treatment. A biopsy prior to treatment is mandatory for all treatments in both phases of the clinical trial. A repeat biopsy after 16 weeks of treatment will be optional for all participants. These samples are required in order for you to take part in this study because the research on the sample is an

important part of the study. The research biopsy will be done to obtain an adequate sample of the cancer cells. The biopsies will be used for genetic analysis to determine if tests can be developed in the future that may better predict who will benefit from this treatment.

In general, the risks of a biopsy are:

- Pain at the site of biopsy
- Bleeding
- Low blood pressure
- Infection
- Fevers or chills
- Perforation (puncture of the stomach wall)
- Side effects related to anesthesia

You will sign a separate consent form before the biopsy is taken, which will be a standard consent form from the institution where the biopsy procedure takes place. Blood and additional tumor tissue will be collected for biobanking, which will be discussed below under optional studies. Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. These results will be available to both the study participants and study doctor.

Neither you nor your health care plan/insurance carrier will be billed for the collection of the biopsy that will be used for this study.

Reproductive risks: You should not get pregnant, breastfeed, or father a baby while in this study. The chemotherapy used in this study could be very damaging to an unborn baby. The effects of these medications on the developing fetus are unknown. For this reason, women of child-bearing potential and men must agree to use adequate contraception including hormonal, barrier, or abstinence. Should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this study, she should inform her treating physician immediately. Both men and women treated or enrolled on this protocol must also agree to adequate contraception prior to the study, for the duration of the study participation, and for 3 months after completion of treatment administration. Men and their partners must use two highly effective forms of contraception in combination.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

What possible benefits can I expect from taking part in this study?

This study has only a small chance of helping you because we do not know if the study drug/study approach is effective. This study may help researchers learn things that may help other people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop 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.

The 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.

The 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.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____ (*insert name of center*) Institutional Review Board at _____ (*insert telephone number*).

What are the costs of taking part in this study?

The olaparib will be supplied by the clinical trial at no charge to you or your insurance while you take part in this study, although the monthly cost is typically \$13,000. The ramucirumab is already FDA approved for your cancer and this will be billed to your insurance, and the monthly cost is approximately \$15,000. The cost of getting the olaparib and ramucirumab ready and giving it to you is not paid by the study sponsor, so you or your insurance company may have to pay for this. It is possible that the olaparib may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

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

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company

may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you retain all your legal rights to receive payment for any injury even though you are in a study.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The National Cancer Institute, the study sponsor.
- The 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 Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.
- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from the Human Investigation Committee (the committee or Institutional Review Board that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance.
- The study doctor and study team.
- Your providers who are participants in the electronic medical record system.
- Data and safety monitoring boards and other authorized to monitor the conduct of study.
- Governmental agencies to which certain diseases (reportable diseases) must be reported.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Any drug company supporting the study.
- Pharmaceutical collaborator for olaparib.

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.

Who can answer my questions about this study?

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).

ADDITIONAL STUDIES SECTION:

This section is about optional studies 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. You will not get health benefits from any of these studies. 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 or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say “no” to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

A repeat biopsy at 16 weeks of treatment will be optional as described below.

Bio-banking:

If you take part in the study, we would like to use leftover blood samples and tumor biopsy samples explained above in the section: “What extra tests and procedures will I have if I take part in this study?” Leftover tumor tissue from these biopsies and/or old tumor tissue samples, and related health information, will be used to conduct additional medical research. The research that will be done is unknown at this time. Storing additional samples for future studies is called “biobanking” and is being run by the Yale Cancer Center.

WHAT IS INVOLVED?

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

- 1) About 1 ½ tablespoons of blood collected from a vein in your arm, cells obtained by a cheek swab, and a sample from the tissue that was collected at the time of your surgery will be sent to the Biobank.
- 2) Your sample and some related health information may be stored in the Biobank, along with samples and information from other people who participate. The samples will be kept until they are used up. Information from your medical record will be updated from time to time.
- 3) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
- 4) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
- 5) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.
- 6) In phase 2 a repeat biopsy at 16 weeks of study will be optional. The biopsy is obtained by inserting a needle between 3 and 6 times into your tumor. The risks of biopsies are described above, and you will sign a separate consent form from your treating institution before a biopsy is taken.

WHAT ARE THE POSSIBLE RISKS?

- 1) The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.
- 2) The common risks of a tumor biopsy are described above under “risks associated with a tumor biopsy.”
- 3) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
- 4) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
- 5) In some cases, this information could be used to make it harder to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance that this will happen is very small, but cannot promise that it will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

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

- 1) When your samples are sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
- 2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and Experimental Therapeutics Clinical Trial Network (ETCTN) staff with access to the list must sign an agreement to keep your identity confidential.

- 3) Researchers to whom ECTTN sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
- 4) Information that identifies you will not be given to anyone, unless required by law.
- 5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

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?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, (*insert name of study doctor for main trial*), at _____ (*insert telephone number of study doctor for main trial*) who will let the researchers know. Then, any sample that remains in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

WHAT IF I HAVE MORE QUESTIONS?

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

Please circle your answer to show whether or not you would like to take part in each option:

SAMPLES FOR THE LABORATORY STUDIES:

1. I agree to optional blood collection for research and I agree that my blood samples and related information may be used for the laboratory studies described above.

YES NO

2. I agree that any leftover blood samples or tumor tissue samples and related information may be used for the laboratory studies described above.

YES NO

3. I agree to have a second tumor biopsy after 16 weeks of treatment to collect tumor samples to be used in the laboratory studies described above.

YES NO

4. I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to learn about results from these studies.

YES NO

SAMPLES FOR FUTURE RESEARCH STUDIES: (All participants)

My tumor tissue samples and related information may be kept in a Biobank for use in future health research.

YES NO

My blood samples and related information may be kept in a Biobank for use in future health research.

YES NO

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

My Signature Agreeing to Take Part in the Main 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 copy of this form. I agree to take part in the main study and 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 _____