**Informed Consent Template for Cancer Treatment Trials**

**(English Language)**

**\*NOTES FOR INFORMED CONSENT AUTHORS:**

1. Model text suggested for use in the informed consent form is in **bold**. It is recommended that the **bold** text be retained when adapting the template to a specific protocol.
2. Instructions and examples for informed consent authors are in *[italics]*.
3. A blank line,\_\_\_\_\_\_\_\_\_\_, indicates that the local investigator should provide the appropriate information before the document is reviewed with the prospective research participant.
4. The term ‘study doctor’ has been used throughout the template because the Principal Investigator of a cancer treatment trial is a physician. If this template is used for a trial where the Principal Investigator is not a physician, another appropriate term should be used instead of ‘study doctor’.
5. The template date in the header is for reference to this template only and should not be included in the informed consent form given to the prospective research participant.

**\*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 template 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>/

1. A blank line,\_\_\_\_\_\_\_\_\_\_, indicates that the local investigator should provide the appropriate information before the document is reviewed with the prospective research participant.
2. Suggestion for Local Investigators: An NCI pamphlet explaining clinical trials is available for your patients. The pamphlet is entitled: "Taking Part in Cancer Treatment Research Studies". This pamphlet may be ordered on the NCI Web site at <https://cissecure.nci.nih.gov/ncipubs/>or call 1-800-4**-**CANCER (1-800-422-6237) to request a free copy.
3. 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.

# SUMMARY OF CHANGES

**NCI Protocol #:**

**Local Protocol #:**

**NCI Version Date:**

**Protocol Date:**

**Protocol Title:**

*Please provide a list of changes from the previous CTEP approved version of the Informed Consent Document (ICD). The list shall identify by page and section each change made to the ICD with hyperlinks to the section in the ICD. All changes shall be described in a point-by-point format (i.e., Page 3, section 1.2, replace ‘xyz’ and insert ‘abc’). When appropriate, a brief justification for the change should be included.*

| **#** | **Section** | **Page(s)** | **Change** |
| --- | --- | --- | --- |
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# Study Title

**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** *[Type/stage/presentation of cancer being studied is briefly described here. For example: “Colon cancer that has spread and has not responded to one treatment”.]*

# 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 get either the [drug/intervention] or the [commonly-used drug/intervention]. You will not get 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 study doctor.**

1. **You will need to supply a complete list of your current medications to the study doctor. This includes over-the-counter medications and herbal supplements. Some medications may interact adversely with** *[study agent]***, and it is important that your study doctor and prescribing physician be aware of any potential risks so that they can prescribe alternative medications as necessary. If you do not already do so, please consider carrying a list of your medications at all times.**
2. *[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 tests and procedures. They are part of regular cancer care.**

1. *[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.**

1. *[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.**

1. *[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 study agents that interact with CYP isoenzymes]* **You will be provided with a wallet-sized information card (“Information on Possible Drug Interactions”) that names your study agent and outlines the specific risk of adverse interactions with other drugs or substances. Should you require any new medications while on study, please consult with your study doctor if possible, and present the card to the prescriber (doctor, pharmacist, physician’s assistant, or nurse practitioner). Please check with your doctor/prescriber or pharmacist before using any new over-the-counter medications or herbal supplements.**

*[For randomized studies:]* **You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an** *[equal/one in three/etc.]* **chance of being placed in any 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 I am 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 than 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 examples.]*

# Study Chart *[Example]*

**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** |
| --- | --- |
| Two days before starting study | 1. Get routine blood tests. |
| Day before starting study | 1. Check-in to \_\_\_\_\_\_\_\_\_\_\_\_\_ the evening before starting study. |
| Day 1 | 1. Begin taking \_\_\_\_\_\_ once a day. Keep taking \_\_\_\_\_ until the end of study, unless told to stop by your health care team. |
| Day 2 | 1. Leave \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and go to where you are staying. |
| Day 8 | 1. Get routine blood tests. |
| Day 15 | 1. Get routine blood tests. |
| Day 22 | 1. Get routine blood tests. |
| Day 28 | 1. Get routine blood tests and exams. 2. Get 2nd chest x-ray for research purposes. |
| Day 29 | 1. Return to your doctor’s office at \_\_\_\_\_\_\_ *[insert appointment time]* for your next exam and to begin the next cycle. |

**Future cycles**

| **Day** | **What you do** |
| --- | --- |
| Days 1-28 | 1. Keep taking \_\_\_\_\_ once a day if you have no bad side effects and cancer is not getting worse. Call the doctor at \_\_\_\_\_\_\_\_\_\_\_\_\_ *[insert phone number]* if you do not know what to do. 2. Get routine blood tests each week (more if your doctor tells you to). 3. Get routine blood tests and exams every cycle (more if your doctor tells you to). 4. Get routine X-rays, CT scans, or MRIs every other cycle (more if your doctor tells you to). |
| Day 29 | 1. Return to your doctor’s office at \_\_\_\_\_\_\_ *[insert appointment time]* for your next exam and to begin the next cycle. |

# Study Plan *[Example]*

**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.**

#### **Start Here**

Breast Cancer Surgery

### Medicines used in this study

### Doxorubicin + Cyclophosphamide by vein – given once every 21 days and repeated 4 times

### **Randomize**

(You will be inone Group or the other)

#### **Group 1**

### Paclitaxel by vein

Every 21 days for 4 visits

#### **Group 2**

### No Paclitaxel

# 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 study doctor 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 the study.”]*

# 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** *[drugs or intervention]***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?

**You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don’t know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the** *[drug(s) or intervention]***. In some cases, side effects can be serious, long lasting, or may never go away.** *[The next sentence should be included if appropriate.]* **There also is a risk of death.**

**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** *[procedures, drugs, interventions, devices]* **include those which are:**

**Likely**

**Less likely**

**Rare but serious**

*[Notes for consent form authors regarding the presentation of risks and side effects:*

* *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 and “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 effects 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 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. 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.** *[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 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** *[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 doctors 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:**

* **Getting treatment or care for your cancer without being in a study**
* **Taking part in another study**
* **Getting no treatment**

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

*[For studies involving end-stage cancer, add the following paragraph as an additional bullet.]*

* **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:**

* *[List relevant organizations like study sponsor(s), pharmaceutical company collaborators, local IRB, etc.]*
* **The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people**

**A description of this clinical trial will be available on** [**http://www.ClinicalTrials.gov**](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.**

*[Note to Informed Consent Authors: the above paragraph complies with the new FDA regulation found at 21 CFR 50.25(c) and must be included verbatim in all informed consent documents. The text in this paragraph cannot be revised.]*

*[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.**

*(If applicable, inform the patient of any tests or procedures for which there is no charge. Indicate if the patient and/or health plan is likely to be billed for any charges associated with these ‘free’ tests or procedures.)*

*(Include the following section if a study agent is manufactured by a drug company and provided at no charge)*

**The** *(identify study agent supplier here using the most appropriate choice of the following options: NCI, Cooperative Group, or another NCI-supported Clinical Trials Network)* **will supply the** *[study agent(s)]* **at no charge while you take part in this study. The** *(insert name of study agent supplier identified in first sentence)* **does not cover the cost of getting the** *[study agent(s)]* **ready and giving it to you, so you or your insurance company may have to pay for this.**

**Even though it probably won’t happen, it is possible that the manufacturer may not continue to provide the** *[study agent(s)]* **to the** *(insert name of study agent supplier identified in first sentence)* **for some reason. If this would occur, other possible options are:**

* **You might be able to get the** *[study agent(s)]***from the manufacturer or your pharmacy but you or your insurance company may have to pay for it.**
* **If there is no** *[study agent(s)]* **available at all, no one will be able to get more and the study would close.**

**If a problem with getting** *[study agent(s)]* **occurs, your study doctor will talk to you about these options.** *(End of section)*

*(Include the following section if a study agent is manufactured by the NCI and provided at no charge)*

**The NCI will provide the** *[study agent(s)]* **at no charge while you take part in this study. The NCI does not cover the cost of getting the** *[study agent(s)]* **ready and giving it to you, so you or your insurance company may have to pay for this.**

**Even though it probably won’t happen, it is possible that the NCI may not be able to continue to provide the** *[study agent(s)]* **for some reason. If this would happen, the study may have to close. Your study doctor will talk with you about this, if it happens.** *(End of section)*

**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**](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, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** *[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.**

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

**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 Institutional 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.**

*[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 informed consent document.]*

*[Example: Quality of Life study]*

*Quality of Life Study*

*We want to know your view of 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 doctors better understand how patients feel during treatments and what effects the medicines are having. In the future, this information may help patients and doctors 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 in 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*

*[Example: Use of Tissue for Research]*

*[The following example of tissue consent has been taken from the NCI Cancer Diagnosis Program’s model tissue consent form found at the following URL:*

<http://www.cancerdiagnosis.nci.nih.gov/> *]*

*Consent Form for Use of Tissue for Research*

***About Using Tissue for Research***

*You are going to have a biopsy (or surgery) to see if you have cancer. Your doctor will remove some body tissue to do some tests. The results of these tests will be given to you by your doctor 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 in research 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.*

*Your tissue may be helpful for research whether you do or do not have cancer. 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 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 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 xyz 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 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.*

***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.*

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

|  |  |
| --- | --- |
| *Yes* | *No* |

*2. My tissue may be kept for use in research to learn about, prevent or treat 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 take part in more research.*

|  |  |
| --- | --- |
| *Yes* | *No* |

# Where can I get more information?

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

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

**You may also visit the NCI Web site at** [**http://cancer.gov/**](http://cancer.gov/)

* **For NCI’s clinical trials information, go to:** [**http://cancer.gov/clinicaltrials/**](http://cancer.gov/clinicaltrials/)
* **For NCI’s general information about cancer, go to** [**http://cancer.gov/cancerinfo/**](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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**