

**Study Title for Study Participants: Testing Cabozantinib, Crizotinib, Savolitinib and Sunitinib in Kidney Cancer Which Has Progressed**

**Note: Since December 2018, for the new patients entering the study, the study is testing only Cabozantinib and Sunitinib.**

**Official Study Title for Internet Search**

**on <http://www.ClinicalTrials.gov>: S1500, "A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET)"**

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

**What is the usual approach to my kidney cancer?**

You are being asked to take part in this study because you have papillary kidney cancer that has spread to other parts of your body or cannot be treated with surgery. Papillary kidney cancer is a rare type of kidney cancer that does not respond well to medications currently approved for kidney cancer treatment. Lab research indicates that the protein/enzyme called MET plays an important role in the growth and spread of papillary kidney cancer. The experimental drugs block the function of the MET protein/enzyme and it is hoped that it will shrink or slow down the growth of the papillary kidney cancer. People who are not in a study are usually treated with one of several FDA approved targeted treatments, including sunitinib, temsirolimus or pazopanib.

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

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

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

## Why is this study being done?

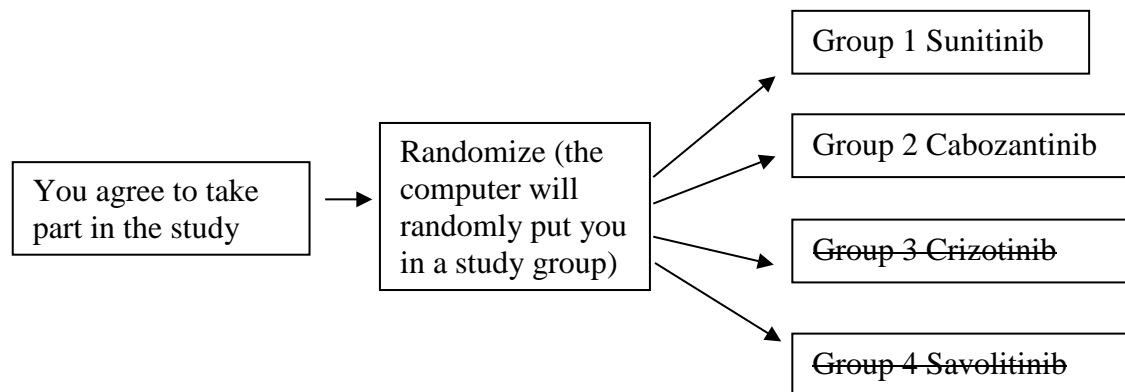
The purpose of this study is to compare three experimental drugs not approved by the FDA to treat advanced kidney cancer (crizotinib, cabozantinib and savolitinib) that block a protein called MET to the drug sunitinib which is currently a standard treatment to see if any of these drugs slow down tumor growth compared to sunitinib. Sunitinib is approved by the FDA for treating advanced kidney cancer, but not specifically for treating papillary kidney cancer. This study will allow researchers to know whether any of these drugs are better, the same, or worse than sunitinib. For any of the experimental drugs to be considered better, the experimental drug should increase life by four and a half months or more compared to the drug sunitinib. There will be about 180 people taking part in this study.

Since December 2018, for new patients entering the study, the study is comparing only two drugs: the experimental drug cabozantinib and the standard treatment drug sunitinib.

## What are the study groups?

A computer will by chance assign you to treatment groups in the study. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the others. Neither you nor your doctor can choose which group you will be in.

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.



This study has four study groups.

\*As of December 5, 2018, only two study groups remain open. You will be placed in either Group 1 or Group 2.

If you are in Group 1 will receive the usual sunitinib drug. You will take sunitinib every day for the first four weeks (28 days) and then not take it for the next two weeks (days 29-42). This six

week period is called a “cycle” and you will repeat this pattern of taking sunitinib every day for four weeks and then not taking it, or resting, for two weeks until your doctor tells you not to take the drug. Sunitinib is to be taken orally with or without food. You should not eat grapefruit or Seville oranges, or drink grapefruit juice, as these can cause a harmful interaction with sunitinib.

If you are in Group 2 will receive the experimental drug cabozantinib. You will take cabozantinib tablets every day. Each six week period is called a “cycle.” Cabozantinib must be taken on an empty stomach. In other words, you must not eat two hours before you take cabozantinib and then not for one hour after you take cabozantinib. You should not eat grapefruit or Seville oranges, or drink grapefruit juice, as these can cause a harmful interaction with cabozantinib. If you miss a dose, you should not take it if it is within twelve hours of your next dose. Cabozantinib must be swallowed whole and cannot be crushed or chewed.

If you are in Group 3 will receive the experimental drug crizotinib. You will take crizotinib capsules every day. Each six week period is called a “cycle.” Crizotinib is to be taken orally with or without food. **(Group closed 12/5/18).**

If you are in Group 4 will receive the experimental drug savolitinib tablets every day. Each six week period is called a “cycle.” Savolitinib must be taken with food (specifically within one hour after the start of a meal). Savolitinib tablets must be swallowed whole with water. You should not eat grapefruit or Seville oranges, or drink grapefruit juice, as these can cause a harmful interaction with savolitinib. **(Group closed 12/5/18).**

No matter which group you are in, you will be asked to keep a medication diary (a calendar showing when you took your medication) to help keep track of the number of tablets/capsules you take and any side effects. This medication diary is also called an Intake calendar and you will need to bring it and the pill container with you for your follow-up visits. You should complete the medication diary daily.

The study doctor will provide you with information in the form of a patient drug information handout and wallet card regarding other drugs you may need to avoid while receiving study drugs.

### **How long will I be in this study?**

You will receive the study drugs for as long as the cancer remains stable or shrinks and you don't experience significant side effects from the treatment. After you finish the study drugs your doctor will continue to watch you for side effects and follow your condition for up to three years.

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

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

Before you begin the study:

A small piece of cancer tissue removed from a previous biopsy will be taken for the study before you begin study drug. This sample is required in order for you to take part in this study because the research on the sample is an important part of the study.

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

Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. You and your study doctor will not know the results of the tests.

## **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 drugs may not be better, and could possibly be worse, than the usual approach for your cancer.**

**The study doctor will provide you with information about other drugs you may need to avoid while receiving the study drugs.**

**The drugs 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 be testing your blood and will let you know if changes occur that may affect your health.**

**There is also a risk that you could have side effects from the study drugs.**

**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 even result in death.**

**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 drugs to try to reduce side effects.**

**The tables below show the most common and the most serious side effects that researchers know about. 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.**

**Possible Side Effects of Sunitinib (Group 1):**

<b>COMMON, SOME MAY BE SERIOUS</b>
In 100 people receiving sunitinib malate, more than 20 and up to 100 may have:
<ul style="list-style-type: none"><li>• <b>Pain</b></li><li>• <b>Constipation, diarrhea, heartburn, nausea, vomiting</b></li><li>• <b>Sores in the mouth</b></li><li>• <b>Tiredness</b></li><li>• <b>Loss of appetite</b></li><li>• <b>Changes in taste</b></li><li>• <b>Sore throat</b></li><li>• <b>Redness, pain or peeling of palms and soles</b></li></ul>

<b>OCCASIONAL, SOME MAY BE SERIOUS</b>
In 100 people receiving sunitinib malate, from 4 to 20 may have:
<ul style="list-style-type: none"><li>• <b>Anemia which may require blood transfusion</b></li><li>• <b>Blurred vision with chance of blindness</b></li><li>• <b>Bloating, passing gas</b></li><li>• <b>Dry mouth, skin</b></li><li>• <b>Chills, fever</b></li><li>• <b>Swelling of arms, legs</b></li><li>• <b>Flu-like symptoms including body aches</b></li><li>• <b>Bruising, bleeding</b></li><li>• <b>Infection, especially when white blood cell count is low</b></li><li>• <b>Dehydration, weight loss</b></li><li>• <b>Dizziness, headache</b></li><li>• <b>Feeling of "pins and needles" in arms and legs</b></li></ul>

- **Depression**
- **Difficulty sleeping**
- **Cough, shortness of breath**
- **Nose bleed**
- **Hair loss, itching, rash, skin changes**
- **Change in hair color**
- **High blood pressure**

**RARE, AND SERIOUS**  
**In 100 people receiving sunitinib malate, 3 or fewer may have:**

- **Anemia, kidney problems which may require dialysis**
- **Blood clot which may cause confusion, paralysis, seizures, swelling, pain, or shortness of breath**
- **Damage to organs (heart, brain) which may cause shortness of breath, swelling of ankles, and tiredness, or changes in thinking**
- **Heart failure, heart attack which may cause shortness of breath, swelling of ankles, and tiredness**
- **Pain and swelling of thyroid**
- **Difficulty swallowing**
- **A tear or hole in internal organs which may cause drainage and may require surgery**
- **Swelling of the liver**
- **Liver damage which may cause yellowing of eyes and skin, swelling**
- **Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat**
- **Flesh-eating bacteria syndrome**
- **Non-healing surgical site**
- **Change in the heart rhythm**
- **Kidney damage which may require dialysis**
- **Muscle pain and/or weakness with dark red urine**
- **Damage to the jawbone which may cause loss of teeth**
- **Stroke**
- **Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome)**
- **Sores on the skin**
- **Severe skin rash with blisters and peeling which can involve mouth and other parts of the body**
- **Cancer of bone marrow caused by chemotherapy**
- **Damage to bone marrow (irreversible) which may cause infection, bleeding, may require transfusions**

**Possible Side Effects of Cabozantinib (XL184) (Group 2):**

<p style="text-align: center;"><b>COMMON, SOME MAY BE SERIOUS</b></p> <p><b>In 100 people receiving XL184 (Cabozantinib s-malate) more than 20 and up to 100 may have:</b></p>
<ul style="list-style-type: none"><li>• <b>Diarrhea, nausea, vomiting</b></li><li>• <b>Tiredness</b></li><li>• <b>Weight loss, loss of appetite</b></li><li>• <b>Changes in taste</b></li><li>• <b>Changes in voice</b></li><li>• <b>Redness, pain or peeling of palms and soles</b></li><li>• <b>High blood pressure which may cause blurred vision</b></li></ul>

<p style="text-align: center;"><b>OCCASIONAL, SOME MAY BE SERIOUS</b></p> <p><b>In 100 people receiving XL184 (Cabozantinib s-malate), from 4 to 20 may have:</b></p>
<ul style="list-style-type: none"><li>• <b>Anemia which may require blood transfusion</b></li><li>• <b>Pain</b></li><li>• <b>Constipation, heartburn</b></li><li>• <b>Dry mouth, skin</b></li><li>• <b>Sores in mouth which may cause difficulty swallowing</b></li><li>• <b>Swelling of arms, legs</b></li><li>• <b>Infection</b></li><li>• <b>Bruising, bleeding</b></li><li>• <b>Dehydration</b></li><li>• <b>Muscle spasms</b></li><li>• <b>Dizziness, headache</b></li><li>• <b>Kidney damage which may require dialysis</b></li><li>• <b>Cough, shortness of breath</b></li><li>• <b>Internal bleeding which may cause coughing up blood, black tarry stool or blood in vomit</b></li><li>• <b>Bleeding from multiple sites including the nose</b></li><li>• <b>Hair loss, rash</b></li><li>• <b>Change in hair color</b></li><li>• <b>Blood clot which may cause swelling, pain, shortness of breath</b></li></ul>

<p style="text-align: center;"><b>RARE, AND SERIOUS</b></p> <p><b>In 100 people receiving XL184 (Cabozantinib s-malate), 3 or fewer may have:</b></p>
<ul style="list-style-type: none"><li>• <b>A tear or hole in internal organs that may require surgery</b></li><li>• <b>Non-healing surgical site</b></li><li>• <b>Damage to the jawbone which may cause loss of teeth</b></li><li>• <b>Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome)</b></li><li>• <b>Lung collapse</b></li></ul>

**Possible Side Effects of Crizotinib (Group 3):**

<b>COMMON, SOME MAY BE SERIOUS</b>
<b>In 100 people receiving crizotinib, more than 20 and up to 100 may have:</b>
<ul style="list-style-type: none"><li>• <b>Visual disturbances</b></li><li>• Swelling of the eye</li><li>• Constipation, diarrhea, nausea, vomiting</li><li>• Swelling of the body</li><li>• Tiredness</li></ul>

<b>OCCASIONAL, SOME MAY BE SERIOUS</b>
<b>In 100 people receiving crizotinib, from 4 to 20 may have</b>
<ul style="list-style-type: none"><li>• Anemia which may require blood transfusion</li><li>• Abnormal heartbeat</li><li>• <b>Pain</b></li><li>• Heartburn</li><li>• Sores in the mouth</li><li>• <b>Cold symptoms such as stuffy nose, sneezing, sore throat</b></li><li>• Infection, especially when white blood cell count is low</li><li>• Loss of appetite</li><li>• Dizziness, headache</li><li>• Changes in taste</li><li>• <b>Damage to nerves that may interfere with walking or organ function which may cause numbness, tingling, weakness</b></li><li>• Rash, <b>itching</b></li></ul>

<b>RARE, AND SERIOUS</b>
<b>In 100 people receiving crizotinib, 3 or fewer may have:</b>
<ul style="list-style-type: none"><li>• Heart failure which may cause shortness of breath, swelling of ankles, and tiredness</li><li>• <b>A tear or hole in the bowels that may require surgery</b></li><li>• <b>Sores in the throat</b></li><li>• Difficulty swallowing</li><li>• Liver damage which may cause yellowing of eyes and skin, swelling</li><li>• Change in the heart rhythm</li><li>• Fainting</li><li>• <b>A sac in the kidney that is filled with fluid</b></li><li>• Damage to the lungs which may cause shortness of breath</li></ul>



**Possible Side Effects of Savolitinib (Group 4):**

<b>COMMON, SOME MAY BE SERIOUS</b> In 100 people receiving savolitinib, more than 20 and up to 100 may have:
<ul style="list-style-type: none"><li>• Nausea, vomiting</li><li>• Tiredness</li></ul>

<b>OCCASIONAL, SOME MAY BE SERIOUS</b> In 100 people receiving savolitinib, from 4 to 20 may have
<ul style="list-style-type: none"><li>• Anemia which may require blood transfusion</li><li>• Constipation, diarrhea</li><li>• Swelling of arms, legs</li><li>• Fever</li><li>• Liver damage which may cause yellowing of the eyes and skin</li><li>• Loss of appetite</li><li>• Rash</li></ul>

<b>RARE, AND SERIOUS</b> In 100 people receiving savolitinib (AZD6094), 3 or fewer may have:
<ul style="list-style-type: none"><li>• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat</li><li>• Severe skin rash with blisters and peeling which can involve mouth and other parts of the body</li><li>• Changes in electrical activity in the heart (detected by an electrocardiogram). Savolitinib may lead to an abnormal ECG result due to heart rhythm changes which usually occur without symptoms. However, in some patients, such changes may cause rapid or irregular heart beating, dizziness, light-headedness, chest discomfort, shortness of breath, losing consciousness and sudden death. These or other new symptoms should be reported immediately to your doctor.</li></ul>

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

**Reproductive risks:** You should not get pregnant, breastfeed, or father a baby while in this study. The study drugs used in this study could be very damaging to an unborn baby. If you are female or male and can have children, you must agree to use an effective contraceptive method while receiving study drug and for three months after your last dose of study drug. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study. If you become pregnant or suspect you are pregnant while participating on this study, tell your study doctor immediately.

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

**It is not possible to know at this time if the study drugs are better than the usual approach so this study may or may not help you. This study will help researchers learn things that may 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 take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

## **What are my rights in this study?**

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

For questions about your rights while in this study, 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?**

The study agents (crizotinib, sunitinib, cabozantinib, and savolitinib) will be supplied at no charge while you take part in this study. The cost of getting the study agent ready and giving it to you is not paid by the study sponsor so you or your insurance company may have to pay for this. It is possible that the study agent may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

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

you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

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

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

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. 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 keep all your legal rights to receive payment for this 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. 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. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

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

- Montana Cancer Consortium
- SWOG, Alliance, NRG and ECOG-ACRIN, and study sponsor and any drug company supporting the study.
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

## **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 optional studies you can choose to take part in**

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor will not know the results.

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

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

#### **1. 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**

## **2. Optional Biobanking for Possible Future Studies**

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

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

If you choose to take part in this study, the study doctor for the main study would like to collect blood and tissue from a previous biopsy for research on markers in your blood that may predict whether or not the drugs used in the study will work.

If you choose to take part, a sample of tissue from your previous biopsy and blood will be collected. The researchers ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for 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 SWOG and supported by the National Cancer Institute.

### **WHAT IS INVOLVED?**

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

- 1) About 1 tablespoon of blood will be collected from a vein in your arm prior to receiving study drug, prior to your second treatment cycle, prior to your third treatment cycle and when you discontinue protocol treatment. These blood samples and a sample from the tissue that was collected at the time of your surgery will be sent to the Biobank.

Your sample 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.

- 2) 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.
- 3) 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.

- 4) 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 sample(s) is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
- 2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and SWOG staff with access to the list must sign an agreement to keep your identity confidential.
- 3) Researchers to whom SWOG sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
- 4) Information that identifies you will not be given to anyone, unless required by law.
- 5) If research results are published, your name and other personal information will not be used.

## **WHAT ARE THE POSSIBLE BENEFITS?**

You will not benefit from taking part. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

### **ARE THERE ANY COSTS OR PAYMENTS?**

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

### **WHAT IF I CHANGE MY MIND?**

If you decide you no longer want your samples to be used, you can call the study doctor, 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 bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

### **WHAT IF I HAVE MORE QUESTIONS?**

If you have questions about the use of your samples for research, contact the study doctor. 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:

### **SAMPLES FOR FUTURE RESEARCH STUDIES:**

**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.

**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)



## **Specimen Consent Supplemental Sheets**

### **How are Specimens Used for Research?**

#### **Where do specimens come from?**

A specimen may be from a blood sample or from bone marrow, skin, toenails or other body materials. People who are trained to handle specimens and protect donors' rights make sure that the highest standards of quality control are followed by SWOG. Your doctor does not work for SWOG, but has agreed to help collect specimens from many patients. Many doctors across the country are helping in the same way.

#### **Why do people do research with specimens?**

Research with specimens can help to find out more about what causes cancer, how to prevent it, how to treat it, and how to cure it. Research using specimens can also answer other health questions. Some of these include finding the causes of diabetes and heart disease, or finding genetic links to Alzheimer's.

#### **What type of research will be done with my specimen?**

Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your specimen may look for genetic causes and signs of disease.

#### **How do researchers get the specimen?**

Researchers from universities, hospitals, and other health organizations conduct research using specimens. They contact SWOG and request samples for their studies. SWOG reviews the way that these studies will be done, and decides if any of the samples can be used. SWOG gets the specimen and information about you from your hospital, and sends the specimen samples and some information about you to the researcher. SWOG will not send your name, address, phone number, social security number or any other identifying information to the researcher.

#### **Will I find out the results of the research using my specimen?**

You will not receive the results of research done with your specimen. This is because research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to people like you in the future.

#### **Why do you need information from my health records?**

In order to do research with your specimen, researchers may need to know some things about you. (For example: Are you male or female? What is your race or ethnic group? How old are you? Have you ever smoked?) This helps researchers answer questions about diseases. The information that will be given to the researcher may include your age, sex, race, diagnosis, treatments and family history. This information is collected by your hospital from your health record and sent to SWOG. If more information is needed, SWOG will send it to the researcher.

#### **Will my name be attached to the records that are given to the researcher?**

No. Your name, address, phone number and anything else that could identify you will be removed before they go to the researcher. The researcher will not know who you are.

**How could the records be used in ways that might be harmful to me?**

If your confidential genetic information is discovered, you may suffer from genetic discrimination. Genetic discrimination occurs if people are treated unfairly because of differences in their genes that increase their chances of getting a certain disease. In the past, this could have resulted in the loss of health insurance or employment. Because of this, The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, was passed by Congress to protect Americans from such discrimination. The new law prevents discrimination from health insurers and employers. This act was signed into federal law on May 21, 2008, and went into effect May 2009. This law does not cover life insurance, disability insurance and long-term care insurance.

While this study has safeguards in place to protect your confidential genetic information and to make it extremely unlikely that your identity would be connected with any special studies that are performed on your tissue, it is possible that this information could be discovered by someone who is unauthorized to have access to it.

**How am I protected?**

SWOG is in charge of making sure that information about you is kept private. SWOG will take careful steps to prevent misuse of records. Your name, address, phone number and any other identifying information will be taken off anything associated with your specimen before it is given to the researcher. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the research process will not have access to results about any one person which will help to protect your privacy.

**What if I have more questions?**

If you have any questions, please talk to your doctor or nurse, or call our research review board at 888-657-3711.