# PATIENT INFORMATION AND CONSENT FORM

## Title

This is a clinical trial, a type of research study. Your research physician will explain the clinical trial to you. Clinical trials include only people who choose to take part in them. Please take your time to make your decision about taking part in this study.

This consent form may contain words that you do not understand. Please ask the research physician or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

You are being asked to take part in this study because

## Why is this study being done?

The purpose of this study is to… [*Limit explanation to why study is being done. Explain in 1-2 sentences. Some examples are provided*].

[*Example: Phase 1 study*]
*Test the safety of* [*drug/intervention*] *at different dose levels. We want to find out what effects, good and/or bad, it has on you and your* [*specify type/stage/presentation of*] *cancer.*

[*Example: Phase 2 study*]
*Find out what effects, good and/or bad,* [*drug/intervention*] *has on you and your* [*specify type/stage/presentation of*] *cancer.*

[*Example: Phase 3 study*]
*Compare the effects, good and/or bad, of* [*drug/intervention*] *with* [*commonly-used drug/intervention*] *on you and your* [*specify type/stage/presentation of*] *cancer to find out which is better. In this study, you will receive either the* [*drug/intervention*] *or the* [*commonly-used drug/intervention*]. *You will not receive both.*

## How many people will take part in the study?

About [*state total accrual goal here*] people will take part in this study. [*If appropriate, a short description about cohorts can be given here. For example: "At the beginning of the study, (enter number of first cohort) patients will be treated with a low dose of the drug. If this dose does not cause bad side effects, it will slowly be made higher as new patients take part in the study. A total of (enter maximum number) patients are the most that would be able to enter the study".*

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

[*List tests and procedures and their frequency under the categories below. Include whether a patient will be at home, in the hospital, or in an outpatient setting*].

**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 research physician.

[*List tests and procedures as appropriate.Use bulleted format*].

**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 exams, tests and procedures. They are part of regular cancer care.

[*List tests and procedures as appropriate.Use bulleted format*].

You will need these tests and procedures that are part of regular cancer care. They are being done more often because you are in this study.

[*List tests and procedures as appropriate. Use bulleted format. Omit this section if no tests or procedures are being done more often than usual*].

You will need these tests and procedures that are either being tested in this study or being done to see how the study is affecting your body.

[*List tests and procedures as appropriate. Use bulleted format. Omit this section if no tests or procedures are being tested in this study or required for safety monitoring*].

[*For randomized studies*] You will be "randomized" into one of the study groups described. 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 research physician can choose the group you will be placed in. You will have an [*equal/one in three/etc.*] chance of being placed in either group.

If you are in Group 1 (often called "Arm A")… [*Explain what will happen for this group with clear indication of which interventions depart from routine care*].
If you are in Group 2 (often called "Arm B")… [*Explain what will happen for this group with clear indication of which interventions depart from routine care*].
[*For studies with more than two groups, an explanatory paragraph containing the same type of information should be included for each group*].

When you are finished taking [*drugs or intervention*]… [*Explain the follow-up tests, procedures, exams, etc. required, including the timing of each and whether they are part of standard cancer care or part of standard care but being performed more often that usual or being tested in this study. Define the length of follow-up*].

[*Optional Feature: In addition to the mandatory narrative explanation found in the preceding text, a simplified calendar (study chart) or schema (study plan) may be inserted here. The schema from the protocol* ***should not*** *be used as it is too complex; however, a simplified version of the schema is encouraged. Instructions for reading the calendar or schema should be included. See example*].

## Study Chart

You will receive [*drug*(s) *or intervention*] every [*insert appropriate number of days or weeks*] in this study. This [*insert appropriate number of days or weeks*] period of time is called a "cycle". The cycle will be repeated [*insert appropriate number*] times. Each cycle is numbered in order. The chart below shows what will happen to you during Cycle 1 and future treatment cycles as explained previously. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

## Cycle 1

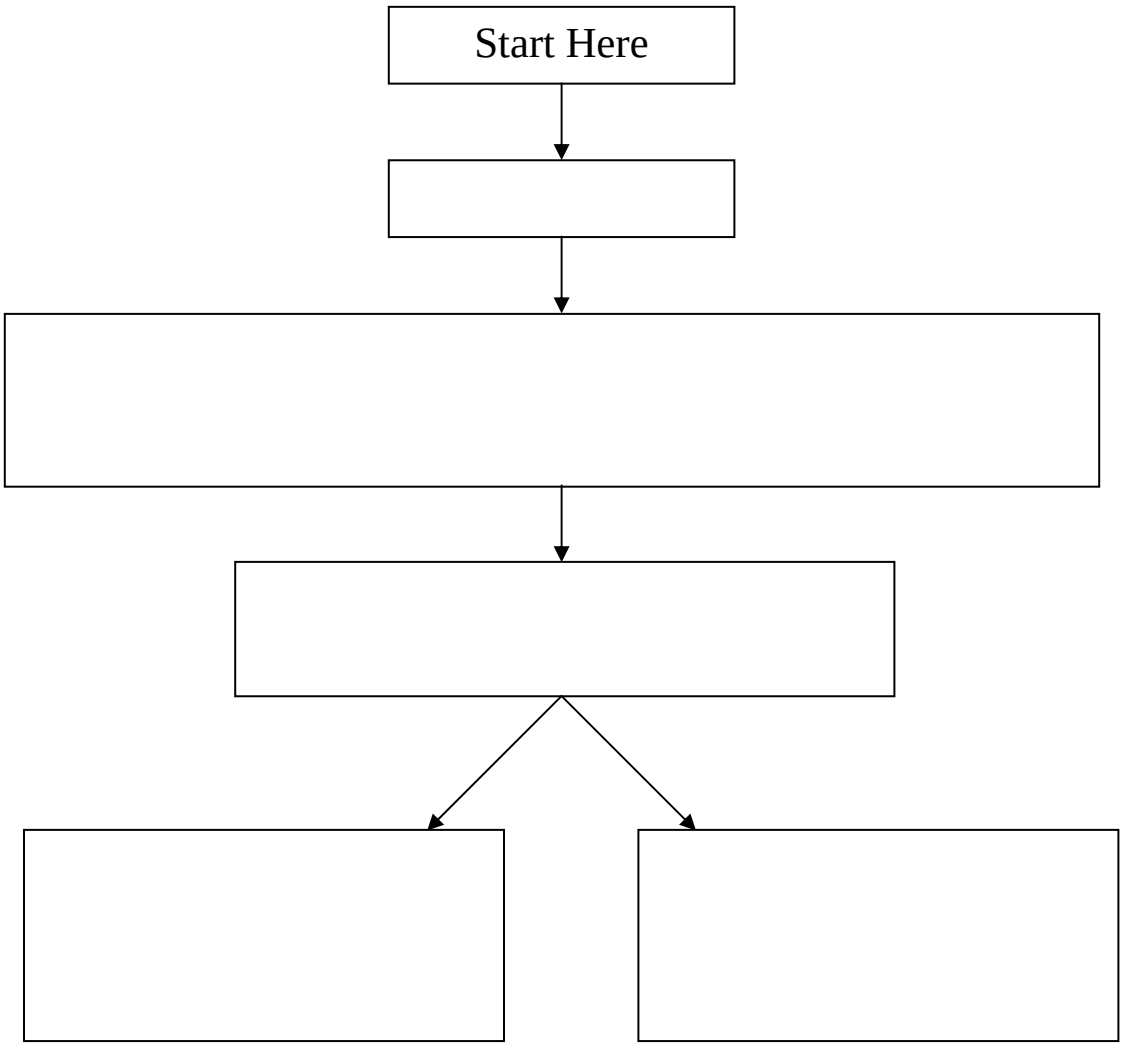
| Day | What you do |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |

## Future cycles

| Day | What you do |
|---|---|
| | |
| | |

## Study Plan

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.




## How long will I be in the study?

You will be asked to take [*drugs or intervention*] for [*months, weeks/until a certain event*]. After you are finished taking [*drugs or intervention*], the research physician will ask you to visit the office for follow-up exams for at least [*indicate time frames and requirements of follow-up. When appropriate, state that the study will involve long-term follow-up and specify time frames and requirements of long-term follow-up. For example, "We would like to keep track of your medical condition for the rest of your life. We would like to do this by calling you on the telephone once a year to see how you are doing. Keeping in touch with you and checking on your condition every year helps us look at the long-term effects of this study*"].

## Can I stop being in the study?

Yes. You can decide to stop at any time. Tell your research physician 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 your research physician if you are thinking about stopping so any risks from the [*drugs or intervention*] can be evaluated by your research physician. Another reason to tell your research physician that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The research physician may stop you from taking part in this study at any time without your permission if:

- continuing treatment would not be in your best medical interest
- your condition worsens
- the side effects of the treatment are too dangerous for you
- new information about the treatment becomes available and this information suggests the treatment may be ineffective or unsafe for you
- you do not follow study instructions
- funding for this research study is stopped
- drug supply is insufficient

## 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, physicians don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the [*drug(s) or intervention*]. In some cases, side effects can be serious, long lasting, or may never go away. **There also is a risk of death.** [*keep this sentence bolded*]

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

TIME AWAY FROM WORK BULLET-the board will not allow this to be listed as a risk. Instead, the following paragraph should be used.

Enrolling in this study may cause you to spend time away from work or other daily activities. This study can be time intensive and the side effects may affect your ability to perform normal daily activities. The potential length of time and possible severity should be discussed with you by the research physician.

Risks and side effects related to the [*procedures, drugs, intervention, devices*] include those which are:

**Likely:**

**Less likely:**

**Rare, but serious:**

*Using a bulleted format, list risks and side effects related to the investigational aspects of the trial. Side effects of supportive medications should not be listed unless they are mandated by the study.*

*List by regimen the physical and nonphysical risks and side effects of participating in the study in three categories:*

1. *"Likely"*
2. *"Less likely"*
3. *"Rare, but serious"*

*There is no standard definition of "likely" and "less likely". As a guideline, "likely" can be viewed as occurring in greater than 20% of patients with "less likely" in less than or equal to 20% of patients. However, this categorization should be adapted to specific study agents by the principal investigator. In the "likely" and "less likely" categories, identify those side effects that may be 'serious'. 'Serious' is defined as side effects that may require hospitalization or may be irreversible, long-term, life threatening or fatal.*

*Side effects that occur in less than 2-3% of patients do not have to be listed unless they are serious and should then appear in the "rare, but serious" category. Physical and nonphysical risks and side effects should include such things as the inability to work. Whenever possible, describe side effects by how they make a patient feel, for example, "Loss of red blood cells, also called anemia, can cause tiredness, weakness and shortness of breath".*

*For some investigational drugs/interventions/devices there may be side effects that have been noted during treatment however not enough data is available to determine if the side effect is related to the drug/intervention/device. Because some local IRBs request to be informed of these possible side effects, this information, when available, is provided to the study chair. Inclusion of this information in the informed consent document is not mandatory. However, if included, these side effects should be listed under a separate category titled "Side effects reported by patients, but not proven to be caused by (drug/intervention/device)". Side effect in this category do not have to be labeled as "likely", "less likely" or "rare, but serious" and should not be repeated here if they appear in a previous category. Similar to the other categories, these side effects should be listed in a bulleted format*].

**Reproductive risks:**

You must not become pregnant or father a baby (*including donating sperm*) while on this study because the drugs in this study can affect an unborn baby. Women must not breastfeed a baby while on this study. It is important you understand that you need to use birth control methods while on this study. Check with your research physician about what kind of birth control methods to use and how long to use them. Some methods might be approved for use in this study.

Appropriate methods of birth control include oral contraceptives ("*the pill*"), condoms, intrauterine devices (*IUD*), Norplant® or abstinence. Ask about counseling and more information about preventing pregnancy. [*Include a statement about possible sterility when appropriate. For example, "Some of the drugs used in the study may make you unable to have children in the future. If appropriate include a statement that pregnancy testing may be required.*]

For more information about risks and side effects, ask the research physician Dr. James L. Wade, III – (217) 876-6600 or contact your regular physician.

## Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While physicians hope [*procedures, drugs, interventions, devices*] 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 physicians learn more about [*procedures, drugs, interventions, devices*] 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:

- Receiving treatment or care for your cancer without being in a study
- Taking part in another study
- Receiving no treatment
- Receiving 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. [*For studies involving end-stage cancer*]

[*Additional bullets should include, when appropriate, alternative specific procedures or treatments*].

Please talk to your research physician 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 is 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: [*List relevant organizations like study sponsor(s), local IRB, etc.*]

- the research base [*give name*]
- the National Cancer Institute (*NCI*)
- the Cancer Trials Support Unit (*CTSU*), a research group sponsored by the National Cancer Institute (*NCI*) to provide patients and physicians greater access to cancer trials
- the Food and Drug Administration (*FDA*)
- the Office for Human Research Protections (*OHRP*)
- the drug manufacturer [*please list*]
- Decatur Memorial Hospital IRB (*which is a group of people who review the research to protect your rights*)
- appropriate research study staff and physicians with Decatur Memorial Hospital (*DMH*) and Cancer Care Specialists of Central Illinois (*CCSCI*) (*or other Investigator*)

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.

As you will recall, prior to being screened for this study, you were informed about The Notice of Privacy Practices and signed a separate authorization verifying your understanding of the procedures used by your physician to protect your personal health information.

## 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 receiving regular cancer treatment.

[*If applicable, inform the patient of any tests, procedures or agents for which there is no charge. The explanation, when applicable, should clearly state that there are charges resulting from performance of the test or drug administration that will be billed to the patient and/or health plan. For example, "The NCI (if not the NCI, state other study sponsor here), is supplying (drug) at no cost to you. However, you or your health plan may need to pay for costs of the supplies and personnel who give you the (drug)"*].

[*Include the following sentence if appropriate*] If, during the study, [*study drug*] becomes approved for use in your cancer, you and/or your health care plan may have to pay for drug needed to complete this study.

You will not be paid for taking part in this study.
[*If applicable, list any form of payment given to the subject by the research base or sponsor. This will include anything that the subject will be able to use to purchase something, such as a gift card or check to the subject.*]

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's web site at
http://cancer.gov/clinicaltrials/payingfor/insurance-coverage

You can print a copy of the "Clinical Trials and Insurance Coverage" information from this web site.

Another way to obtain 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 research physician, [*investigator's name(s)*], if you feel that you have been injured because of taking part in this study. You can tell the research physician in person or call him/her at (217) 876-6600.

You will receive 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 receive your medical care from our institution.

We will tell you about any new information or changes in the study that may affect your health or your willingness to continue in the study. [*Delete this paragraph if there is a DSMB*].

[*When a Data Safety and Monitoring Board exists; if the DSMB is not mandated by the NCI, please omit that portion of the statement*]
A Data Safety and Monitoring Board, an independent group of experts, mandated by the National Cancer Institute (*NCI*), will be reviewing the data from this research throughout the study. We will inform you about any 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?

For questions about the study or a research-related injury, contact the researchers:

| | | **Office** | **On-Call** |
|---|---|---|---|
| Dr. | James L. Wade, III | (217) 876-6600 | (217) 876-8121 |
| Dr. | Benjamin T. Esparaz | (217) 876-6600 | (217) 876-8121 |
| Dr. | Perry P. Guaglianone | (217) 876-6600 | (217) 876-8121 |
| Dr. | Mario R. Velasco, Jr. | (217) 876-6600 | (217) 876-8121 |
| Dr. | Dolores A. Estrada-Garcia | (217) 876-6600 | (217) 876-8121 |
| Dr. | Sebastien S. Kairouz | (217) 876-6600 | (217) 876-8121 |
| Dr. | Philip A. Dy | (217) 342-2066 | (217) 342-2066 |
| Dr. | Irene A. Dy | (217) 342-2066 | (217) 342-2066 |
| Dr. | Hanna M. Saba | (217) 342-2066 | (217) 342-2066 |

[*For studies involving RT, add*]

| | | | |
|---|---|---|---|
| Dr. | Michael L. Bruin | (217) 342-2066 | (217) 342-2066 |
| Dr. | Edward C. Elliott | (217) 876-4700 | (217) 876-8121 |
| Dr. | Mary Anne de Paz | (217) 876-4700 | (217) 876-8121 |
| Dr. | Harold A. Yoon | (217) 876-4700 | (217) 876-8121 |

For questions about your rights while taking part in this study, call the Decatur Memorial Hospital Institutional Review Board (*a group of people who review the research to protect your rights*) at:
[*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*].

Decatur Memorial Hospital Institutional Review Board

2300 North Edward Street
Decatur, IL  62526
(217) 876-4756

A Chairperson of this committee will discuss the matter with you.

Please note: This section of the 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.

[*Insert information about companion studies here. Provide yes/no options at each decision point. The following studies are included as examples, therefore, are written with italicized font. Any text provided for patients should use the same non-italicized font as used for the rest of the consent form.*

## *Quality of Life Study*

We want to know your view on how your life has been affected by cancer and its treatment. This "Quality of Life" study looks at how you are feeling physically and emotionally during your cancer treatment. It also looks at how you are able to carry out your day-to-day activities.

This information will help physicians better understand how patients feel during treatments and what effects the medicines are having. In the future, this information may help patients and physicians as they decide which medicines to use to treat cancer.

You will be asked to complete 3 questionnaires: one on your first visit, one 6 months later, and the last one 12 months after your first visit. It takes about 15 minutes to fill out each questionnaire.

If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

If you decide to take part in this study, the only thing you will be asked to do is fill out the three questionnaires. You may change your mind about completing the questionnaires at any time.

Just like the main study, we will do our best to make sure that your personal information will be kept private.

Please circle your answer.

I choose to take part in the Quality of Life Study. I agree to fill out the three Quality of Life Questionnaires.

**YES** **NO** _____

**Initials**

## *Consent Form for Use of Tissue for Research*

**About Using Tissue for Research**

You have had or are going to have a biopsy (*or surgery*) to see if you have cancer. Your physician has removed or will remove some body tissue to do some tests. The results of these tests have been or will be given to you by your physician and will be used to plan your care.

We would like to keep some of the tissue that is left over for future research. If you agree, this tissue will be kept and may be used to learn more about cancer and other diseases. Please read the information sheet called "How is Tissue Used for Research" to learn more about tissue research. This information sheet is available to all at the following web site:
http://cdp.cancer.gov/humanSpecimens/ethical_collection/patient.htm

The research that may be done with your tissue 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 tissue will not be given to you or your physician. These reports will not be put in your health record. The research will not have an affect on your care.

**Things to Think About**

The choice to let us keep the left over tissue 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 tissue 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 tissue. Then any tissue that remains will no longer be used for research.

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

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

Your tissue will be used only for research and will not be sold. The research done with your tissue may help to develop new products in the future. You should be aware that new products might be developed and commercially sold as a result of research done on your tissue. You will receive no economic benefit from this.

**Benefits**

The benefits of research using tissue 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.

A federal law called the Genetic Information Nondiscrimination Act (*GINA*) generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

**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 research physician or study nurse, or call our institutional review board at (217) 876-4756.

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

My tissue and blood may be kept for use in research to learn about, prevent, or treat cancer.

**YES** **NO** _____

**Initials**

My tissue and blood may be kept for use in research to learn about, prevent, or treat other health problems (*for example: diabetes, Alzheimer's disease and heart disease*).

**YES** **NO** _____
**Initials**

Someone may contact me in the future to ask me to take part in more research.

**YES** **NO** _____
**Initials**

Please read the information below called "How is Tissue Used for Research" to learn more about tissue research. Tissue can include materials from your body such as skin, hair, nails, blood, and urine.

## HOW IS TISSUE USED FOR RESEARCH?

**Where does tissue come from?**

Whenever a biopsy (or surgery) is performed, the tissue that is removed is examined under the microscope by a trained physician to determine the nature of the disease and assist with the diagnosis. Your tissue will always be used first to help make decisions about your care. After all tests have been done, there is usually some left over tissue. Sometimes, this tissue is not kept because it is not needed for the patient's care. Instead, a patient can choose to have the tissue kept for future research. People who are trained to handle tissue and protect the donor's rights make sure that the highest standards are followed by the ___. Your research physician does not work for the ___, but has agreed to help collect tissue from many patients. Many physicians across the country are helping in the same way. If you agree, only left over tissue will be saved for research. Your physician will only take the tissue needed for your care during surgery

**Why do people do research with tissue?**

Research with tissue 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 tissue 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 tissue?**

Many different kinds of studies use tissue. 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 tissue may look for genetic causes and signs of disease.

**How do researchers get the tissue?**

Researchers from universities, hospitals and other health organizations conduct research using tissue. They contact ___ and request samples for their studies. The ___ reviews the way that these studies will be done, and decides if any of the samples can be used. The ___ obtains the tissue and information about you from your hospital, and sends the tissue samples and some information about you to the researcher. The ___ 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 tissue?**

No, you will not receive the results of research done with your tissue. This is because research can take a long time and must use tissue samples from many people before results are known. Results from research using your tissue 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.

Though research involves the test results of many different people, your biopsy result involves only you. Your physician will give you the results of your biopsy when results are known. These test results are ready in a short time and will be used to make decisions about your care.

**Will I benefit from the research using my tissue?**

There will be no direct benefit to you because your tissue may not be used for sometime after you donate it and because research can take a long time. However, it is hoped that the results of research on your tissue and tissues from other patients will provide information that will help other patients in the future. Your tissue will be helpful whether you have cancer or not.

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

In order to do research with your tissue, 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 possibly some family history. This information is collected by your hospital from your health record and sent to ___ but without your name or other identifying information. If more information is needed, ___ 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.

**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. For diseases caused by gene changes, the information in one person's health record could be used against family members.

**How am I protected?**

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

## Where can I get more information?

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

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

You may 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/

Prior to participating in this trial, you and/or your legally authorized representative will receive a copy of this signed and dated form.

# DOCUMENTATION OF INFORMED CONSENT

You are voluntarily making a decision to participate in this study. Your signature means that you have read, or have had read to you in a language that was understandable, and understood the information presented and have decided to participate. Your signature also means that the information on this consent form has been fully explained to you and all your questions have been answered to your satisfaction. If you think of any additional questions during this study, you should contact the researcher(s).

I agree to take part in this study.

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Signature of Participant or Legally Authorized Representative Date

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Printed Name

I certify that all the elements of informed consent described in this consent form have been explained fully to the participant. In my judgment, the participant has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this study. I, being the person who has conducted the consent discussion, have signed this consent form in the presence of the participant.

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Signature of Person Conducting Informed Consent Discussion Date

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Printed Name of Person Conducting Informed Consent Discussion

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Signature of Investigator (*if different from above*) Date

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Printed Name of Investigator

*If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:*

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

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Signature of Witness Date

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Printed Name of Witness IRB Approved: xx/xx/xx

**Must be initialed and signed in BLUE INK**