Research Study Informed Consent Document

Study Title for Participants: Targeted Treatment (rucaparib) for 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:

S1900A, "A Phase II Study of Rucaparib in Patients with Genomic LOH High And/Or Deleterious BRCA1/2 Mutation Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)"
(NCT 03845296)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. 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, and your tumor sample has a biomarker which is positive for LOH (loss of heterozygosity) or BRCA1/2 mutations that matches one of the treatment studies that are open.

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 lung cancer growing or spreading by using a drug that targets a biomarker present in your tumor?

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 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. 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 Food and Drug Administration (FDA) approved for patients with previously untreated non-small cell lung cancer whose tumors have high expression of a marker called PD-L1, as well as for patients who previously received chemotherapy and then had progression of their cancer.

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 (rucaparib), until your disease gets worse or the side effects become too severe.

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 for the first year, then every 6 months up to 3 years from the time you go on study. 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 sub-study. As before, the new sub-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 a different sub-study, you will be assigned to one of these sub-studies randomly (by chance). A sub-study may be available if your tumor does not have any additional biomarkers being tested or you were not eligible to participate in other 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:

- Nausea and vomiting
- Diarrhea and constipation
- Tiredness
- Decreased appetite
- Changes in taste
- Sensitivity to sunlight

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

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

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

Benefits

There is evidence that rucaparib could shrink your type of cancer or prevent it from returning. It is unlikely that it will work in everyone with your cancer or help you live longer. This study will 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, 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 is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (SWOG). 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 LOH-positive (Loss of Heterozygosity, which is a genomic variation in the make-up of your cells) or BRCA-positive (a mutation in either the BRCA1 or BRCA2 genes, which are tumor suppressor genes). LOH and BRCA are changes in genes that may make your cancer respond to a poly (ADP) ribose polymerase (PARP) inhibitor. A PARP inhibitor is a drug that blocks the PARP enzyme in cells. The PARP enzyme helps cancer cells to be able to repair, and inhibiting this enzyme can cause cancer cells to die. For this sub-study, you will be assigned to treatment with an investigational drug called rucaparib, a PARP inhibitor.

The purpose of this study is to test the good and bad effects of the study drug, rucaparib. Rucaparib is a drug that works by slowing or stopping the growth of cancer cells, but it could also cause side effects, which are described in the risks section below. The study doctors hope to learn if the study drug will shrink the cancer by at least one quarter compared to its present size. Another purpose of this study is for the study doctors to learn if a biomarker test for LOH or BRCA 1 or BRCA 2 genes is helpful in assigning treatment.

Rucaparib is not approved by the FDA for use in advanced lung cancer. There will be up to 88 people taking part in this study.

What are the study groups?

This study has 2 study groups. Both groups will receive rucaparib.

Rucaparib will be taken twice daily at about the same time every day. The tablets will be swallowed whole without crushing. You will take the tablets with at least 8 oz. of water with or without food. **You will not make up skipped doses.**

- **Group 1 – Receive rucaparib for your squamous cell lung cancer**

  If you are in this group, you will get the study drug called rucaparib for your squamous cell lung cancer. Rucaparib will be given by mouth twice a day 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 tablets. You will receive rucaparib until your disease gets worse or the side effects become too severe. Each cycle lasts 21 days.

  You also will keep a pill diary. This helps you keep track of when you take your pills. The study doctor will show you how to use this diary. Each time you visit the clinic, you must bring the pill diary, any remaining pills, and the pill bottle.

  There will be up to 44 people in this group.

- **Group 2 – Receive rucaparib for your non-squamous cell lung cancer**

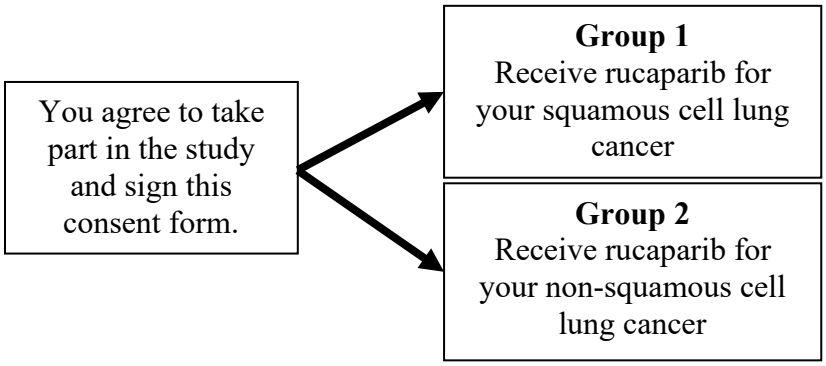
  If you are in this group, you will get the study drug called rucaparib for your non-squamous cell lung cancer. Rucaparib will be given by mouth twice a day about the same time every day as close to 12 hours apart as possible. It is important to swallow whole and not to chew the tablets. You will receive rucaparib until your disease gets worse or the side effects become too severe. Each cycle lasts 21 days.

  You also will keep a pill diary. This helps you keep track of when you take your pills. The study doctor will show you how to use this diary. Each time you visit the clinic, you must bring the pill diary, any remaining pills, and the pill bottle.

There will be up to 44 people in this group.

You will be put into Group 1 if you have squamous cell lung cancer. You will be put into Group 2 if you have non-squamous cell lung cancer.

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, there are some extra tests that you will need to have if you take part in this study:

- 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. 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 information collected will help the study doctors learn about tumor abnormalities that may play a role in tumor evolution. 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.

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

General Risks

If you choose to take part in this study, there is a risk that the study approach may not be as good as the usual approach for your cancer 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 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 6 months after you have completed the study.

Side Effect Risks

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

Possible side effects of rucaparib are listed in the tables below.

Possible Side Effects of Rucaparib
(Table Version Date: November 2, 2020)

COMMON, SOME MAY BE SERIOUS In 100 people receiving rucaparib, more than 20 and up to 100 may have:
• **Anemia which may cause tiredness, or may require blood transfusion** • **Bruising and bleeding** • **Pain in belly** • **Constipation** • **Diarrhea** • **Nausea** • **Vomiting** • **Tiredness** • **Decreased appetite** • **Changes in taste**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving rucaparib, from 4 to 20 may have:
• **Bloating** • **Heartburn** • **Dry mouth** • **Painful swelling and sores inside the mouth** • **Swelling of mucous linings in the body** • **Swelling of arms, legs** • **Fever** • **Infection especially when white blood cell count is low** • **Cold symptoms such as stuffy nose, sneezing, sore throat** • **Infection which may cause painful and frequent urination** • **Dehydration** • **Pain in joints** • **Pain in back** • **Pain in muscles, bone, ligaments, nerves** • **Pain in arms, legs** • **Dizziness** • **Headache** • **Worry** • **Depression** • **Difficulty sleeping** • **Cough** • **Shortness of breath**

- **Hair loss**
- **Dry skin**
- **Redness of the skin**
- **Increased risk of sunburn**
- **Itching**
- **Rash**
- **Hot flash**
- **High blood pressure which may cause headaches, dizziness, blurred vision**

RARE, AND SERIOUS

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

- **Damage to bone marrow (irreversible) which may cause infection, bleeding, and may require transfusions**
- **Cancer of the blood and bone marrow such as acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS)**
- **Damage to the lungs which may cause shortness of breath**

Additional Drug Risks

Photosensitivity Reaction

It is possible that rucaparib may make your skin and eyes more sensitive to sunlight. You should take all of the usual sun protection precautions when going outside. It is advised that you avoid excessive sun exposure, wear protective clothing (including wearing a hat and sunglasses), and use sunscreens regularly (sun protection factor 50 or greater).

Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML)

Myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) have been reported in a very small number of patients treated with rucaparib. MDS is a pre-cancerous condition where the bone marrow is not as good at producing blood cells (red and/or white blood cells and/or platelets) as it was before. People with MDS need transfusions (red blood cells and/or platelets) and/or other treatments. In some cases, MDS will progress to AML, which is a cancer of the bone marrow where more abnormal and immature white blood cells (also called blasts) are made than normal white blood cells. People with AML need treatment with chemotherapy and/or a transplant. Patients may develop AML without first being diagnosed with MDS.

Cases of MDS and AML have also been reported with PARP inhibitors similar to rucaparib. At this time, it is not known whether rucaparib or other PARP inhibitors cause MDS or AML, or if these developed as a result of previous chemotherapy these patients received. Your study doctor

will closely monitor your blood cell levels during treatment. If your study doctor has any concerns about your blood counts you may be asked to have a biopsy of your bone marrow.

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 rucaparib. If you are taking metformin (for diabetes), drugs that inhibit a substance known as BCRP (such as the statin rosuvastatin, often called Crestor), or warfarin (such as Coumadin, for blood clots) while you are taking rucaparib, your doctor will monitor you closely during treatment. Throughout your treatment, you should inform your doctor about any medication changes.

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. You must continue to use your approved method of birth control during the study and for 6 months after last dose.
For men: Do not father a baby while taking part in this study. You must continue to use your approved method of birth control during the study and for 3 months after last dose. Do not donate sperm while taking part in this study and for 3 months after your last dose of study treatment.
For all: Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 6 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 standard of care 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.
- the costs of getting the study agent (rucaparib) ready and giving it to you.
- your insurance co-pays and deductibles.

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

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

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

- The collection or testing of the circulating tumor DNA at the beginning of the study.

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

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

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

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

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

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

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

Who will see my medical information?

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

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

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

Some of these organizations are:

- The study sponsor, SWOG and any company supporting the study now or in the future.
- The Institutional Review Board, (IRB), 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 re assigned to, etc.) will be transferred using a computer program called TRIAD or 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.

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, we don't know what research may be done in the future using your information. This means that:

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

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

Where can I get more information?

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

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

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

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

Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading 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 to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

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 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 blood samples will be collected and stored. Storing samples for future studies is called "biobanking." The biobank is being run by SWOG and is supported by the NCI. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use.

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

This means that:

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

What is involved in this optional sample collection?

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

1. About 2 tablespoons of blood will be collected from a vein in your arm (at the same time as other study blood tests) on Weeks 4, 7, 10, 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, _____ *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)*, who will let the biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

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

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. My samples and related 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's signature (or legally authorized representative)

_____

Date of signature _____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature _____