# Informed Consent

## Study Title for Study Participants: Testing cabozantinib in patients with advanced pancreatic neuroendocrine and carcinoid tumors

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

A021602 – Randomized, double-blinded phase III study of cabozantinib versus placebo in patients with advanced neuroendocrine tumors after progression on everolimus

This study is conducted by the Alliance for Clinical Trials in Oncology, a national clinical research group supported by the National Cancer Institute. The Alliance is made up of cancer doctors, health professionals, and laboratory researchers, whose goal is to develop better treatments for cancer, to prevent cancer, to reduce side effects from cancer, and to improve the quality of life of cancer patients.

## What is the usual approach to my neuroendocrine tumor?

We are asking you to take part in this study because you have a pancreatic neuroendocrine tumor or carcinoid tumor that cannot be removed by surgery at this time or is known to have spread, and your cancer has been treated in the past with everolimus. Depending on each person's circumstances, people who are not in a study may be treated with best supportive care only, interventional radiology therapy, chemotherapy, radiation therapy, or a combination of any of these approaches. There are several FDA-approved chemotherapy drugs that can be used to treat neuroendocrine tumors, including everolimus, lanreotide, octreotide, and lutetium Lu 177 dotatate. Sunitinib and streptozocin are also FDA-approved chemotherapy drugs that can be used to treat pancreatic neuroendocrine tumors.

## 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 as described above.
- You may choose to take part in a different study, if one is available.
- You may choose not to be treated for cancer and may want to receive comfort care to relieve symptoms.

## Why is this study being done?

The purpose of this study is to compare any good and bad effects of using cabozantinib to using a placebo (a pill that contains no active drug). Cabozantinib is a chemotherapy drug known as a tyrosine kinase inhibitor, and it targets specific tyrosine kinase receptors, that when blocked, may slow tumor growth. Cabozantinib is already FDA-approved for use in thyroid and kidney cancers. The use of cabozantinib may or may not slow the growth of your cancer, but it could also cause side effects. This study will allow the researchers to know whether treatment with cabozantinib is better, the same, or worse than placebo. To be better, the study drug should extend life without tumor growth by 3.8 months or more compared to placebo for patients with pancreatic neuroendocrine tumors and 5 months or more compared to placebo for patients with carcinoid tumors. There will be about 395 people taking part in this study.

## What are the study groups?

This study has two groups:

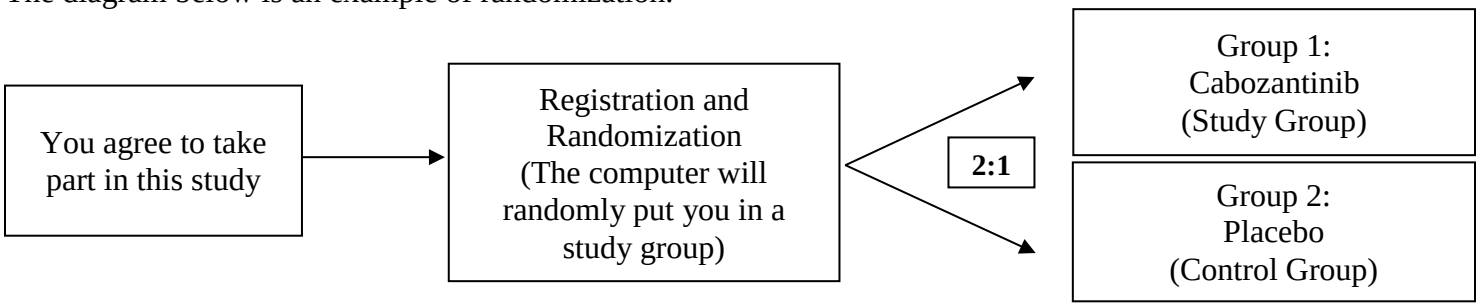
- Group 1 will receive the study drug, cabozantinib. You will take three 20 mg tablets by mouth once daily.
- Group 2 will receive the placebo. A placebo is a pill that looks like the study drug but contains no medication. You will take three 20 mg tablets by mouth once daily.

You will take the study drug or placebo on every day of each treatment cycle, and one cycle of treatment is 28 days. Patients in both Group 1 and Group 2 will be asked to keep a pill diary. Each time you visit the clinic, you must bring the pill diary, any remaining pills, and the pill bottle.

We will use a computer to assign you to one of the study groups (also called "randomization"). This means that you will be put into a group by chance, like flipping a coin. We assign patients in this way because no one knows if one treatment is better or worse than the others. The computer will randomize patients to the study groups in a 2 to 1 fashion, meaning that you are twice as likely to be randomized to Group 1 (cabozantinib) as you are to be randomized to Group 2 (placebo). In the event that your cancer gets worse while you are on study, you will not be able to crossover to Group 1 if you had been in Group 2.

Neither you nor your doctor will be told if you are getting cabozantinib or the placebo. However, in the case of an emergency, your doctor may be able to find out whether you are getting the cabozantinib or the placebo. If this happens, you will be required to stop taking study treatment (regardless of which group you are in). Even after you have completed study treatment, you and your doctor will not be told whether you received cabozantinib or a placebo tablet.

The diagram below is an example of randomization.




## How long will I be in this study?

You will receive the cabozantinib/placebo on every day of each treatment cycle, and treatment cycles will continue until your cancer gets worse, an unacceptable toxicity occurs, or you decide to no longer continue participating. After you finish chemotherapy, your doctor will continue to follow your condition and watch you for side effects for eight years from the day you registered; if you stop chemotherapy before your cancer gets worse, these follow-up visits will occur in clinic every 3 months until your cancer gets worse or you start a different treatment; and if you stop chemotherapy because your cancer gets worse or you start a different treatment, then your doctor will follow-up with you either in clinic or by phone at least every 6 months.

## 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 to make sure it is safe for you to take part. If you join the study, there will be exams, tests, and procedures that will be done to closely monitor your safety and health. Most of these are included in the usual care you would receive even if you were not in a study.

Listed below are those exams, tests, and procedures that may not be needed with the usual approach, but are needed or are needed more frequently if you are in the study. The purpose of these procedures is to ensure your safety. We will use them to carefully monitor the effects of the study treatment, including preventing and managing side effects.

Before you begin study treatment, in addition to your doctor's usual safety review, you will be asked to complete the following assessments and tests:

- Two Quality of Life Assessments
- An electrocardiogram (ECG). An ECG measures the electrical activity of the heart.
- Two blood tests to see how well your blood clots

Additionally, before you begin study treatment, a sample of your tumor tissue that had been collected during your previous biopsy or surgery is required to be sent to the Alliance Biobank, and then to an Alliance pathologist (a type of doctor who uses test results to figure out a diagnosis) to confirm your diagnosis at a later point. There will be no additional procedures necessary for the tissue submission and review, and the results of the review will not impact your ability to participate in this study.

During Cycles 1 and 2 only, you will be asked to complete the following exams and tests every 2 weeks, rather than every 4 weeks:

- A physical examination and blood tests

During study treatment, in addition to your doctor's usual follow-up of your condition, you will be asked to complete the following assessments and tests:

- A daily medication log where you will record the day, number of tablets taken, and the time of each dose of cabozantinib/placebo. You will be asked to bring the log (diary) with you to your clinic visits.
- A Quality of Life Assessment on the first day of each treatment cycle and at the end of study treatment
- An ECG on the first day of Cycle 2 and Cycle 3.

Because images of your type of cancer can be difficult to interpret, a copy of your imaging scans will be sent to a central radiology lab, the Alliance Imaging Lab at the Ohio State University, after any information that could identify you (e.g. your name) has been removed. In the event that your local doctors determine your cancer has gotten worse, the copy of your images will be reviewed by a group of Alliance radiologists as part of a "central review" to confirm that your cancer has gotten worse. You may continue taking the study drug/placebo until the results of the central review are available. If the central reviewer determines your cancer has gotten worse, then you will stop taking cabozantinib/placebo. If the central reviewer determines your cancer has not gotten worse, then you have the option to continue taking cabozantinib/placebo.
The insurance coverage information for the tests and other parts of the study is listed in a later section, "What are the costs of taking part in this study."

## 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 or private questions which you normally do not discuss
- The study drug may not be better, and could possibly be worse, than the usual approach for your cancer

The therapy 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 side effects from the study drugs or study approach.

Here are important points 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, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may result in hospitalization, irreversible illness, permanent disability, or even death.

You can ask the study doctor questions about side effects at any time. Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different, so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drug to try to reduce side effects.

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

**Risk Profile for XL184 (Cabozantinib) (CAEPR Version 2.4, December 17, 2018)**

| **COMMON, SOME MAY BE SERIOUS**<br>In 100 people receiving XL184 (cabozantinib), more than 20 and up to 100 may have: |
|---|
| • Diarrhea, nausea, vomiting<br>• Tiredness<br>• Weight loss, loss of appetite<br>• Changes in taste<br>• Redness, pain or peeling of palms and soles<br>• High blood pressure which may cause headaches, dizziness, blurred vision |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving XL184 (cabozantinib), from 4 to 20 may have: |
|---|
| • Anemia which may require blood transfusion<br>• Pain<br>• Constipation, heartburn |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving XL184 (cabozantinib), from 4 to 20 may have: |
|---|
| • Dry mouth, skin<br>• Sores in the mouth which may cause difficulty swallowing<br>• Swelling of arms, legs<br>• Infection<br>• Bruising, bleeding<br>• Dehydration<br>• Muscle weakness<br>• Dizziness, headache<br>• Cough, shortness of breath<br>• Internal bleeding which may cause black tarry stool, blood in vomit, coughing up blood, or blood in urine<br>• Bleeding from multiple sites including the nose<br>• Changes in voice<br>• Hair loss, rash<br>• Change in hair color<br>• Blood clot which may cause swelling, pain, shortness of breath |

| **RARE, AND SERIOUS**<br>In 100 people receiving XL184 (cabozantinib), 3 or fewer may have: |
|---|
| • A tear or hole in internal organs that may require surgery<br>• Non-healing surgical site<br>• Damage to the jawbone which may cause loss of teeth<br>• Bleeding in the brain which may cause confusion<br>• Stroke which may cause paralysis, weakness<br>• Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome)<br>• Lung collapse |

Reproductive Risks:
You should not get pregnant, breastfeed, or father a baby while in this study. The chemotherapy drug used in this study could be very harmful to an unborn or newborn baby. It is important you understand that you must use birth control while receiving study treatment and for at least 4 months after completing or discontinuing study treatment. Check with the study doctor about what types of birth control or pregnancy prevention to use and for how long while in this study.

Tell your study doctor right away if you suspect that you (or your partner) have become pregnant during the study or within 6 months after your last dose of study drug. They will ask for health information about the pregnancy.

Additional Drug Risks:
As noted above in the table, there is a risk of a blood clot forming which may cause swelling, pain, and/or shortness of breath when taking the study drug, but there is also a risk for a more serious type of blood clot forming specifically in your arteries. Arteries are the blood vessels that carry blood with oxygen to body tissues, and if a

serious blood clot forms in one of your arteries, it could block or stop the blood flow to your major organs which could cause side effects such as a heart attack or stroke.
The study drug could interact with other drugs, as well as with certain foods and beverages. You should be careful when taking other drugs that are processed by your liver, interact with similar molecules that move drug throughout your body, or affect your heart's electrical activity, and you should not drink or eat grapefruit/juice or Seville oranges while on cabozantinib/placebo. Your doctor may give you a drug information handout and a wallet card that lists these possible interactions. Share this information with your family members, caregivers, pharmacists, and other healthcare providers at all visits.

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

This study may or may not help you. It is not possible to know at this time if the study drug is better than the usual approach. This study will help researchers learn things that will help 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 remove you from the study, if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available
- You do not follow the study rules
- 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, you may contact the Operations Office of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) at 888-657-3711.

## What are the costs of taking part in this study?

<u>Your Potential Costs:</u>
You and/or your health plan/insurance company will be responsible for:

- The delivery of the study drug, non-study drugs, and all premedications, fluids and procedures.
- Exams, tests, and procedures that may be needed to manage side effects and to monitor your safety.

You are responsible for all copays and deductibles according to your insurance plan.

It is important for you to speak to your insurance plan to ensure that you understand your coverage and whether you might need approval to take part in a study. While most plans cover clinical trials, it is your responsibility to check with them.

If you take part in a Medicare Advantage Plan, your health care bills will be sent to the regular Medicare. This may result in a higher copay. The copay should be directed to your Medicare Advantage plan for payment after Medicare reimburses you.

Ask your doctor, nurse, case manager, or financial advisor if you are unsure which costs will be billed to your insurance plan. If you have other questions about what your plan covers, you may also ask to speak to a financial advisor or case manager at the hospital or clinic.

Costs Paid by the Study:
Exams, tests, and procedures done for research purposes only will not be billed to you or your insurance plan. These include the central review of your imaging scans and the central confirmation of your diagnosis.

The cabozantinib/placebo will not be billed to you or your insurance plan while you take part in this study. Rarely, unexpected problems in drug supply could occur, but if that event occurs, your doctor will talk with you about your options.

- The extra ECG before you begin study treatment and on the first day of Cycles 2 and 3 will be paid for by the drug company supporting this study as these would not be included in the usual care you would receive even if you were not in a study.
- The extra blood tests before you begin study treatment will be paid for by the drug company supporting this study as these would not be included in the usual care you would receive even if you were not in a study.

You will not be paid for taking part in this study. If the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

## 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 tell your study doctor. Contact information for your study doctor is listed on the consent cover page. 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 have legal rights to receive payment for this injury even though you are in a study.

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 and the researchers will make every effort to protect it. However, 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 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. Your health information in the database may also be shared with these organizations. They are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- Montana Cancer Consortium
- The Alliance, and any of its agents

- Exelixis, or any drug company supporting this study, and any of its agents
- Imaging and Radiation Oncology Core at Ohio (IROC Ohio)
- The Institutional Review Board (IRB), 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 National Cancer Institute (NCI) in the U.S.

## 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 information for your study doctor is listed on the consent cover page.

## Additional Studies Section
## (This section is about the optional studies and biobanking you can choose to take part in.)

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

Neither you nor your insurance will be billed for the optional studies and biobanking. You can still take part in the main study even if you say “no” to either or both the optional studies and the biobanking for future studies. If you sign up for, but cannot complete either the optional studies or biobanking for any reason, you can still take part in the main study.

Circle your choice of “yes” or “no” for each of the following options.

## Optional Quality of Life Study

If you choose to take part in this quality of life study, you will be asked to fill out forms with questions about your physical and emotional well-being, as well as about any side effects you may experience. These forms are in addition to the Quality of Life Assessments you are asked to fill out as part of the main study.

Researchers will use this information to view how your life has been affected by cancer and its treatment. This “Self-reporting of Symptoms” part of the study looks at how you are feeling physically and emotionally during your cancer treatment. It also looks at how you are able to carry out your day-to-day activities.

This information will help doctors better understand how patients feel during treatments and what effects the medicines are having. In the future, this information may help patients and doctors as they decide which medicines to use to treat cancer.

You will be asked to fill out three forms at the following time points:

- At the time of registration
- About every 12 weeks (i.e. every 3 cycles) until the event that your cancer gets worse or your doctor decides to start a new anticancer treatment

The forms will take about 15 minutes to complete at each of these time points. The forms will ask about things like fatigue, diarrhea, and depression. You may feel uncomfortable answering some of the questions, and you can skip any you do not want to answer.

Please circle your answer: I choose to take part in the Quality of Life study and will fill out these forms:

YES NO

## Optional Sample Collections for a Known Laboratory Study and/or Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer and other health problems using samples from people's tissue, blood, or other fluids. By conducting research on these samples, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about how genes affect health and disease and how people respond to treatment. Genes carry information about features that are found in you and your family, from the color of your eyes to health conditions for which you may be at risk. Research that studies your genes is known as genomics or genetics.

**Known Future Study**

If you choose to take part in this optional study, researchers will collect blood samples for research on how your body processes the cabozantinib/placebo. The researchers are interested in how the study drug is broken down, how much of the study drug is absorbed, how much of the study drug remains in your body over time, and whether those amounts of study drug in your body are related to any side effects you may experience or to how your cancer responds to treatment. While you are on study, approximately 1 teaspoon of additional blood for this research will be collected at the following time points:

- On the first day of treatment (Cycle 1 Day 1)
- Approximately 2 weeks after beginning treatment (Cycle 1 Day 15)
- Approximately 1 month after beginning treatment (Cycle 2 Day 1)
- Approximately 1.5 months after beginning treatment (Cycle 2 Day 15)
- Approximately 2 months after beginning treatment (Cycle 3 Day 1)

In addition, you will be asked to complete a questionnaire to provide information about when you have been taking the cabozantinib/placebo for the 48 hours prior to your clinic visits during Cycles 1 through 3. The questionnaire will take about 2 minutes to complete at each of these time points.

**Biobanking for Unknown Future Studies**
If you choose to take part, blood and tissue samples will be collected and stored, along with related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for future medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking." The Biobank is being run by the Alliance for Clinical Trials in Oncology and is supported by the National Cancer Institute.

If you choose to take part in this optional biobanking, the researchers would like to collect some of the tissue that was already collected from your diagnostic biopsy or surgery.

In the event that your cancer gets worse and you require a biopsy or surgery (or you experience a side effect that may be related to the study treatment and require a biopsy or surgery), the researchers would also like to collect some of the tissue that would have already been collected during your biopsy or surgery.

The researchers would like to collect additional samples of your blood. They would like to investigate whether substances in your blood (sometimes called biomarkers) are related to the way that your body responds or doesn't respond to the therapy you receive in this trial. While you are on the study, approximately 2 tablespoons of additional blood for this research would be collected at the following time points:

- On the first day of treatment (Cycle 1 Day 1)
- Approximately 1 month after beginning treatment (Cycle 2 Day 1)
- In the event that your cancer gets worse

## What is involved?

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

1) About 1 teaspoon of blood will be collected from a vein in your arm at the time points listed above for the known future study. This blood will be sent directly to the Alliance Laboratory at the University of Pittsburgh along with your initials and the collection date and time. About another 2 tablespoons of blood will be collected from a vein in your arm at the time points listed above for the unknown future studies. In addition, a sample from the tissue that was collected at the time of your previous (or future) biopsy or surgery will be sent to the Biobank for the unknown future studies.
2) Your samples and some related health information may be stored in the Biobank, along with samples and information from other people who take part. 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.

## 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) 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.
3) 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.
4) In some cases, this information could be used to make it harder for you 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 these things will happen is very small, but cannot promise that they 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 by the Biobank to the qualified 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 samples and health information. Any Biobank and Alliance staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom the Alliance sends your samples 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, who will let the researchers know. Contact information for your study doctor is listed on the consent cover page. Then, any sample that remains in the Biobank will either be destroyed or returned to your doctor and related health information will no longer be collected. This will not apply to those samples or related information that have already been given to or used by qualified researchers.

## What if I have questions?

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 to show whether or not you would like to take part in each option:

## Optional samples for the known future research study:

I agree to have my blood collected, and I agree that my blood samples and related information may be used for the laboratory study described above.

YES NO

## Optional samples for biobanking for unknown future research studies:

I agree to have my blood and tissue collected, and I agree that my blood and tissue samples and related information may be kept in a Biobank for use in future health research.

YES NO

## Contact for future research:

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.

## Signature:

This study has been explained to me, and I have been told what my enrollment in the study involves. I have read all pages of this consent and have had my questions answered to my satisfaction at this time. I consent to participate in this study and any additional studies where I circled 'yes'. I understand that by signing this form I have not given up any of my legal rights. I will be given a copy of this consent form. I may also request a copy of the protocol (full study plan).

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

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