Template Date: 04/01/2004

Informed Consent Template for Chemoprevention Trials

(Based on the NCI treatment consent template)

*NOTES FOR INFORMED CONSENT AUTHORS:

- Model text is in **bold**. It is recommended that the **bold** text be retained when adapting the template to a specific protocol.
- Instructions and examples are in *[italics]*.
- A blank line, _____, indicates that the local investigator should fill in the appropriate information before the document is reviewed with the prospective participant.
- The term "study doctor" is used throughout this template because the Principal Investigator of a chemoprevention 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.
- The template date in the header refers 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 summarizes 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 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 in 1998 by the Comprehensive Working Group on Informed Consent in Cancer Clinical Trials for the National Cancer Institute. The Web site for this document is http://cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/page2.
- A blank line, _____, indicates that the local investigator should provide the appropriate information before the document is reviewed with the prospective participant.
- An NCI pamphlet explaining chemoprevention clinical trials is available. The pamphlet is entitled, "Taking Part in Clinical Trials: Cancer Prevention Studies: What Participants Need to Know." This pamphlet may be ordered on the NCI Web site at http://cissecure.nci.nih.gov/ncipubs/details.asp?pid=149, or call 1-800-4- CANCER (1-800-422-6237) to request a free copy.
- Optional feature for Local Investigators: Reference and attach drug sheets, pharmaceutical information for the public, or other material on risks. Check with your local IRB regarding review of additional materials.

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

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 are at increased risk for _____ cancer. *[Reference and attach information about the type of cancer and eligibility requirements, if desired.]*

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 risk for _____ cancer.

[Example: Phase 2 study]

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

[Example: Phase 3 study]

Compare the effects, good and/or bad, of [drug/intervention] with [currently-used drug/intervention or placebo] on you and your risk of _____ 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 take part in the study?

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

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

[If appropriate, list tests and procedures and their frequency under the categories below. Include whether the participant 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 procedures are part of regular care for someone at increased risk of _____ cancer. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- *[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 care for someone at increased risk for _____ cancer.

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

You will need these tests and procedures that are part of regular care for someone at increased risk for _____ cancer. 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 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.]*

If you are in group 2 (often called "Arm B")… *[Explain what will happen for this group.]*

[For studies with more than two groups, an explanatory paragraph containing the same type of information should be included for each group.]

[NOTE: Specify how subjects will take the study agent (times/day, dosage, and route. List all paperwork (i.e., diaries, questionnaires, etc.) that the participant will be asked to complete. List specimens to be collected including frequency and amount.]

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

[Explain the follow-up requirements, tests, procedures, exams, etc. required, including the timing of each.]

[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]*

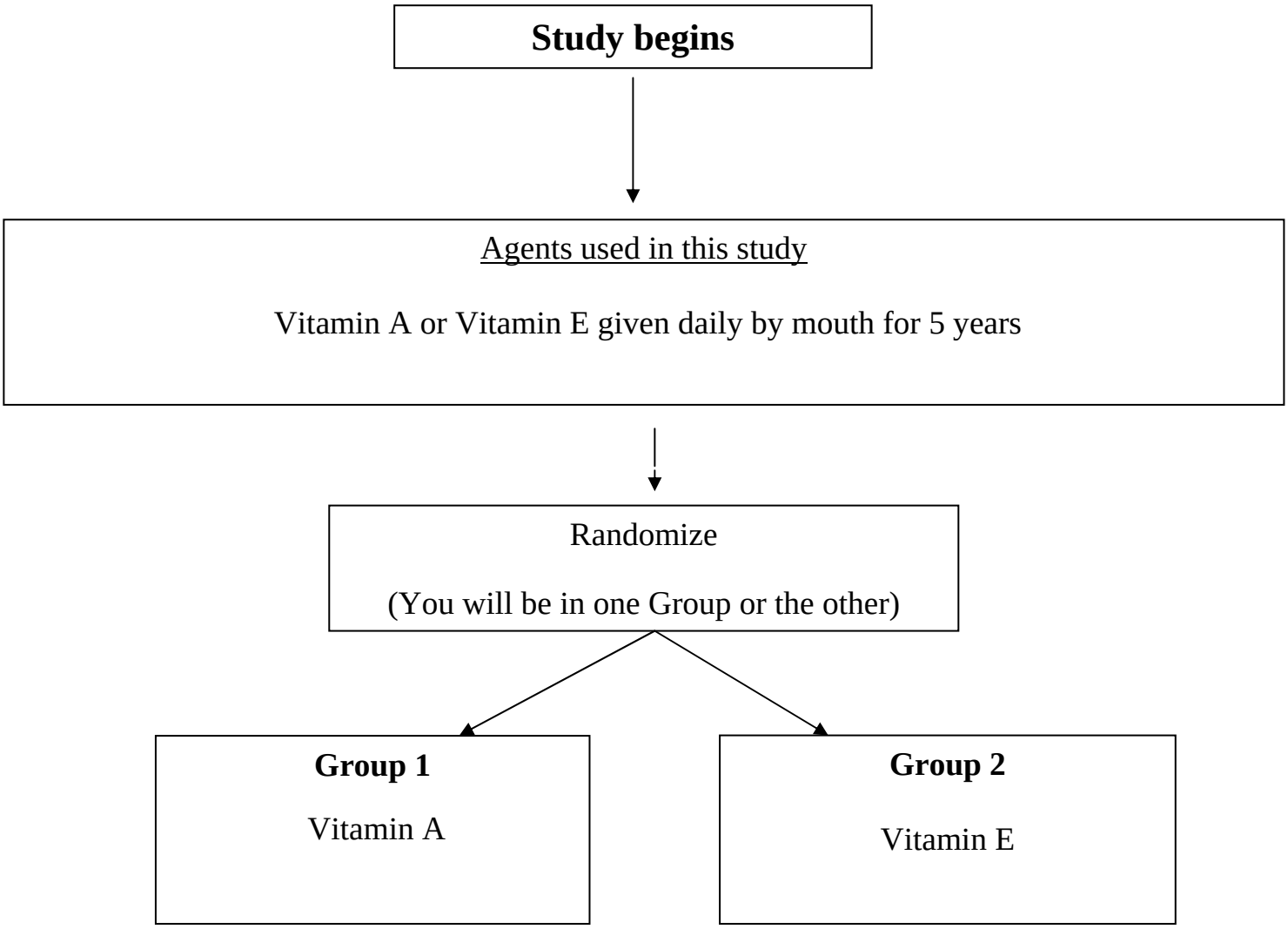
You will receive *[drug(s) or intervention]* **every** *[insert appropriate number of days or weeks]* **in this study. The chart below shows what will happen to you study.**

Study Calendar *(example)*

Day	**What you do**
Two days before starting study drug	• Get required study blood tests.
First day of taking study drug	• Begin taking _____ once a day. Keep taking _____ until the end of study, unless told to stop by your health care team. Begin study diary.
Day 8 of the study	• Complete Quality of Life Questionnaire.
Day 28	• Return to clinic for blood tests. Bring diary and questionnaire.
Etc…	•

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.



How long will I be in the study?

You will be asked to take *[drugs or intervention]* **for** *[months, weeks]. [When appropriate, state that the study will involve long-term follow-up and specify time frames and requirements of long-term follow-up.]*

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.

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,]* **include those which are:**

Likely

-
-
-
-

Less Likely

-
-
-
-

Rare but serious

-
-
-
-

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[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 participants and "less likely" in less than or equal to 20% of participants. 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 participants 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 participant feel, for example, "Loss of red blood cells, also called anemia, can cause tiredness, weakness and shortness of breath."*
- *For some investigational drugs/intervention there may be side effects that have been noted during administration 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 participants, 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. 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 *[drug, intervention]* **will be more useful in preventing, there is no proof of this yet. We do know that the information from this study will help doctors learn more about** *[drug, intervention]* **as an agent in cancer prevention. 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:
[*If appropriate*: You may get study drugs at this center and other centers even if you do not take part in the study.] **Please talk to your regular doctor about these and other options.**

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

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), 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.**

[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?

Taking part in this study may lead to added costs to you or your insurance company. Please ask about any expected added costs or insurance problems.

[If applicable, inform the participant 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 that will be billed to the participant and/or health plan.]

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

You will not be paid for taking part in this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage . You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, _____ *[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 participant 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.]

[If applicable to the protocol:]
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, and therefore are written with italicized font. Any text provided for participants 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 the use of this chemoprevention agent. This "Quality of Life" study looks at how you are feeling physically and emotionally during your time on 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*

[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 Web site: ***http://www.cancerdiagnosis.nci.nih.gov/specimens/model.pdf****.]*

Consent Form for Use of Tissue for Research

About Using Tissue for Research

You are going to have a biopsy as part of the main study. Your doctor will remove some body tissue to do some tests.

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 [research clinic name] 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) or **TTY: 1-800-332-8615**

You may also visit the NCI Web site at http://cancer.gov/

- **For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/**
- **For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/**

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

Signature

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

Participant _____

Date _____