SWOG S0820
Protocol Version: Amendment #2
Date 1/27/2017

NCI Commuity Oncology Research Program – Kansas City (NCORP-KC)

S0820, "A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III - Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)"

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.

You are being asked to take part in this study because you have a history of Stage 0, I, II, or III colon or rectal cancer that has been treated with surgery alone or in combination with radiation or chemotherapy.

Why is this study being done?

Colorectal adenomas are tiny growths in the colon that may eventually lead to cancer. The purpose of this study is to determine if eflornithine and sulindac, taken alone or in combination, can decrease the risk of high-risk adenomas or second primary colorectal cancers in patients who have been treated for Stage 0, I, II, or III colon or rectal cancer. ("Second primary colorectal cancer" means a new colorectal cancer developing within the colorectum.)

The study drugs eflornithine and sulindac are tablets which are taken orally. Sulindac is commercially available but is not approved for this indication. Oral eflornithine is an investigational agent and not approved by the FDA.

How many people will take part in the study?

About 480 people will take part in this study.

Approval Date 7/13/2017 to 7/12/2018

Assurance#: FWA00003582

What will happen if I take part in this research study?

Before you begin the study …

You will need to have the following exams, tests or procedures to find out if you can be in the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor. These tests will be performed in the outpatient setting.

- Medical History, including access to your medical records (colonoscopy report, pathology reports, current supplement and medication use, etc.)
- Physical exam (including height, weight)
- Bloodwork to check your general health
- Computed tomography (i.e., CT, "CAT") scan of the body (chest/abdomen/pelvis) if your study doctor feels it is necessary
- Audiogram to check hearing
- Blood sample for carcino embryonic antigen (CEA) test only for patients with certain tumor types (this will be determined by your study doctor). This test measures the amount of protein in blood which may be elevated in people with colon cancer and rectal cancer. The test is used, along with other indicators, to find out how widespread the cancer is and to check the success of treatment.

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will be asked whether you want to submit blood specimens for use in future research studies (see optional studies at the end of this form), and a blood sample for these studies will be collected and submitted to a special laboratory.

Starting the study …

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in any group.

If you are in Group 1 (often called "Arm 1"), you will take two (light tan) eflornithine placebo tablets once a day and one (golden-yellow) sulindac placebo tablet once a day. Placebo tablets look identical to the eflornithine and sulindac tablets, but they do not contain any medication.

If you are in Group 2 (often called "Arm 2"), you will take two (light tan) eflornithine tablets once a day and one (golden-yellow) sulindac placebo tablet once a day. The placebo tablet looks identical to the sulindac tablet, but it does not contain any medication. Effective April 14, 2017, patients will no longer be enrolled to this arm.

If you are in Group 3 (often called "Arm 3"), you will take two (light tan) eflornithine placebo tablets once a day and one (golden-yellow) sulindac tablet once a day. The placebo tablet looks identical to the eflornithine tablets, but they do not contain any medication. Effective April 14, 2017, patients will no longer be enrolled to this arm.

If you are in Group 4 (often called "Arm 4"), you will take two (light tan) eflornithine tablets once a day and one (golden-yellow) sulindac tablet once a day.

The eflornithine/placebo tablet needs to be taken with food to decrease stomach upset. The sulindac/placebo tablet needs to be taken with food and plenty of water to decrease stomach upset and should be taken with plenty of water to reduce the risk of kidney stones.

You will be given a 3-month supply of study drugs along with the "intake calendar" where you will record the number of pills you take each day and any side effects.

While receiving treatment on this study, you may not take corticosteroids (like prednisone or methylprednisolone) or anticoagulants (like heparin or coumadin®). Nonsteroidal anti-inflammatory drugs (NSAIDs) (like ibuprofen, Advil®, Motrin®, Aleve®, Ketoprofen, or Orudis®) may not be taken more frequently than 10 days per month. Aspirin may be taken as long as the dose is 100 mg or less per day or two 325 mg tablets or less per week.

Every 3 months for the first year while on the study …

You will need these tests and procedures that are being done to see how the study drugs are affecting your body.

- Follow-up visits (approximately 20 minutes) – check for side effects, count pills, review your calendar, do bloodwork
- Physical exam (including height, weight)
- Blood work to check your general health
- CEA test (if your study doctor feels it is necessary) This test measures the amount of protein in blood which may be elevated in people with colon and rectal cancer. The test is used, along with other indicators, to find out how widespread the cancer is and to check the success of treatment.

You will be given a 3-month supply of study drugs at each clinic visit. You will take study drug through Month 36.

Every 3 months during Years 2 and 3, you will need to come to the clinic to pick up study drug. You will not be seen by study doctor at months 15, 21, 27, and 33. The purpose of these visits is to pick up study drug.

Every 6 months during the 2nd and 3rd years while on the study …

You will need these tests and procedures that are being done to see how the study drugs are affecting your body.

- Physical exam (including height, weight); assessment of side effects, count pills, and review your calendar
- Blood work to check your general health
- CEA test (if your study doctor feels it is necessary)

At Month 12, Month 24 and Month 36…

- CT scan (if your study doctor feels it is necessary)

At the end of 36 months …

At the end of 36 months, (and at any time while you are on study, if your study doctor feels it is necessary) you will have a colonoscopy. Your study doctor will provide you with the description and instructions for this procedure.

You will also have:

- Physical exam (including height, weight); assessment of side effects, count pills, and review your calendar
- Bloodwork to check your general health
- Audiogram to check hearing
- Blood sample for carcino embryonic antigen (CEA) test (if your study doctor feels it is necessary). This test measures the amount of protein in blood which may be elevated in people with colon and rectal cancer. The test is used, along with other indicators, to find out how widespread the cancer is and to check the success of treatment.

How long will I be in the study?

You will be asked to take the study drug for 36 months. Then you will come to the clinic once a year for 5 more years to check your general health.

Eight years after registration to this study, you will have a colonoscopy.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop.

It is important to tell the study doctor if you are thinking about stopping so any risks from the study drug can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing that could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

If you are found to have abnormal tests during the course of this study, drugs may be stopped and this abnormality evaluated per your doctor's plan. If you are found to have a high grade polyp(s) or colon cancer or any other cancer, you will be taken off study.

The researcher may also decide to take you off this study if: you become pregnant; the side effects of the study drug are too dangerous for you; new information about the study intervention becomes available and this information suggests the intervention will be ineffective or unsafe for you. It is unlikely, but the study may be stopped early due to lack of drug supply or lack of funding.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the study drug. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to eflornithine include:

<u>Likely</u>

- **Nausea**
- **Vomiting**
- **Diarrhea**

<u>Less Likely</u>

- **Hearing loss***
- **Rash**
- **Hair loss**
- **Loss of appetite**
- **Abdominal pain**
- **Decrease of white blood cells, platelets and red blood cells****

Rare but serious
- Seizures

* Previous clinical trials using eflornithine showed a small increase in side effects related to hearing (ototoxicity). Therefore, you will be monitored closely for hearing loss throughout the study.

** This decrease in white blood cells, platelets and red blood cells is called Myelosuppression. Myelosuppression and seizures have occurred at higher doses than what is being given in this study. Lower white blood cell counts may lead to infection which could be life-threatening. Lower platelets may lead to bruising or bleeding which could be life-threatening. This side-effect may require you to receive a transfer of blood platelets from a donor. Lower red blood counts may cause you to feel tired or have shortness of breath and may require you to have a transfer of red blood cells from a donor. Lower red blood counts could be life-threatening.

Risks and side effects related to sulindac include:

Less Likely
- Stomach upset
- Nausea
- Swelling of hands/arms/feet/legs
- Itching
- Rash
- Abdominal pain
- Constipation
- Diarrhea
- Indigestion
- Cramping
- Bleeding (in the stomach or intestinal tract or other bleeding)
- Impaired wound healing
- Stomach ulcers
- Decreased appetite
- Feeling nervous
- Ringing in ears
- Headache
- Dizziness
- Liver impairment (decreased liver function)
- Kidney impairment (decreased kidney function)
- Nephritis (inflammatory kidney condition)
- Nephritic Syndrome (Protein leakage in urine)

- Renal Stone Disease (kidney stone formation)
- Heart attack
- Stroke
- Inflammation of the pancreas
- Fever
- Decrease blood counts

Rare but Serious

- Anaphylaxis (severe allergic reactions)
- Cardiovascular events (side effects related to the heart)
- Prolonged bleeding time
- GI perforation (rupture in the GI tract)
- Exfoliative dermatitis (peeling of the skin)
- Steven-Johnson syndrome (a potentially life-threatening condition resulting in severe reaction of the skin and gut lining that may include rash and shedding or death of tissue)
- Toxic epidermal necrolysis (a potentially life-threatening condition affecting skin in which cell death causes the epidermis [outer layer] to separate from the dermis [middle layer])
- Inflammation of the blood vessels
- High Blood pressure
- Arrhythmias (abnormal heart rate)

NOTE: In the prior clinical trial of these agents in combination (eflornithine plus sulindac) compared to placebo among 267 colorectal adenoma (polyp) patients, a numerically greater number of cardiovascular "events" (i.e., stroke, heart attack, chest pain, congestive heart failure, coronary artery disease) were noted for the treatment group (16 events) compared to the placebo group (9 events). Subsequent detailed analysis of cardiovascular events in that trial indicated that patients at high cardiovascular risk prior to that study's initiation experienced the majority of cardiovascular events in the eflornithine plus sulindac group. Excluding these patients from the analysis revealed a similar number of cardiovascular events in the treatment (7 events) and placebo (6 events) groups. Therefore all patients with uncontrolled high blood pressure, heart attack, stroke, uncontrolled chest pains, or advanced heart failure, or known uncontrolled high cholesterol are excluded from S0820. All patients on the study will be monitored closely for cardiotoxicity.

Reproductive risks: You should not become pregnant or father a child while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.

Risks associated with blood draws:

The withdrawal of blood from a vein will cause brief pain when the needle is inserted. There could also be some bruising or infection at the site.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While doctors hope the combination of drugs used in this study will be useful in preventing second primary colorectal cancers and prevention of colorectal adenomas, there is no proof of this yet. We do know that the information from this study will help doctors learn more about eflornithine and sulindac for the prevention cancer. We hope the information learned from this study will benefit other patients with adenomatous polyps in the future.

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

If you do not participate in this study, you will still receive the current standard of care follow-up for cancer screening. This may include: standard surveillance colonoscopies as per national guidelines (American Society of Clinical Oncology, National Comprehensive Cancer Network, American Gastroenterological Association).

Talk to your doctor about your choices before you decide if you will take part in this study.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- SWOG
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- Cancer Prevention Pharmaceuticals
- Watson Pharmaceuticals
- The Cancer Trials Support Unit (CTSU), a service sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials.

- UC Irvine personnel and UC Irvine Genetic Epidemiology Research Institute (GERI)

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.

What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment. You will not have to pay for the hearing test.

The National Cancer Institute (NCI) will provide you with the study agents eflornithine/placebo and sulindac/placebo at no charge while you take part in this study.

Even though it probably won't happen, it is possible that the manufacturer may not continue to provide the study agents to the NCI for some reason. If this would occur, your study doctors will talk to you about other possible options.

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

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/learningabout/payingfor/how-insurance-companies-decide. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

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

It is important that you tell your study doctor, _____ *[name(s)]*, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at_____ *(telephone number)*.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

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

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about important new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor _____ *[name(s)]* at _____ *(telephone number).*

For questions about your rights while taking part in this study, call the NCI Community Oncology Research Program – Kansas City Institutional Review Board (a group of people who review the research to protect your rights) at 913-948-5588.

Future Contact

Occasionally, researchers working with SWOG may have another research idea that relates to people who were on a SWOG study. In some cases, to carry out the new research, we would need to contact patients in a particular study. You can agree or not agree to future contact by circling "yes" or "no".

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 Research Studies That Involve Specimens

Please note: This section of the informed consent form is about additional research studies that are being done with people who are taking part in the main study. You may take part in these additional studies if you want to. You can still be a part of the main study even if you say 'no' to taking part in the additional studies.

You can say "yes" or "no" to the following study. Please circle your choice.

1. Submission of specimens for study-specific testing

If you agree, a sample of your blood will be sent to an outside lab for analysis. The blood sample will be collected before you begin treatment and at the end of study treatment (Month 36) or at any time you come off study for any reason.. The research that may be done with your specimens is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

My specimens may be used for the special testing described as part of this study.

Yes No

2. Banking of specimens for use in future, unspecified research

(This section applies to patients who responded "yes" to #1 above.)

As described in #1 above, some of your blood sample will be sent to an outside lab for analysis.

We would like to keep some of the blood that is left over for future research. If you agree, this specimen will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How are Specimens Used for Research" to learn more about specimen research. Reports about research done with your specimens will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

The choice to let us keep the left over specimens for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your specimens can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your specimens. Then any specimens that remain will no longer be used for research.

In the future, people who do research may need to know more about your health. While SWOG may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes specimens is used for genetic research (about diseases that are passed on in families). Even if your specimens are used for this kind of research, the results will not be put in your health records.

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.

Your specimens will be used only for research and will not be sold. The research done with your specimens may help to develop new products in the future.

Benefits

The benefits of research using specimens include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

Risks

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

Making Your Choice

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No." If you have any questions, please talk to your doctor or nurse, or call our research review board at IRB's phone number.

No matter what you decide to do, it will not affect your care.

1. **My specimens may be kept for use in research to learn about, prevent, treat or cure cancer.**

Yes **No**

2. **My specimens may be kept for use in research about other health problems (for example: diabetes, Alzheimer's disease, or heart disease).**

Yes **No**

3. **Someone may contact me in the future to ask me to allow other uses of my specimens.**

Yes **No**

If you decide to withdraw your specimens from the SWOG Repository in the future, a written withdrawal of consent should be submitted through your study doctor to the SWOG Operations Office. Please designate in the written withdrawal whether you would prefer to have the specimens destroyed or returned to the study doctor.

Optional Research Studies that DO NOT Involve Specimens

Please note: This section of the informed consent form is about an additional research study that is being done with people who are taking part in the main study. You may take part in this additional study if you want to. You can still be a part of the main study even if you say 'no' to taking part the additional study.

You can also change your mind about study participation at any time, by just letting us know.

We are interested in whether or not lifestyle factors, such as diet, physical activity after diagnosis, smoking history, and family history of colorectal cancer will have an effect on your treatment. We would like your permission to send you a reply sheet along with questionnaires to

complete and a stamped return envelope. If you change your mind about the questionnaires, you can let us know through the reply sheet. The questionnaires should take you between 45 and 60 minutes to complete. We will ask you to complete the questionnaires at the beginning of your treatment. We would like your permission to call you on the telephone to remind you about the questionnaires if we do not receive them within 2-3 weeks and also offer you the opportunity to answer the questions by phone if that is your preference.

Except for the information we receive to be able to contact you, the information you give to us will not have your name or any other personal identifying information on it. They will have only an ID number that will be assigned to you. The information that links your name with the code number and the signed consent forms will be maintained by the University of California-Irvine Genetic Epidemiology Research Institute and only certified investigators will have access to it.

You can say "yes" or "no" to the following study. Please mark your choice.

1. **I give permission for a researcher to mail me questionnaires that ask about lifestyle habits during my treatment.**

   Yes ____ No ____

2. **I give permission for a researcher to contact me by phone to remind me about the questionnaires (if they are not returned) or to offer me the opportunity to answer the questions by phone.**

   Yes ____ No ___

Please print your contact information below:
Name_____
Address_____
_____
Telephone Number_____

Signature:_____ **Date** _____

Optional Pharmacokinetic Study for Designated Sites (Arizona Cancer Center, M.D. Anderson Cancer Center, UC-Irvine Medical Center and Wichita CCOP)

Please note: This section of the informed consent form is about an additional research study that is being done with people who are taking part in the main study. You may take part in this additional study if you want to. You can still be a part of the main study even if you say 'no' to taking part in the additional study.

You can say "yes" or "no" to the following study. Please mark your choice below.

Pharmacokinetic or "PK" analysis is a type of research that uses blood plasma to learn how a drug works in the body. PK analysis studies how a drug is absorbed by the body, distributed through the body, metabolized or used by the body, and then removed from the body. In this study, researchers would like to perform PK studies to learn how the drug eflornithine alone or in combination with sulindac works in the body.

Not all patients will be offered participation in PK studies. Only patients being treated at designated PK sites will be offered participation.

If you agree to participate, you will have 5 blood draws at the 3 month clinic visit and 5 blood draws at the 12 month clinic visit while taking study drugs. You must not take the study drugs on your own on these days. The staff will watch you take the pills so that they can accurately record the time that you took them. The blood draws will occur at the following times: first thing in the morning before you eat breakfast, then at hours 1, 2, 4 and 8 after taking the study drug. At each of these blood draws you will have about 1 teaspoon of blood taken for this testing.

Blood draws may result in bruising, infection and minor pain or discomfort comparable to a needle prick.

Your study doctor may choose to place a central venous catheter in order to make blood draws easier. A catheter is a tube placed into a large vein in your chest or arm. This tube will be one of two types. 1) It can come out through the skin or 2) it can be attached to a small container with the entire device under your skin. Either one of these central vein catheters will allow blood to be drawn without the need for repeated needle sticks. In most patients, the catheter can be placed under local anesthesia. Problems that can be associated with these catheters include pain, bleeding, infection, or clotting. In a minority of patients (<10%), these problems lead to the catheter being removed.

Please circle "yes" or "no" for the question below:

I agree to the blood draws and to let my specimens be used in the pharmacokinetic analysis.

Yes **No**

Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. If you want more information about this study, ask your study doctor.

Release

By singing this form you authorize NCORP-KC to access and obtain information that is required for the study. This may include your medical record, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

Signature

I have been given a copy of all 18 pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Participant _____

Participants Signature _____

Date _____

Person Obtaining consent _____

Signature of person obtaining consent _____

Date _____

SWOG S0820
Protocol Version: Amendment #2
Date 1/27/2017

Specimen Consent Supplemental Sheet

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. If you agree, only left over specimens will be saved for research.

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 specimens 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 specimens 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 receive the results of your biopsy, but you will not receive the results of research done with your tissue. 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 specimens 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 the researcher. The researcher will not know who you are.

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

Sometimes, health records have been used against patients and their families. For example, insurance companies may deny a patient insurance or employers may not hire someone with a certain illness (such as AIDS or cancer). The results of genetic research may not apply only to you, but to your family members too. For disease caused by gene changes, the information in one person's health record could be used against family members.

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 tissue 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 913-948-5588