Research Study Informed Consent Document

Study Title for Participants: Testing the Use of Targeted Treatment for RET Fusion-Positive Advanced Non-Small Cell Lung Cancer

LUNGMAP, "A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)"

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

S1900B, "A Phase II Study of Selpercatinib (LOXO-292) in Patients with RET Fusion-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)" (NCT 04268550)

Overview and Key Information

What am I being asked to do?

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

We are asking you to take part in this research study because you have non-small cell lung cancer that has spread outside your lungs. Your tumor sample has a biological marker, which is positive for a RET gene fusion that matches one of the treatment studies that is open. If a gene change (mutation) affects one or more proteins in a pathway, the proteins may not be able to be turned on or off as expected. This can cause cells to grow out of control and lead to cancer.

Taking part in this study is your choice.

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

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

Why is this study being done?

This study is being done to answer the following question:

Can we lower the chance of your RET Fusion-Positive Advanced Non-Small Cell Lung Cancer growing or spreading by using the study drug LOXO-292 (Selpercatinib))?

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

What is the usual approach to my lung cancer?

The usual approach for patients who are not in a study is treatment with chemotherapy or immunotherapy drugs which are both Food and Drug Administration (FDA) approved. If you have already received chemotherapy, other chemotherapy drugs or immunotherapy may be an option. If you have already received immunotherapy, chemotherapy may be an option. In addition, immunotherapy has been FDA approved for patients who previously received chemotherapy and whose cancer has grown. If you have not received immunotherapy in the past, you are encouraged to discuss this with your doctor.

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

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

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

If you decide to take part in this study, you will get the study drug selpercatinib (LOXO-292) daily until your disease gets worse, the side effects become too severe, or you desire to discontinue the study. Selpercatinib (LOXO-292) is a drug that inhibits RET, a biomarker present in your tumor.

After you finish your study treatment, your doctor will continue to follow your condition for up to three years from the time you went on study and watch you for side effects. If your disease has not gotten worse, follow up visits will occur every 3 months. If your disease has gotten worse, follow up visits will occur every 6 months for 2 years, then at the end of the 3 years from the time you go on study. At the follow-up visits you will have a physical exam, blood tests, and scans. Your doctor may give you other tests or procedures if they think they are needed for the regular care of your disease.

Should your disease worsen, you have the option to participate in a different treatment study. As before, the new treatment study that you will be offered will depend on a combination of the results of the previous testing done on your tumor sample and the sub-studies available. If the tests show that your tumor has more than one biomarker that qualifies you for different treatment study, you will be assigned to one of these sub-studies randomly (by chance). A treatment study may be available even if your tumor does not have any additional biomarkers being tested or if you were not eligible to participate in the other randomly assigned (by chance) sub-studies.

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

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

Risks

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

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

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

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

- Diarrhea
- Dry mouth
- Tiredness
- Change in heart rhythm
- Headache
- High blood pressure

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

Benefits

Recent scientific research indicates that selpercatinib (LOXO-292) may shrink your type of cancer in living humans. It is not known that it will work in everyone with your type of cancer or help you live longer. This study may help the study doctors learn things that may help other people in the future.

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

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. This may mean slowly stopping the study drug so that there is not a sudden, unsafe change or risk to your health. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

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

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

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

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

End of Overview and Key Information

What is the purpose of this study?

There are several investigational treatments that are being tested in various sub-studies as part of this study. You will have already received the information on your biomarker testing. You have been assigned to this treatment study because your tumor sample is positive for a RET fusion. For this treatment study, you will be assigned to treatment with an investigational drug called selpercatinib (LOXO-292).

The purpose of this study is to test the good and bad effects of the drug called selpercatinib (LOXO-292). Selpercatinib (LOXO-292) could shrink your cancer, but it could also cause side effects, which are described in the risks section below.

The study doctors hope to learn if the treatment will shrink your tumor. Another purpose of this study is for the study doctors to learn if a biomarker test for RET fusions is helpful in assigning treatment.

Selpercatinib (LOXO-292) is not approved by the FDA for use in advanced non-small cell lung cancer. There will be up to 124 people taking part in this study.

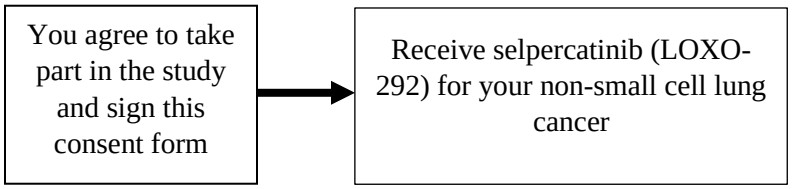
What are the study groups?

In this study, you will get the study drug called selpercatinib (LOXO-292). Treatment will be given in cycles, with each cycle lasting 28 days.

Treatment Schedule: You will take selpercatinib (LOXO-292) by mouth twice daily about the same time every day as close to 12 hours apart as possible. It is important to swallow whole and not to chew the capsules. Selpercatinib (LOXO-292) may be taken with or without food.

Patient Diary: You will be asked to complete a patient diary to track any late or missed doses as well as if you took any histamine-2 (H2) blocking agents (acid reducers) or antacids while you are taking selpercatinib (LOXO-292).

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



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

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

These exams, tests, and procedures to monitor your safety and health include:

- Vital signs
  You will be required to have your vitals taken for blood pressure, heart rate, respiratory rate, and body temperature. These vital signs will be taken during the first 6 cycles, and then every 12 weeks while you are on treatment.

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

- Blood Test (circulating tumor DNA)
  You will be required to have about 2.5 tablespoons of your blood collected for the circulating tumor DNA testing. Circulating tumor DNA is found in the bloodstream and refers to DNA that comes from cancerous cells and tumors. These blood draws will occur prior to starting treatment, if your disease becomes worse, and/or at the end of your treatment. An attempt will be made to do this blood draw at the same time as other blood draws. There is a chance that you will have another stick to obtain the blood. This blood will be tested for DNA not normally found in cells but that is present in your blood because it has been released from the tumors in your body. The results of this blood test are not part of normal clinical decision making. You and your doctor will not receive the results of this blood test. The information collected will help the study doctors learn about tumor abnormalities that may play a role in tumor development.

- Electrocardiograms (ECGs)
  You will be required to have an ECG done prior to starting treatment. An ECG is a test that measures the electrical activity of the heart. You will be asked to lie flat on a table and several small electrode pads (like stickers) will be placed on your body. This test takes about 10 minutes. There is no pain or risk associated with having an ECG. There may be some minor discomfort when the ECG stickers are removed.

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

General Risks

If you choose to take part in this study, there is a risk that selpercatinib (LOXO-292) may not be as good as the usual approach for the type of cancer you have at shrinking or stabilizing the 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 drug used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for at least 3 months after you have stopped taking selpercatinib (LOXO-292). If you are a female, you should not breastfeed during the study and for at least 3 months after you have stopped taking selpercatinib (LOXO-292). If you are a male, you should not donate sperm during the study and for at least 6 months after you have stopped taking selpercatinib (LOXO-292).

For patients whose tumor tested positive for the RET fusion biomarker from a prior test outside of this study or testing done as part of this study, there is a chance of a false positive or a false negative result from the genetic testing. A "false positive" refers to the identification of a biomarker that is not present. A "false negative" is the failure to find a biomarker that indeed exists. The tests have been designed to ensure that the possibility of incorrect results is low. Either a false positive or a false negative test would mean that your treatment assignment would not include the correct targeted treatment. However, because we do not know whether targeted treatment will work for you, we cannot say whether an incorrect treatment assignment would be worse.

Blood Draw Risks

Common side effects of a blood draw are a small amount of bleeding at the time of the blood draw, brief pain, and maybe a bruise.

Side Effect Risks

The selpercatinib (LOXO-292) 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 the study drug.

Here are important things to know about side effects:

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

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

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

Drug Risks

The tables below show the most common (occasional) and sometimes 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 selpercatinib (LOXO-292) are listed in the tables below.

Possible Side Effects of Selpercatinib (LOXO-292)

COMMON, SOME MAY BE SERIOUS In 100 people receiving selpercatinib (LOXO-292), more than 20 and up to 100 may have:
• Dry mouth • High blood pressure which may cause headaches, dizziness, blurred vision

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving selpercatinib (LOXO-292), from 4 to 20 may have:
• Belly pain • Constipation, diarrhea, nausea, vomiting • Swelling of arms, legs • Tiredness • Change in the heart rhythm • Bruising, bleeding • Infection, especially when white blood cell count is low • Changes in taste • Headache • Rash

RARE, AND SERIOUS In 100 people receiving selpercatinib (LOXO-292), 3 or fewer may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat

Additional Drug Risks

Drug Interactions

Over the counter, herbal medicines and other prescribed drugs will be reviewed by the study team for potential drug interactions. Your doctor or a member of the study team will tell you if you need to stop, modify or change any of these medicines or drugs before you start taking selpercatinib (LOXO-292).

Selpercatinib (LOXO-292) could interact with other drugs and certain foods. Avoid ingesting grapefruit juice, grapefruit and Seville oranges and herbal supplements such as St. John's Wort®. Do not take medicines called proton pump inhibitors, such as Prilosec®, Prevacid® and Nexium® during study treatment. Avoid medications known to prolong heart rhythm. Your doctor will monitor you closely during treatment. Throughout your treatment, you should inform your doctor about any medication changes. Your study doctor will give you a drug information handout and wallet card that lists these possible interactions. Share this information with your family members, caregivers, other health care providers, and pharmacists.

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

What are my responsibilities in this study?

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

- Keep your study appointments.
- Tell your doctor about:
    - all medications and supplements you are taking
    - any side effects
    - any doctors' visits or hospital stays outside of this study
    - and if you have been or are currently in another research study.

For women: Do not get pregnant or breastfeed while taking part in this study.
For men: Do not father a baby while taking part in this study. Do not donate sperm while taking part in this study and for 6 months after your last dose of study treatment.
For all: You must continue to use your approved method of birth control during the study and for 3 months after last dose. Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 3 months after your last dose of study treatment.

What are the costs of taking part in this study?

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

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

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

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

You or your insurance provider will not have to pay for the study drug selpercatinib (LOXO-292), exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- the study drug selpercatinib (LOXO-292).
- the ECG in this study done before you begin treatment.

- the collection or testing of the circulating tumor DNA at the beginning of the study, if your disease has gotten worse, and/or when you come off study treatment.

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

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

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

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. Contact information for your study doctor is listed on the consent cover page. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

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

No funds have been set aside to compensate you in the event of injury.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

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

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these

organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- Montana Cancer Consortium
- The study sponsor, SWOG Cancer Research Network, and any company supporting the study now or in the future. This would include any organization helping the company with the study.
- The National Cancer Institute Central Institutional Review Board, NCI CIRB, which 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, FDA, and the groups it works with to review research.
- The National Cancer Institute, NCI, and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research.
- Transmission of Imaging and Data (TRIAD) and Imaging and Radiation Oncology Core (IROC)-Your medical images with clinical study data (e.g., the treatment Group you are assigned to, etc.) will be transferred using a computer program called TRIAD to IROC, a central imaging laboratory sponsored by the NCI and located at Ohio State University in Columbus, Ohio. Your medical images will be reviewed by physicians at this organization as part of the study analysis for this trial.

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

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

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

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases,

employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact information for your study doctor is listed on the consent cover page.

For questions about your rights while in this study, call the Operations Office of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) at 888-657-3711.

Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading these optional studies 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.

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

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

Future contact

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

Yes **No**

Optional sample collections for known laboratory studies and/or storage for possible future studies

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

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

Unknown future studies

If you choose to take part in this optional study, your samples will be collected and stored. Storing samples for future studies is called "biobanking." The biobank is being run by SWOG Cancer Research Network and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don't know what research may be done in the future using your blood samples.

This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may be passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes.

What is involved in this optional sample collection?

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

1. About 2 teaspoons of blood will be collected from a vein in your arm (at the same time as other study blood tests) before you begin treatment, on Cycles 2, 3, 4, and again if your cancer gets worse.
2. Your samples will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

1. The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
2. Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
3. In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

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

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

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

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this optional sample collection?

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

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

If you decide you no longer want your samples to be used, you can call the study doctor who will let the biobank know. Contact information for your study doctor is listed on the consent cover page. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor. Contact information for your study doctor is listed on the consent cover page.

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

Samples for unknown future studies:

1. I agree that my samples and related health information may be kept in a biobank for use in future health research.
YES NO

This is the end of the section about optional studies.

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)
(Required for initial consent only)