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Sponsored and Funded by the National Cancer Institute

CONSENT FORM

CIRB S0337: A Phase III Blinded Study Of Immediate Post-TURBT Instillation Of Gemcitabine Versus Saline In Patients With Newly Diagnosed Or Occasionally Recurring Grade I/II Superficial Bladder Cancer.

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CIRB S0337: A Phase III Blinded Study Of Immediate Post-TURBT Instillation Of Gemcitabine Versus Saline In Patients With Newly Diagnosed Or Occasionally Recurring Grade I/II Superficial Bladder Cancer.

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 newly diagnosed superficial bladder cancer or superficial bladder cancer that has come back.

Who is doing this study?

The Southwest Oncology Group (SWOG) is sponsoring this trial. SWOG is an adult cancer clinical trials organization. SWOG is funded through the National Cancer Institute, and its network consists of almost four thousand physicians at almost three hundred institutions throughout the United States. Your study doctor has met all requirements to be a member of SWOG and to perform National Cancer Institute-funded research through this Group.

Why is this study being done?

The type of bladder tumor that you have has a relatively high chance of coming back in your bladder after it has been removed. It usually comes back in a different spot of your bladder than where it was originally.

The purpose of this study is to determine if gemcitabine, a chemotherapy drug that is effective against very advanced bladder cancer when given through a vein (intravenously) is also effective against earlier stage bladder cancers when given into your bladder (intravesically). Specifically, the study will determine whether gemcitabine is more likely than saline (salt water) to lower the chances of your tumor recurring if given into the bladder within 3 hours after your tumor is removed.

In this study, the drug gemcitabine is being used in a new (investigational) way.

Since the final pathology will not be available until after you receive treatment, there is a possibility that you may not have cancer, but still may undergo treatment. The likelihood of this is extremely small in view of known data that indicates that experienced urologists are capable of accurately assessing the presence of tumor.

How many people will take part in the study?

About 340 people will take part in this study.

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. 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.

- Your doctor will review your medical history and perform a physical examination.
- Your doctor will perform a cystoscopy (looking into the bladder with a flexible or rigid endoscope, usually in the clinic under local anesthesia) to look inside your bladder, with the collection of urine for cytology (a laboratory evaluation for cancer cells in the urine).
- An x-ray of your kidneys (intravenous pyelogram or CAT scan) will be performed if you have not had that done within the last six months.
- Your urine will be collected for urinalysis and urine culture. If you have a urinary tract infection you cannot participate on this study. Tell your doctor if you believe you have developed a urinary tract infection since the urine culture was collected.
- Routine blood tests will be performed to evaluate your white cells, red cells and platelets, and the function of your liver and kidneys.

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 will need the following tests and procedures.

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. Neither you nor your doctor will either know or choose the group you will be in. You will have an equal chance of being placed in either group.

- After you agree to take part in the study but before you receive treatment, your urine will be collected for research studies. The tests performed will be the NMP-22 Bladder Chek and BTA Stat test. Part of this study is to see whether these tests can predict recurrence as well as cystoscopy alone. Your urine will be collected once every three months for the first two years for these tests.
- The study involves one intravesical instillation treatment of either gemcitabine or saline (salt water) into the bladder immediately following the TURBT (trans-urethral resection of bladder tumor) procedure. Saline (salt water) is a placebo, not a form of treatment for superficial bladder cancer. It does not contain any medication. You will have a catheter tube inserted in your bladder through the urethra. About ¼ cup of liquid containing either the study drug (gemcitabine 2,000 mg in 100 mL of saline) or saline alone (100 mL) will be instilled into your bladder after all the urine has been drained out. You will be asked to hold

the liquid in your bladder for about 1 hour. After about 1 hour the liquid will be drained from the bladder through the catheter. If you experience discomfort while the liquid is in your bladder, you should notify your urologist who may choose to drain your bladder earlier than the 1 hour dwell time. Similarly, if you wish the liquid to be drained earlier than planned, notify your urologist and the infusion will be stopped and the bladder drained. Additionally, if immediately after your surgery your urine is found to be quite bloody, your urologist may choose to irrigate your bladder with liquid. If the urine becomes clear within 3 hours, the liquid could still be instilled at the time.

- If your urologic surgeon believes for any number of reasons, including that there is too much post-operative bleeding, or that removal of the tumor went so deep into the bladder wall that instilling the liquid might be dangerous, he/she will not place the liquid into your bladder.
- You will be asked to keep track of any side effects you have during the treatment, and will be asked about them by your doctor or the study nurse.
- Between 7 and 14 days after you receive the intravesical treatment, routine blood tests will be performed to evaluate your white cells and platelets and to test your liver function.
- Every 3 months for the first two years, then every 6 months for the next two years, your doctor will review your medical history and perform a physical examination.
- Every 3 months for the first two years, then every 6 months for the next two years, your doctor will perform a cystoscopy (looking into the bladder with a flexible or rigid endoscope, usually in the clinic under local anesthesia) to look inside your bladder, with the collection of urine for cytology (a laboratory evaluation for cancer cells in the urine). At each evaluation, if either test is abnormal your doctor will arrange for you to have a bladder biopsy performed. If the cancer comes back, your doctor will discuss with you other options for treatment of your cancer at that point. We will continue to follow you to see how you are doing for up to 4 years after you start the study.

How long will I be in the study?

You will continue as detailed above for up to 4 years from the start of the study. You will need routine follow-up evaluations (cystoscopy and urinary cytology) every 3 months the first and second year and every 6 months for the next two years.

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 intravesical gemcitabine/saline 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 end your participation 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?

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 the gemcitabine/saline instillation. 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 the bladder tumor resection (TURBT) and intravesical gemcitabine include:

Likely

- **Bladder irritation causing urinary frequency or burning**
- **Hematuria (blood in the urine)**
- **Bladder spasms**

Less Likely

- **Bladder perforation (a hole in your bladder). This usually will require you to have a draining catheter for several days longer than normal after your surgery, and rarely might require you to undergo an operation to repair your bladder.**
- **If gemcitabine is put into your bladder, there might be other risks including the risk of the drug getting into your blood stream. If this happens, you may also experience low white blood cell or platelet counts, which could cause increased susceptibility to infection or bleeding. Very rarely anemia (low red blood cell count) causing fatigue and sometimes requiring transfusions may occur.**

Rare but Serious

In a few patients who received gemcitabine through a vein, the following rare, but serious side effects were seen:

- **Fluid in your lungs, which could make you short of breath, wheeze or cough**
- **Kidney stress or damage as shown by abnormal kidney function tests. You may notice blood and/or protein in your urine.**

Risks and side effects related to the bladder tumor resection (TURBT) and intravesical saline include:

Likely

- **Bladder irritation causing urinary frequency or burning**
- **Hematuria (blood in the urine)**
- **Bladder spasms**

Less Likely

- **Bladder perforation (a hole in your bladder). This usually will require you to have a draining catheter for several days longer than normal after your surgery, and rarely might require you to undergo an operation to repair your bladder.**

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 regulation (regulation highly effective: abstinence, IUD, birth control pills, tubal ligation or partner's vasectomy and less effective: condom, diaphragm or cervical cap) while on this study. Check with your study doctor about what kind of birth regulation (regulation highly effective: abstinence, IUD, birth control pills, tubal ligation or partner's vasectomy and less effective: condom, diaphragm or cervical cap) 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 intravesical gemcitabine 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 intravesical gemcitabine 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. This may include other intravesical treatments, surgery to remove the bladder, radiation therapy to the bladder, or systemic chemotherapy,**
- **Taking part in another study,**
- **Getting no treatment.**

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 National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- The Southwest Oncology Group
- Lilly Pharmaceuticals

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. Because instillation of chemotherapy immediately after surgery is frequently done for bladder cancer, you and/or your insurance company may need to pay for this as well. If there are complications of the surgery or the drug instillation, you or your health insurance may be required to pay for the expenses created by caring for/or correcting these complications.

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)*. Lilly Pharmaceuticals has agreed to pay (up to a defined amount per test) for the NMP-22 Bladder Chek and BTA Stat tests.

Lilly Pharmaceuticals will provide you with the investigational agent gemcitabine or saline at no cost to you.

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/understanding/insurance-coverage> . 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 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 the number listed on the cover page.

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 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 at the number listed on the cover page.

For questions about your rights while taking part in this study, call the MultiCare Health System Institutional Review Board (a group of people who review the research to protect your rights) at 253-403-3877.

*You may also call the Operations Office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the continental US only).

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.

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

Consent Form for Use of Specimens for Research

About Using Specimens for Research

Prior to receiving gemcitabine or placebo, you will have a biopsy (TURBT) to remove your bladder cancer. In addition, if your cancer recurs in the future, additional biopsies will be performed at that time. We would like to obtain some of the tissue that was removed both before and after the treatment so that we can do some research tests on the tissue. We would also like to collect a sample of your blood 3 months after you receive gemcitabine or placebo. The goal of these research tests is to improve our understanding of your type of bladder cancer and its response to the intravesical gemcitabine treatment.

Your tissue will be kept at:

Southwest Oncology Group Tumor Tissue Bank:
University of Colorado HSC at Fitzsimons
Department of Pathology
RC-1 South, Room L18-5104
12801 East 17th Avenue
Aurora, CO 80010
Phone: 303/724-3086

We would like to keep some of the tissue and blood that is 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 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 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 treating physician 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 treating physician.

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 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.

Patient's name (printed or typed)

Patient's Signature Date

Physician name (printed or typed)

Physician Signature Date

Signature of person conducting the
Informed consent discussion

Date

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 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 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?

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 253-403-3877.

Authorization to Use or Disclose (Release) Identifiable Health Information For Research

1. What is the purpose of this form?

The **Southwest Oncology Group** is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your identifiable health information, you must sign and date this form to give them your permission.

2. What health information do the researchers want to use?

The researchers want to abstract and use the portions of your medical record that they will need for their research. If you enter a Southwest Oncology Group research study, information that will be used and/or released may include your complete medical record, and in particular, the following:

- the history and diagnosis of your disease
- specific information about treatments you received
- information about other medical conditions that may affect your treatment
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, X-rays, photographs of radiation therapy target areas, and pathology results
- information on side effects (adverse events) you may experience, and how these were treated
- long-term information about your general health status and the status of your disease
- tissue and/or blood samples, associated data related to the analysis of the samples

You may request a blank copy of the Southwest Oncology Group data forms from the Northwest CCOP to learn what information will be shared.

3. Why do the researchers want my health information?

The Northwest CCOP will collect your health information and share it with the Southwest Oncology Group if you enter a Cooperative Group research study, or to evaluate your eligibility for a study. The Southwest Oncology Group researchers will use your information for the following cancer research study(ies).

S0337, " A Phase III Blinded Study of Immediate Post-TURBT Instillation of Gemcitabine Versus Saline in Patients with Newly Diagnosed or Occasionally Recurring Grade I/II Superficial Bladder Cancer."

The purpose of this study is to determine if gemcitabine, a chemotherapy drug that is effective against very advanced bladder cancer when given through a vein (intravenously) is also effective against earlier stage bladder cancers when given into your bladder (intravesically). Specifically, the study will determine whether gemcitabine is more likely than saline (salt water) to lower the chances of your tumor recurring if given into the bladder within 3 hours after your tumor is removed.

In this study, the drug gemcitabine is being used in a new (investigational) way.

4. *Who will be able to use my health information?*

The Northwest CCOP will use your health information for research. As part of this research, they may give your information to the following Groups taking part in the research. The Northwest CCOP may also permit staff from these Groups to review your original records as required by law for audit purposes.

- the Southwest Oncology Group
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute to provide greater access to cancer trials
- public health agencies and other government agencies (including non-U.S.) as authorized or required by law
- other people or organizations assisting with Southwest Oncology Group research efforts.
- central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed above.

5. *How will information about me be kept private?*

The Southwest Oncology Group will keep all identifiable health information confidential to the extent possible, even though they and other federal research groups are not subject to the same federal privacy laws governing clinical centers. The Southwest Oncology Group will not release identifiable health information about you to others except as authorized by this form, or required by law. If your identifiable health information must be shared with other organizations, the privacy laws that govern those organizations would apply.

6. *What happens if I do not sign this authorization form?*

If you do not sign this authorization form, you will not be able to take part in a research study for which you are being considered.

7. *If I sign this form, will I automatically be entered into the research study?*

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a separate research consent form.

8. What happens if I want to withdraw my authorization?

You can change your mind at any time and withdraw this authorization. This request for withdrawal must be made in writing. Beginning on the date you withdraw your authorization, no new identifiable health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your authorization, you will be removed from the research study at that time.

To withdraw your authorization, please contact the person below. She will make sure your written request to withdraw your authorization is processed correctly.

Karyn Hart, RHIT, CCRP
Program Coordinator
Northwest CCOP
315 Martin Luther King, Jr. Way
Tacoma, WA 98405
(253) 403-1461

9. How long will this authorization last?

If you agree by signing this form that researchers can use your identifiable health information, this authorization has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding my identifiable health information?

You have the right to refuse to sign this authorization form. You have the right to review and/or copy records of your health information kept by the Northwest CCOP. You do not have the right to review and/or copy records kept by the Southwest Oncology Group or other researchers associated with the research study.

Signatures

I agree that my identifiable health information may be used and disclosed for research purposes described in this form.

Signature of Patient or Patient's Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

Representative's Authority to Act for Patient: _____

Signature of Person Obtaining Authorization: _____

Printed Name of Person Obtaining Authorization: _____