ATTACHMENT 22E

Sample Informed Consent Template and Instructions for Use in Chemoprevention Clinical Trials

(Based on the National Cancer Institute treatment consent template, 2009 update)

Use of the National Cancer Institute (NCI) Informed Consent Template (IC) for Chemoprevention Trials:

****

Study Title: *insert title here*

Introduction

This is a clinical trial, a type of research study. Your study doctor may have already explained the purpose of the clinical trial to you. Clinical trials include only people who choose to participate in the research. Please take your time to make your decision about serving as a volunteer. You may talk about your decision with your friends and loved ones. You can also discuss this study with your regular personal health care provider. If you have any questions, you can ask your study doctor to provide more information and to answer any questions. You should only agree to participate in this study when you feel that you have all the information you will need to make a decision about participating.

For use when applicable.
You are being asked to participate in this study because you are at increased risk for developing _____ cancer. *[Reference and attach information about the type of cancer and eligibility requirements, if desired.]*

What is the purpose of this study?

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] given at different dose levels. In addition, we want to find out what effects, good and/or bad, it has on you and your risk of developing _____ cancer.

[Example: Phase 2 study]

Find out what effects, good and/or bad, [drug/intervention] has on you and your risk of developing _____ cancer.

[Example: Phase 3 study]

Compare the effects, good and/or bad, of the [drug/intervention] with the [currently-used drug/intervention or placebo] on you and your risk of developing _____ cancer to find out which is better. In this study, you will get either the [drug/intervention] or the [currently-used drug/intervention or placebo]. You will not get both. [Explain in 1-2 sentences. Examples are: "Currently there is no effective way to prevent this type of cancer in people at increased risk," or, "We do not know which of these two commonly used drugs is better."]

How many people will participate in the study?

About *[state total target accrual goal here]* **people will take part in this study.**

What will happen if I participate in this research study?

Before you begin participating in the study …

You will need to have the following exams, tests or procedures in order to find out if you can participate in the study. The exams, tests or procedures may be a part of regular medical care for someone at increased risk of developing _____ cancer. If you have had some of the exams, tests, or procedures recently, they may not need to be repeated. The doctor in charge of the study will decide which exams, tests or procedures you should have.

During the study …

The exams, tests and/or procedures will show if you can be in the study. If you choose to take part, then you will need the following tests and procedures.

These tests and procedures may be part of regular care for someone at increased risk for developing _____ cancer. The tests and procedures may be done more often because you are participating in this study.

You may be asked to write down information about the medication you are taking and how you are feeling in a diary ("study diary" in English).

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

[For randomized studies:] **You will be "randomized" into one of the study groups described below. Randomization means that you are selected to participate into a group at random.**

A computer program will select you to participate 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.**

When I am finished taking [drugs or intervention]**…**

[Explain the follow-up requirements, tests, procedures, exams, etc. required, including the approximate length of time involved (duration) when taking each test. And for how much time will the tests need to be done.

[Optional Feature: In addition to the required narrative explanation found in the preceding text, a simplified calendar (study chart) or schema (study plan) may be inserted here. Instructions for reading the calendar or schema should be included. See examples.]

Study Plan *(Example)*

You will receive *[drug(s) or intervention]* **every** *[insert appropriate number of days or weeks]* **while you are participating in this study. The study calendar below shows what will happen to you while you are participating in the study.**

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Study Calendar *(Example)*

Day	**What you do**
Two days before you begin taking the study drug	Get the required blood tests for the study.
First day you take the study drug	Begin taking _____ once a day. Keep taking _____ until the end of study, unless your medical research health care team tells you to stop. Begin study diary.
8 days after the study begins	Complete Quality of Life Questionnaire. For example, return to the clinic to have a biopsy.
28 days after the study begins	Return to clinic to have blood tests. Bring diary and questionnaire. Also bring your pill bottle and any pills that you did not use, or bring the empty pill bottle if you used them all.

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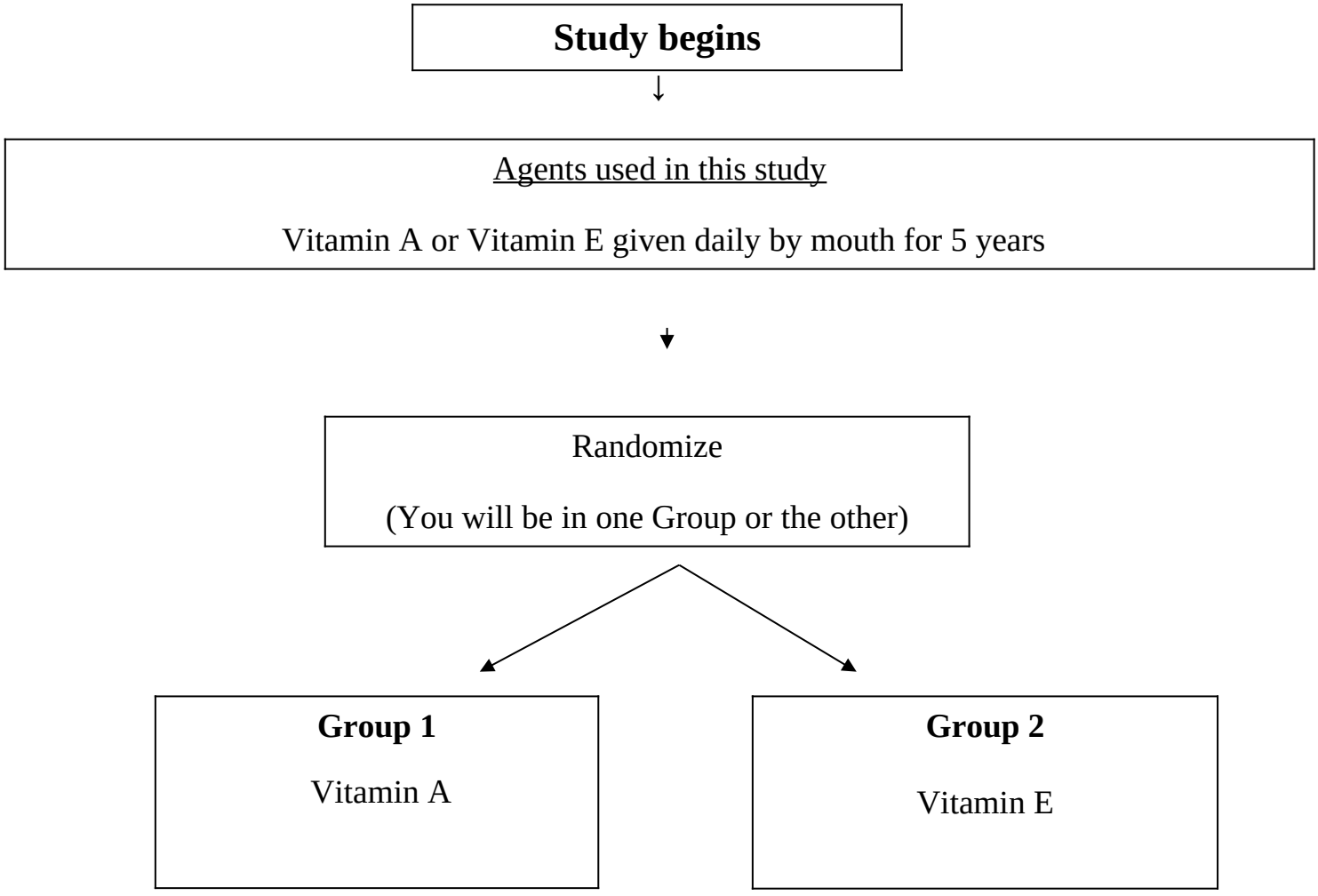
Study Flow Chart *[Example]*

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



How long will I participate in the study?

You will be asked to take *[drugs or intervention]* **for** *[months, weeks]*.

Can I stop participating in the study?

Yes. You can decide to stop participating at any time. Tell the study doctor if you are thinking about no longer participating or decide to stop. He or she will tell you how to stop participating without causing you any harm.

If you decide to stop taking the drug being used in the study, you may still participate in other parts of the study. You may be asked if we can still use your medical information. You can also decide that you do not want us to use your information such as test results and responses to questions.

The study doctor may stop you from participating in this study at any time for any of the following reasons:

- **If he/she believes stopping your participation is in your best interest.**
- **If you do not follow the rules of the study.**
- **Or if the study itself is stopped.**

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

You may or may not have side effects while you participate in the study. Everyone participating in the study will be looked after 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 medical research team may give you medicines to help reduce 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, last a long time, or may never go away.** *[The next sentence should be included if appropriate.* **There may also be the 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, please separate by category]* **include those which are:**

<u>Likely</u> e.g. *occurring in <u>greater</u> than 20% of participants*

- _
- _
- _
- _

<u>Less likely</u> e.g. *occurring in <u>less</u> than or equal to 20% of participants*

- _
- _
- _

- _

<u>Rare but Serious</u> e.g. *occurring in <u>less</u> than or equal to 2-3% of participants*

- _
- _
- _

Reproductive risks: For a woman, this means that she should not become pregnant while participating in the study. For a man, this means that he should not get a woman pregnant while participating in this study. This is 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. Talk 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 while you are participating in this study. For more information about risks and side effects, ask your study doctor.

Effects of other drugs you may be taking:
It is important to tell the doctor or study staff if you are taking any prescription or over the counter drugs, vitamins, minerals, dietary supplements, teas, or herbal supplements. We will need this information to make sure that there is no interaction with the study agent.

You may be asked to avoid donating blood during the time you participate in this study and for one month after you stop taking the drug used in this study.

What are the benefits of participating in this study?

Taking part in this study may or may not make your health better. **The doctors hope that the** *[drug or intervention]* **will be useful in cancer prevention. But right now there is no proof that the drug being used in this study will prevent cancer. We do know that the information collected in this study will help doctors learn more about** *[drug, intervention]* **as an agent to prevent cancer. This information could help improve the public health.**

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

Your other choices may include:

[*If appropriate*: You may be able to take the drugs being used in this study at this center and other centers even if you do not take part in the study.] **Please talk to your regular personal health care provider about these and other options.**

Will my medical information be kept private?

We will do what we can to make sure the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be shared 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, such as the Food and Drug Administration (FDA). These two government organizations are involved in keeping medical research safe for people.**

How much does it cost to participate in this study?

You and your health insurance company will need to pay for some or all of the costs of cancer treatment you will receive while you participate in this study. Some health insurance companies will not pay for cancer treatment costs for people who are participating in a clinical trial. Check with your health insurance company to find out what costs they will pay for. Participating in this study may or may not cost your insurance company more than the cost of regular cancer treatment.

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

The National Cancer Institute will provide the *[study agent(s)]* **at no charge while you take part in this study. The National Cancer Institute 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 National Cancer Institute 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://www.cancer.gov/clinicaltrials/learning/insurance-coverage* (only aviable in English.)**

You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site. The information is only available in English.

Another way to get the information is to call the *Cancer Information Service in English or Spanish* 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy. There are no shipping and handling charges when ordering 20 items or less.

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 can request medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will need to pay 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 stop

participating 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 the medical care you receive. You can still get your medical care from the institution conducting the study.

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 or release the institution from liability for negligence.

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 in order to protect your rights) at _____ *(telephone number).*

Please note: This section of the informed consent document is about additional research studies that are being done with people who are taking part in the [insert the title of the study here]. 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 participating 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.

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[Example: Quality of Life study]
Quality of Life Study

We want to know your view of how your life has been affected by the use of this chemoprevention agent. This "Quality of Life" study looks at how you are feeling physically and emotionally during the time you participate in this study.

This information will help doctors better understand what effects the chemoprevention agents are having. In the future, this information may help patients and doctors as they decide which medicines to use to prevent 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*

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[Example: Use of Tissue for Research]

Educational booklet on donating tissue for medical research:
In English:
www.cancer.gov/clinicaltrials/resources/providingtissue
In Spanish:
www.cancer.gov/espanol/cancer/tejidos-estudios-clinicos

Consent Form for Use of Body Tissue for Medical Research

*Using **Your Body** Tissue for Medical Research*

You are going to have a biopsy as part of the [insert the title of the study here].Your doctor will remove some body tissue to do some tests. Tissue can be a tumor that was removed during a biopsy. Any blood, urine, hair, nails, and skin that was removed from the body is also called tissue.

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 medical 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 using tissue in medical 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 the medical care you receive.

*Things **for You** to Think About*

The choice to let us keep the left over tissue for future research is yours to make. No matter what you decide to do, it will not affect the medical care you receive.

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 medical research.

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In the future, people who are doing medical research with your tissue may need to know more about your health. The [research clinic name] may give the people who are doing medical research with your tissue reports about your health. However, your [research clinic name], 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 medical 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 medical 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 the medical care you receive.

1. I give permission to have my tissue kept for use in medical research in case it is needed to learn about, preventing, or treating cancer.

Yes *No*

2. I give my permission to have my tissue kept for use in medical research in case it is needed to learn about, preventing or treating other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

Yes *No*

3.I give my permission in case someone needs to contact me in the future to ask me to take part in more medical research.

Yes *No*

Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service in English or Spanish at:

1-800-4-CANCER (1-800-422-6237)
TTY (only in English): 1-800-332-8615

You may also visit the National Cancer Institute Web site at
In Spanish: http://www.cancer.gov/espanol
In English: http://www.cancer.gov/

- **For clinical trials information at the** National Cancer Institute**, go to:**
  In Spanish: http://www.cancer.gov/espanol/cancer/estudios-clinicos
  In English: http://cancer.gov/clinicaltrials/

- **For general information about cancer from the** National Cancer Institute**, go to: English http://www.cancer.gov/cancertopics (only available in English)**

You will get a copy of this form. If you want more information about this study, please ask the study doctor.

Signature

I have received a copy of all _____ *[insert total of number of pages]* **pages of this form. I have read it or someone has read it to me. I understand the information and have had my questions answered. I agree to take part in this study.**

Participant _____

Date _____

Phrases and definitions to include in the glossary in English and Spanish:

- Informed consent: When a person who is interested in participating in a clinical trial gives their permission to participate. Before making a decision, a person is given facts about a medical procedure or treatment, a clinical trial, or genetic testing. The person also receives information about the possible risks and benefits.
- Study flow chart: A diagram or drawing that describes how a clinical trial will be conducted.
- Internal Review Board (IRB): A group of people that review and approve clinical trials at healthcare facilities that do clinical research. The group of people includes doctors, clergy, consumers and scientists. IRBs make sure that clinical trials will not cause harm to people who are participating.
- Study protocol: A document that explains in detail what a study is about, how it will be done, and why it is being done.
- Quality of life questionnaire: A questionnaire that measures physical and mental health of a person.
- Randomization: The process in which participants are assigned to participate in separate groups that compare different treatments or other medical interventions.
- Side effects: Medical problems that happen as a result of treatment.
- Study doctor: The doctor in charge of the study.
- Arm: The group that is receiving the drug being tested in a clinical trial.
- Study calendar: A calendar that provides the dates and schedules for events in a clinical trial. It includes when medical tests and medications will be given to people who participate in clinical trials and how long the clinical trial will last.
- Study diary: A daily written record in which a person participating in a clinical trial includes information about their health. Examples may include any changes in a person's health, such as headaches, and when the person took a medication.
- Intervention: A medical treatment to prevent or treat disease, or improve health in other ways.
- Procedure: The act of giving a diagnosis or providing medical treatment.
- Research participant= A person who is volunteering to participate in a clinical trial.
- Placebo: A pill that has no medicinal effect.
- Agent: A clinical trial that studies whether taking certain medicines, vitamins, minerals, or food supplements can prevent cancer.
- Outpatient: A patient who visits a health care facility for diagnosis or treatment without spending the night in the hospital.
- Biopsy: The removal of cells or tissues for examination by a type of doctor called a pathologist.
- Tissue: Any materials the body produces. For example, blood, urine, nails, hair, and skin. Any tumors or growths removed during surgery or a biopsy are also tissue.
- Regular personal health care team: Nurses, doctors and healthcare professionals that provide regular medical attention to patients.
- Medical research health care team: Nurses, doctors and healthcare professionals that provide medical care for people who are participating in a clinical trial.