Study Title for Study Participants: "Testing Two Different Versions of BCG (Bacillus Calmette–Guérin) In the Bladder and Testing the Benefit of BCG Vaccination In Addition to Standard BCG for Patients Who Have High Grade Non-Muscle Invasive Bladder Cancer"

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: S1602, "A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer."

What is the usual approach to my bladder cancer?

You are being asked to take part in this study because you have high grade bladder cancer that has not entered the muscle. In the U.S., people who are not in a study are usually treated with BCG LIVE (TICE® BCG) (an abbreviation for Bacillus Calmette–Guérin), which is a bacterium. When it is given directly into and infects the bladder, BCG stimulates the immune system to fight the bladder cancer. BCG is usually tolerated well by patients with normal immune system function.

For patients who receive the usual approach for bladder cancer, about 40 out of 100 are free of cancer at five years.

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 your bladder 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 test two things:

- **Compare any good and bad effects of using the Tokyo-172 version of BCG with the currently used BCG LIVE (TICE® BCG) version of BCG on people with bladder cancer receiving BCG in the bladder. The study will be considered successful if approximately the same number of patients who receive the different treatments are free from high grade recurrence of their bladder cancer after one year of treatment.**
- **Using the Tokyo-172 version of BCG, compare any good and bad effects of adding a BCG vaccination (given under the skin) in addition to placing BCG in only the bladder. The study will be considered successful if the vaccination results in an 8%**

improvement in the number of patients who are free from high grade recurrence of their bladder cancer after one year of treatment.

The Tokyo-172 version of BCG is commonly used in other parts of the world to treat high grade bladder cancer. However, the TOKYO-172 version of BCG is not approved by the U.S. Food and Drug Administration and is considered investigational for this study.

The side effects of the Tokyo-172 version of BCG are believed to be similar to the BCG LIVE (TICE® BCG) version currently used in the United States. In this study of 969 people, the response to and side effects of the TOKYO-172 version of BCG will be compared to BCG LIVE (TICE® BCG) which is currently used in the United States.

Some patients on the study will also receive a vaccination (injected under the skin) of Tokyo-172 BCG prior to receiving the BCG directly in the bladder. The benefits and potential side effects of this additional vaccine are unknown.

This study will allow the researchers to know whether the Tokyo-172 version with or without the vaccination is better, the same, or worse than the usual approach using the BCG LIVE (TICE® BCG) version in the bladder alone.

About 969 people will take part in this study.

What are the study groups?

This study has three study groups.

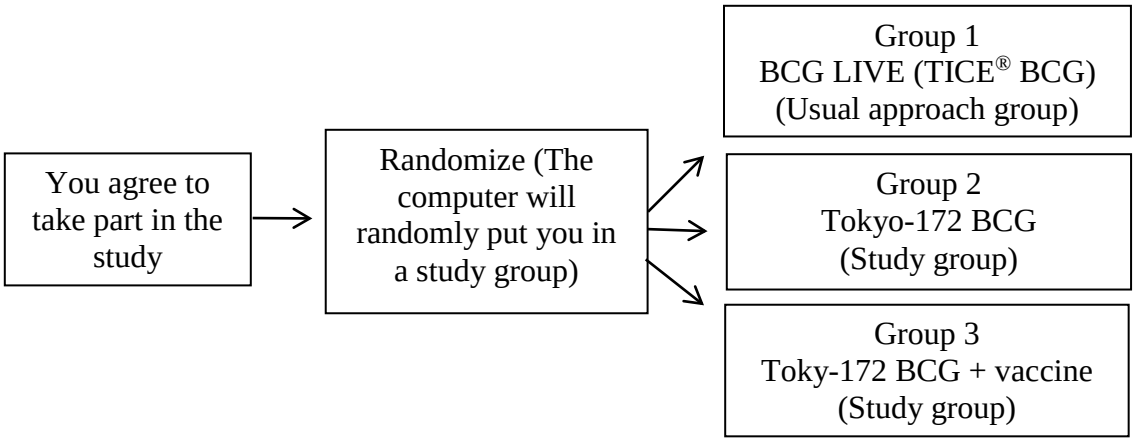
- Group 1 will receive the usual BCG LIVE (TICE® BCG) version of BCG in the bladder.
- Group 2 will receive BCG in the bladder but it will be the Tokyo-172 version of BCG instead of the BCG LIVE (TICE® BCG) version.
- Group 3 will receive a vaccination as an injection under the skin with the Tokyo-172 version of BCG followed by receiving the Tokyo-172 version in the bladder.

The BCG administration into the bladder requires the insertion of a catheter tube in your bladder through the urethra. The liquid containing the study drugs will be instilled into your bladder after all the urine has been drained out.

BCG vaccination for Group 3 is given as a shot just under your skin.

A computer will assign you to treatment groups in the study by chance. 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 will be able to choose your treatment.

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:



How long will I be in this study?

In Groups 1, 2 or 3, you will receive BCG in your bladder once a week for six (6) consecutive weeks (this is called Induction) and then weekly for three (3) consecutive weeks at 3 months, 6, 12, 18, 24, 30, and 36 months (this is called Maintenance) following the start of BCG. This is the usual way that BCG is provided to people with bladder cancer.

Only Group 3 will receive a BCG vaccination prior to starting Induction.

After you finish BCG treatment, your doctor will continue to watch you for side effects and follow your condition for 2 more years. This will include office visits and cystoscopies (a visual examination of the bladder through a small viewing device inserted through the urethra with local anesthesia) every 6 months for 2 years. Thus the study is 5 years long including 3 years of treatment and 2 additional years of follow-up.

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 bladder cancer. However, there are some extra tests and procedures that you will need to have if you take part in this study.

Before you begin treatment…
You will need to have the following extra procedures before you are given treatment:

- PPD test (PPD is an abbreviation for purified protein derivative) - This test is normally used to evaluate for exposure to tuberculosis. As part of the study, the PPD test is being conducted in order to confirm that you have not been exposed to tuberculosis and to evaluate your response to the BCG treatment. The PPD is given at the beginning of the study is standard because tuberculosis exposure may cause a higher risk of future side effects. The extra testing will be at 3 months. The PPD test may be repeated at 6 months

after starting the treatment (3 months later) if the first PPD test was read as negative. The extra testing is for research. It is thought that patients who go from a negative PPD test to a positive PPD test during treatment may have a longer response to treatment.

- You will be asked to provide details to study staff persons of your use of tobacco (if any) before you begin treatment.

During your treatment…

- Questionnaires – you will complete questionnaires to collect information about how you are feeling physically and emotionally and how you are performing your daily activities before and during your treatment. It will take about 30 minutes to complete the questionnaires. Four (4) questionnaires will be given to you at the beginning of the study (before you start treatment), two (2) questionnaires at Week 6, one (1) questionnaire at Month 3, three (3) questionnaires at Month 6, two (2) questionnaires at Month 12, and one (1) questionnaire at Month 24. These thirteen questionnaires are required for patients who can fill them out in English or Spanish. If any questions make you feel uncomfortable, you may skip those questions and not give an answer. The questionnaires are not part of regular cancer care, but are being done as part of this research study to learn more about how your diagnosis and treatment is impacting your life. This information along with that from other patients will help researchers better address patients' needs and concerns. If you stop treatment early, you will still be asked to complete the questionnaires.

- If you have carcinoma in situ (CIS), you will need to have a standard of care biopsy 6 months after your study treatment begins (this is also required for the research):

  For these patients subsequently and all other patients, biopsy is recommended but optional at any time the urine is positive for cancer cells or at any time tumor is visible at cystoscopy.

  You will sign a separate consent form before the biopsy is taken. This will be a standard surgical consent form from the institution where the biopsy procedure takes place and will explain the specific risks related to the biopsy procedure you need. You and/or your health plan/insurance company will need to pay for the cost of this biopsy as this is considered a routine procedure.

- You will be asked to provide details to study staff persons of your use of tobacco (if any) at one year and at two years after starting treatment.

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**
- **The study drug(s)/study approach may not be better, and could possibly be worse, than the usual approach for your cancer.**

- **You may be asked sensitive or private questions that you normally do not discuss.**

There is also a risk that you could have side effects from the study drug(s)/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 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 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 PPD skin test:

COMMON, SOME MAY BE SERIOUS In 100 people receiving PPD test, more than 20 and up to 100 may have:
• **Redness at injection site** • **Swelling at injection site**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving PPD test, from 4 to 20 may have:
• **Itching at injection site** • **Pain at injection site**

RARE, AND SERIOUS In 100 people receiving PPD test, 3 or fewer may have:
• **Injection site ulcer or skin breakdown** • **Injection site scar**

(Group 3 only) Possible Side Effects of BCG vaccine administered into the skin of the shoulder (Intradermal):

COMMON, SOME MAY BE SERIOUS In 100 people receiving intradermal BCG vaccine, more than 20 and up to 100 may have:
• **Redness or swelling at injection site**

COMMON, SOME MAY BE SERIOUS In 100 people receiving intradermal BCG vaccine, more than 20 and up to 100 may have:
• **Conversion to a positive PPD test**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving intradermal BCG vaccine, from 4 to 20 may have:
• **Moderate swelling of lymph nodes in the neck or under the armpit** • **Blister or pustule of skin at injection site** • **Ulceration of skin at injection site** • **"flu-like" symptoms including low-grade (less than 101°F) fever, chills, malaise, or muscle aches** • **Injection of glass particles into the skin**

RARE, AND SERIOUS In 100 people receiving intradermal BCG vaccine, 3 or fewer may have:
• **Enlarged lymph nodes with draining pus (suppurative lymphadenitis)** • **Pus drainage at puncture site** • **Serious infections with temperature of 103°F or greater** • **BCG infection of the bone (osteitis) – the BCG may cause areas of your bones to become red, swollen and painful** • **BCG infection in other organs–the BCG bacteria may multiply, spread and infect other organs such as lungs** • **Damage or inflammation of a vein (phlebitis)** • **Granulomas – a mass of inflammatory tissue**

Possible Side Effects of BCG administered into the bladder with a catheter (intravesical):

COMMON, SOME MAY BE SERIOUS **In 100 people receiving intravesical BCG, more than 20 and up to 100 may have:**
• **Increased daytime and/or nighttime frequency of urination** • **Increased urgency of urination** • **Burning or pain during urination** • **"flu-like" symptoms including low-grade (less than 101°F) fever, chills, malaise, or muscle aches** • **Blood in the urine (hematuria)**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving intravesical BCG, from 4 to 20 may have:
• **Infection of the bladder (cystitis)** • **Cramps/pain in bladder**

RARE AND SERIOUS In 100 people receiving intravesical BCG, 3 or fewer may have:
• **Infection of the epididymis or testicle** • **Infection of the prostate (prostatis)** • **Rigors (shaking chills)** • **Nausea and/or vomiting** • **Arthritis** • **Headache/dizziness** • **Urinary incontinence (accidental leakage of urination)** • **Anorexia, weight loss** • **Abdominal pain** • **Disseminated BCG infection – the BCG bacteria may multiply and cause flu-like symptoms** • **BCG bone infection (osteitis) – the BCG may cause area in your bones to become red, swollen and painful**

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. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

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

It is not possible to know at this time if the study drug(s)/study approach is better than the usual approach so this study may or may not help you. This study will help researchers learn things that will help people in the future. While study doctors hope that adding the BCG vaccine will be more useful against cancer compared to the current practice, there is no proof of this yet. In addition, while study doctors expect the Tokyo-172 BCG version is just as good as the BCG LIVE (TICE® BCG) version, there is no proof of this yet.

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?

If you are in Groups 2 and 3, the Tokyo-172 BCG (both in the bladder and vaccine) will be supplied at no charge while you take part in this study. The cost of placing a catheter into the bladder and administering the intravesical BCG is not paid by the study sponsor so you or your insurance company will have to pay for this. It is possible that the Tokyo-172 BCG 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.

If you are in Group 1, the BCG LIVE (TICE® BCG) will be supplied at no charge while you take part in this study. The cost of placing a catheter into the bladder and administering the TICE BCG is not paid by the study sponsor so you or your insurance company will have to pay for this. It is possible that the BCG LIVE (TICE® BCG) 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. The PPD test at three months and if needed at six months will be paid for by the study.

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. 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/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
- The study sponsor SWOG.
- Merck and Japan BCG Laboratories (JBL) the drug companies supporting the study.
- Cooperative groups that conduct clinical trials including NRG, the ALLIANCE, and ECOG-ACRIN.
- 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.

How will the research findings be disclosed to study participants?

At the direction of the Data and Safety Monitoring Committee, publication information regarding the results of this study will be posted on the SWOG website (www.swog.org) and on clinicaltrials.gov.

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.

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.

Future Contact

I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

Yes No

Optional Sample Collections for Laboratory Studies and/or 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 paraffin-embedded tissue, blood and urine for research. Researchers would collect tissue (that was obtained at the time of your initial biopsy) and evaluate the tissue for the presence of immune cells that could predict whether or not you are likely to benefit from BCG. Researchers would collect blood samples at the time blood is collected for laboratory tests, before you begin the study and at weeks 1, 3, and 6 of induction. Researchers would also collect urine samples at Weeks 1, 3, and 6 of induction. The urine would be used to evaluate response to BCG therapy as

proteins are released into the urine following BCG therapy. Researchers are hoping that measurement of urine proteins released in the urine after BCG can help distinguish which patients are responding well to BCG from those patients that are not benefiting from BCG.

If you choose to take part, a sample of your tissue from your previous biopsy, blood, and urine samples while on BCG will be collected. These tests would only be used for research and not to guide your medical care.

The researchers also ask your permission to store and use 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 5 tablespoons of urine will be collected at Week 1, 3 and 6 and sent to the Biobank. A sample from the tissue that was collected at the time of your prestudy surgery will be sent to the Biobank. About 2 teaspoons of blood will be collected before you start treatment, and about 1 teaspoon will be collected at Weeks 1, 3, and 6 (at the same time as blood collection for lab tests) and sent to the Biobank.
2) 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.
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. However, the blood sample will be drawn when you are having blood drawn for laboratory tests needed to check your general health. There are no risks for obtaining urine.

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) 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.
2) 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.
3) Information that identifies you will not be given to anyone, unless required by law.
4) 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. Most samples will be destroyed. If it is possible to return them, they may be returned to the submitting study doctor. 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 tissue and blood samples and related information may be kept in a "Biobank" for use in future health research.

YES NO

My urine samples and related information may be kept in a "Biobank" for use in future health research.

YES NO

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.