Informed Consent Model for S0819

*NOTES FOR LOCAL INSTITUTION INFORMED CONSENT AUTHORS:

This model informed consent form has been reviewed by the DCT/NCI and is the official consent document for this study. Local IRB changes to this document are allowed. (Institutions should attempt to use sections of this document that are in bold type in their entirety.) Editorial changes to these sections may be made as long as they do not change information or intent. If the institutional IRB insists on making deletions or more substantive modifications to the risks or alternatives sections, they may be justified in writing by the investigator and approved by the IRB. Under these circumstances, the revised language, justification and a copy of the IRB minutes must be forwarded to the Southwest Oncology Group Operations Office for approval before a patient may be registered to this study.

Please particularly note that the questions related to banking of specimens for future study are in bolded type and may not be changed in any way without prior approval from the Southwest Oncology Group Operations Office.

Readability Statistics:	
Flesch Reading Ease	60.2 (targeted above 55)
Flesch-Kincaid Grade Level	8.3 (targeted below 8.5)

- Instructions and examples for informed consent authors are in *[italics]*.
- A blank line, _____, indicates that the local investigator should provide the appropriate information before the document is reviewed with the prospective research participant.
- The term "study doctor" has been used throughout the model because the local investigator for a cancer treatment trial is a physician. If this model is used for a trial in which the local investigator is not a physician, another appropriate term should be used instead of "study doctor".
- The dates of protocol updates in the header and in the text of the consent is for reference to this model only and should not be included in the informed consent form given to the prospective research participant.
- The local informed consent must state which parties may inspect the research records. This includes the NCI, the drug manufacturer for investigational studies, any companies or grantors that are providing study support (these will be listed in the protocol's model informed consent form) and the Southwest Oncology Group.

  The "Southwest Oncology Group" must be listed as one of the parties that may inspect the research records in all protocol consent forms for which patient registration is being credited to the Southwest Oncology Group. This includes

consent forms for studies where all patients are registered directly through the Southwest Oncology Group Data Operations Office, all intergroup studies for which the registration is being credited to the Southwest Oncology Group (whether the registration is through the SWOG Data Operations Office or directly through the other group), as well as consent forms for studies where patients are registered via CTSU and the registration is credited to the Southwest Oncology Group.

- When changes to the protocol require revision of the informed consent document, the IRB should have a system that identifies the revised consent document, in order to preclude continued use of the older version and to identify file copies. An appropriate method to identify the current version of the consent is for the IRB to stamp the final copy of the consent document with the approval date. The stamped consent document is then photocopied for use. Other systems of identifying the current version of the consent such as adding a version or approval date are allowed as long as it is possible to determine during an audit that the patient signed the most current version of the consent form.

*NOTES FOR LOCAL INVESTIGATORS:

- The goal of the informed consent process is to provide people with sufficient information for making informed choices. The informed consent form provides a summary of the clinical study and the individual's rights as a research participant. It serves as a starting point for the necessary exchange of information between the investigator and potential research participant. This model for the informed consent form is only one part of the larger process of informed consent. For more information about informed consent, review the "Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials" prepared by the Comprehensive Working Group on Informed Consent in Cancer Clinical Trials for the National Cancer Institute. The Web site address for this document is http://cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/
- A blank line, _____, indicates that the local investigator should provide the appropriate information before the document is reviewed with the prospective research participant.
- Suggestion for Local Investigators: An NCI pamphlet explaining clinical trials is available for your patients. The pamphlet is titled: "If You Have Cancer…What You Should Know about Clinical Trials". This pamphlet may be ordered on the NCI Web site at *http://cissecure.nci.nih.gov/ncipubs/details.asp?pid=1035* or call 1-800-4- CANCER (1-800-422-6237) to request a free copy.
- Optional feature for Local Investigators: Reference and attach drug sheets, pharmaceutical information for the public, or other material on risks. Check with your local IRB regarding review of additional materials.

*These notes for authors and investigators are instructional and should not be included in the informed consent form given to the prospective research participant.

S0819, "A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)"

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 advanced non-small cell lung cancer.

Why is this study being done?

The purpose of this study is compare the effects, good and/or bad, of cetuximab on lung cancer. *(7/29/09) (sentences deleted 7/29/09)*

How many people will take part in the study?

About 1,546 people will take part in this study.

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

Before you begin the study …

You may need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join 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.

- Physical exam
- Blood tests for blood counts, clotting time, electrolytes, kidney function, liver function
- Urine tests
- Brain CT/MRI
- Other scans
- EKG

During the study …

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you may need the following tests and procedures. They are part of regular cancer care.

- Physical exam about once every 3 weeks
- Blood tests for blood counts, electrolytes, and kidney and liver function (about every 3 weeks) *(7/12/10)*
- Urine tests for kidney function before every other treatment with bevacizumab (no urine test is necessary for patients not taking bevacizumab)
- Other scans (about every 6 weeks)

The following tests and procedures are being done to see how the study is affecting your body. Samples of your tumor tissue and blood are required for current scientific studies. *(5/18/11) (paragraph updated 11/11/11)*

- A tissue specimen from the biopsy or surgery used to diagnose your cancer plus blood specimens from pre-treatment, at Week 7 and when you stop treatment will be sent to a special laboratory for testing to see if we can predict who should receive cetuximab as a part of their treatment in the future. *(5/18/11)* The blood specimens will be taken at the same time that blood is taken for laboratory tests. 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.

Treatment Plan

You will be "randomized" to receive either chemotherapy without cetuximab or chemotherapy with cetuximab. 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 either group to receive cetuximab or not. *(4/5/10)* The decision about whether you will receive bevacizumab will be made by you and your doctor based on several considerations related to your health history.

If you are in Group 1, you will have six three-week cycles of chemotherapy with paclitaxel, carboplatin and bevacizumab. All of these are given by IV (through your veins). You will receive the drugs once every 3 weeks. You will receive the paclitaxel over 3 hours. Right after that, you will receive the carboplatin over 30 minutes. Finally, one hour after that, you will receive the bevacizumab. The first time you receive bevacizumab, it will take about 90 minutes. Your doctor may be able to shorten this for future treatments if you tolerate it well. The table below may help explain the treatment plan. Total time to receive treatment in the first cycle will be about seven hours for all of the drugs. Later cycles may be a bit shorter.

Drug	Length of time - All Drugs are given by IV	Frequency
Paclitaxel	Will take 3 hours.	Every 3 weeks
Carboplatin	Will begin right after paclitaxel and take 30 minutes.	Every 3 weeks
Bevacizumab	Will begin 1 hour after carboplatin and take 90 minutes. (The time may be shortened if you tolerate it well.)	Every 3 weeks

After these six cycles of chemotherapy, you will continue bevacizumab without the other drugs on the same schedule as before.

If you are in Group 2, you will have six three-week cycles of chemotherapy with paclitaxel and carboplatin. These are given by IV (through your veins). You will receive the drugs once every 3 weeks. You will receive the paclitaxel over 3 hours. Right after that, you will receive the carboplatin over 30 minutes. The table below may help explain the treatment plan. Total time to receive treatment in the first cycle will be about three to four hours for both of the drugs.

Drug	Length of time - All Drugs are given by IV	Frequency
Paclitaxel	Will take 3 hours.	Every 3 weeks
Carboplatin	Will begin right after paclitaxel and take 30 minutes.	Every 3 weeks

If you are in Group 3, you will have six three-week cycles of chemotherapy with cetuximab, paclitaxel, carboplatin and bevacizumab. All of these are given by IV (through your veins). You will receive cetuximab once per week and the other drugs once every 3 weeks. The cetuximab will take about one hour. After a one hour break, you will receive the paclitaxel over 3 hours. Right after that, you will receive the carboplatin over 30 minutes. Finally, one hour after that, you will receive the bevacizumab. The first time you receive bevacizumab, it will take about 90 minutes. Your doctor may be able to shorten this for future treatments if you tolerate it well. The table below may help explain the treatment plan. Total time to receive treatment in the first cycle will be nine hours for all of the drugs. Later cycles will take about seven hours to receive all of the drugs.

Drug	Length of time - All Drugs are given into a vein	Frequency
Cetuximab	1 hour (the first dose will take 2 hours)	Once per week
Paclitaxel	Will begin 1 hour after cetuximab and take 3 hours.	Every 3 weeks
Carboplatin	Will begin right after paclitaxel and take 30 minutes.	Every 3 weeks
Bevacizumab	Will begin 1 hour after carboplatin and take 90 minutes. (The time may be shortened if you tolerate it well.)	Every 3 weeks

After these six cycles of chemotherapy, you will continue bevacizumab and cetuximab without the other drugs on the same schedule as before.

If you are in Group 4, you will have six three-week cycles of chemotherapy with cetuximab, paclitaxel and carboplatin. All of these are given by IV (through your veins). You will receive cetuximab once per week and the other drugs once every 3 weeks. The cetuximab will take about one hour. After a one hour break, you will receive the paclitaxel over 3 hours. Right after that, you will receive the carboplatin over 30 minutes. The table below may help explain the treatment plan. Total time to receive treatment in the first cycle will be five to six hours for all of the drugs.

Drug	**Length of time - All Drugs are given into a vein**	**Frequency**
Cetuximab	1 hour (the first dose will take 2 hours)	Once per week
Paclitaxel	Will begin 1 hour after cetuximab and take 3 hours.	Every 3 weeks
Carboplatin	Will begin right after paclitaxel and take 30 minutes.	Every 3 weeks

After these six cycles of chemotherapy, you will continue cetuximab without the other drugs on the same schedule as before.

For all patients copies of all of your scans while you are in the study will be sent to a central location for review. This central review will be done for research purposes only. The result of the central review will not be sent back to you or your doctor.

How long will I be in the study?

If you are taking bevacizumab and/or cetuximab, you will be asked to take these study drugs as long as your disease does not get worse and the side effects are not too bad. If you are receiving carboplatin and paclitaxel, your treatment on the study will end after six cycles. After you are finished taking the study drugs, the study doctor will ask you to visit the office for follow-up exams every six weeks until your disease gets worse then every 3 months for the first year, and then every 6 months for up to 3 years. During these visits, many of the scans and lab tests that you had during the study treatment will be repeated.

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. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the study drugs 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 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.

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

If you choose to take part in this study, there is a risk that: *(Section updated 10/3/16)*

- **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 bevacizumab 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 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 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.

<u>Risks and side effects related to carboplatin and paclitaxel include those that are</u>:

Likely:

- **Fatigue**
- **Lowered white blood count, which may increase risk of infection**
- **Lowered platelets, which may lead to an increase in bruising or bleeding**
- **Lowered red blood cells, which may lead to anemia, tiredness, or shortness of breath**
- **Loss of appetite and weight loss**
- **Complete hair loss**
- **Numbness, pain or tingling in fingers or toes**
- **Pain in muscles and joints**
- **Sores in mouth and throat (may result in difficulty swallowing), or on other parts of the body**

- **Changes in taste**
- **Nausea, vomiting, diarrhea, constipation and abdominal pain**
- **Weakness**
- **Fever with or without chills**
- **Headache**

Less likely:

- **Allergic reaction**
- **Increase in temperature**
- **Seizures**
- **Infection**
- **Vision problems**
- **Ringing in the ears and hearing loss (hearing loss usually reversible but occasionally does not improve)**
- **Dizziness**

Rare but serious:

- **Inflammation of the lung (interstitial lung disease). This could be life-threatening.**
- **Inflammation of the liver, liver failure, death of liver tissue**
- **Death of colon tissue**

Additional risks from bevacizumab: *(Section Updated 10/3/16)*

COMMON, SOME MAY BE SERIOUS In 100 people receiving bevacizumab, more than 20 and up to 100 may have:
• **High blood pressure which may cause headache or blurred vision**

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving bevacizumab, from 4 to 20 may have:
• **Anemia which may require blood transfusion** • **Low white cell count that may increase the risk of infection** • **Infection, including collection of pus in the belly or rectum** • **Abnormal heartbeat which may cause palpitations or fainting** • **Pain in the belly, rectum, chest, joints, muscles, or tumor** • **Low appetite, constipation, diarrhea, heartburn, nausea, vomiting, or dehydration** • **Internal bleeding which may cause black tarry stool, blood in vomit, coughing up blood, or blood in urine** • **Bleeding from other sites, including the vagina or nose** • **Blockage of internal organs which may cause vomiting or inability to pass stool** • **Sores in the mouth** • **Allergic reaction during or after infusion of bevacizumab which may cause fever, chills, rash, itching, hives, low blood pressure, wheezing, shortness of breath, swelling of the face or throat** • **Delay in healing of wounds or spontaneous opening of wounds** • **Weight loss, tiredness, or dizziness** • **Muscle weakness** • **Damage to organs which may cause loss of teeth or loss of motion** • **Headache** • **Numbness, tingling or pain in the fingers or toes** • **Hoarseness, stuffy nose, or cough** • **Dry skin** • **Swelling and redness of the skin or face** • **Blood clot in limbs or lungs which may cause swelling, pain, shortness of breath** • **Leakage of protein in the urine, which can rarely lead to damage to the kidney**

RARE, AND SERIOUS In 100 people receiving bevacizumab, 3 or fewer may have:
• **Clots in the arteries, causing stroke (which may cause paralysis or weakness) or heart attack (which may cause chest pain or shortness of breath). This risk is significantly increased in patients who are elderly or with history of diabetes** • **Heart failure which may cause shortness of breath, swelling of ankles, and tiredness** • **Bowel perforation (a tear in the bowel) that can cause pain or bleeding and require surgery to repair** • **A tear or hole (fistula) in internal organs such as the nose, throat, lungs, esophagus, rectum, or vagina. These conditions may cause serious infections or bleeding and require surgery to repair** • **Sores in the throat** • **Flesh-eating bacteria syndrome, an infection in the deep layers of skin** • **Bleeding in the tumor, brain, belly or lungs which may cause confusion, blood in stool or coughing up blood** • **Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome)** • **Kidney damage which may require dialysis** • **Redness, pain or peeling of palms and soles** **Additional Notes: Risk in children or adolescents: abnormal bone changes which may interfere with growth. Risk in pre-menopausal women: more likely to develop menopause when taking bevacizumab.**

<u>Risks and side effects related to cetuximab include those that are:</u> *(updated 6/7/10)*

***Likely*:**

- **Acne** *(updated 6/7/10)*
- **Diarrhea** *(added 6/7/10)*
- **Nausea or the urge to vomit** *(added 6/7/10)*
- **Fatigue or tiredness** *(added 6/7/10)*
- **Fever** *(added 6/7/10)*
- **Headache or head pain** *(added 6/7/10)*
- **Dry skin** *(added 6/7/10)*
- **Skin rash with the presence of macules (flat discolored area) and papules (raised bump)** *(added 6/7/10)*

Less likely: *(section updated 6/7/10)*

- **Lack of enough red blood cells (anemia)**
- **Inflammation (swelling and redness) of the skin of outer ear and canal**
- **Noise in the ears, such as ringing, buzzing, roaring, clicking**
- **Inflammation (swelling and redness) of the conjunctiva (the outermost layer of the eye and the inner surface of the eyelids). Commonly called "pink eye".**

- **Dry eye**
- **Inflammation (swelling and redness) of the middle layer of the eye (uvea)**
- **Excessive tearing in the eyes**
- **Belly pain**
- **Inflammation (swelling and redness) of the lip**
- **Constipation**
- **Dry mouth**
- **Heartburn**
- **Irritation or sores in the lining of the mouth**
- **Vomiting**
- **Chills**
- **Swelling of the arms and/or legs**
- **Flu-type symptoms (including body aches, fever, chills, tiredness, loss of appetite, cough)**
- **Reaction that can occur during or following infusion of the drug. The reaction may include fever, chills, rash, low blood pressure, and difficulty breathing.**

- **Chest pain not heart-related**
- **Allergic reaction by your body to the drug product that can occur immediately or may be delayed. The reaction may include hives, low blood pressure, wheezing, swelling of the throat, and difficulty breathing.**
- **Infection**
- **Decreased number of a type of white blood cell (neutrophil/granulocyte)**
- **Weight loss**
- **Decrease in the total number of white blood cells (leukocytes)**
- **Loss of appetite**
- **Dehydration (when your body does not have as much water and fluid as it should)**
- **Decreased blood level of calcium**
- **Decreased blood level of magnesium** *(updated 6/7/10)*
- **Joint pain**
- **Back pain**
- **Muscle pain**
- **Fainting**
- **Stuffy or runny nose, sneezing**
- **Sudden constriction of the small airways of the lung that can cause wheezing and shortness of breath**
- **Cough**
- **Shortness of breath** *(updated 6/7/10)*
- **Hoarseness**
- **Hair loss**
- **Loss of some or all of the finger or toenails**
- **Increased skin sensitivity to sunlight**
- **Itching**
- **Area of bleeding within the skin causing a reddish purple discoloration**
- **Sore or destruction of skin**
- **Hives**
- **Low blood pressure**
- **Formation of a blood clot that plugs the blood vessel; blood clots may break loose and travel to another place, such as the lung**

Rare but Serious:

- **Inflammation of the lining of the brain and spinal cord** *(updated 6/7/10)*
- **Serious, life-threatening allergic reaction requiring immediate medical treatment by your doctor. The reaction may include extremely low blood pressure, swelling of the throat, difficulty breathing, and loss of consciousness.** *(updated 6/7/10)*
- **Inflammation of the lungs that may cause difficulty breathing and can be life-threatening** *(updated 6/7/10)*
- **Fluid build-up in the lungs that is not due to a heart problem that can be life-threatening** *(added 6/7/10)*
- **Swelling and redness of the skin on the palms of the hands and soles of the feet** *(added 6/7/10)*

Additional risk information for protocols involving chemotherapy and cetuximab in patients with advanced NSCLC *(section added 6/7/10)*

- **In clinical trials involving patients with advanced, non-small cell lung cancer, the combination of cetuximab and chemotherapy may increase the risk of life-threatening complications, some of which may be fatal, in elderly patients (65 years old or more), particularly those with pre-existing cardiac disease.**

Reproductive risks: You should not become pregnant or father a baby 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 and for 6 months after your last dose of bevacizumab or for 3 months after your last dose of cetuximab (whichever is later). 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.

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 that this treatment will be more useful against cancer compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about these drugs as a treatment for cancer. This information could help future cancer patients.

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

Your other choices may include:

- **Getting treatment or care for your cancer without being in a study**
- **Taking part in another study**
- **Getting no treatment**
- **Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.**

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:

- The Southwest Oncology Group
- Qualified representatives of Bristol Myers Squibb and ImClone *(7/29/09)*
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- The Cancer Trials Support Unit (CTSU), a service sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials.

[Note to Local Investigators: The NCI has recommended that HIPAA regulations be addressed by the local institution. The regulations may or may not be included in the informed consent form depending on local institutional policy.]

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.

Administration of the drug will be *(provided free of charge/charged in the usual way).* The parts of the research consisting of keeping research records will be paid by those organizing and conducting the research. The research requires that you receive certain standard medical tests and examinations. These standard tests and examinations will be *(charged in the usual way/provided at a reduced rate). (local institutions must choose the option that best fits the hospital's situation)*

Bristol Myers Squibb/ImClone will provide you with cetuximab free of charge while you are participating in this study. *(7/29/09)*

Carboplatin, bevacizumab and paclitaxel are commercially available.

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://www.cancer.gov/clinicaltrials/learningabout/payingfor/how-insurance-companies-decide. *(updated 5/1/13)* 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, _____ *[investigator's 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.

A Data and Safety 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 on 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 _____ *[name of center]* Institutional Review Board (a group of people who review the research to protect your rights) at _____ *(telephone number).* *[Note to Local Investigator: Contact information for patient representatives or other individuals in a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can be listed here.]*

You may also call the Operations Office of the NCI Central Institution Review Board (CIRB) at 888-657-3711 (from the Continental US only). [*Only applies to sites using the CIRB.]

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 any of these additional studies.

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

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. Storage and Use of Specimens for Future, Unspecified Research

This study requires submission of tissue from the biopsy (or surgery) used to diagnose lung cancer.

It also requires submission of blood specimens at pre-treatment, at 7 weeks after starting treatment and at the end of treatment. *(11/11/11)* This will be used for special testing as outlined earlier.

(section deleted 11/11/11)

We would like to keep some of the specimens that are left over for future research. If you agree, these specimens 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 tissue research.

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.

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 leftover 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 the Southwest Oncology Group 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 are 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.

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 a Southwest Oncology Group Specimen Repository in the future, a written withdrawal of consent should be submitted through your study doctor to the Southwest Oncology Group Operations Office. Please designate in the written withdrawal whether you would prefer to have the specimens destroyed or returned to the study doctor.

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) or TTY: 1-800-332-8615

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.

Signature

I have been given a copy of all _____ *[insert total of number of pages]* 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 (or legally authorized representative)_____ *(5/1/13)*

Date _____

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 the Southwest Oncology Group. Your doctor does not work for the Southwest Oncology Group, 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 the Southwest Oncology Group and request samples for their studies. The Southwest Oncology Group reviews the way that these studies will be done, and decides if any of the samples can be used. The Southwest Oncology Group gets the specimen and information about you from your hospital, and sends the specimen samples and some information about you to the researcher. The Southwest Oncology Group 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 the Southwest Oncology Group. If more information is needed, the Southwest Oncology Group 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

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?

The Southwest Oncology Group is in charge of making sure that information about you is kept private. The Southwest Oncology Group 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 (Insert IRB's Phone Number).