**SUMMARY OF CHANGES – Consent**

**NCI Protocol #:**

**Local Protocol #:**

**Protocol Version Date:**

**Protocol Title:**

**Informed Consent Version Date:**

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** |
| --- | --- | --- | --- |
|  |  |  | *If there are no changes to the ICD, please use the following statement in the change memo of your protocol:*  There are no changes to the content of the ICD. The date has been changed to match the most recent version of the protocol. |
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NCI Informed Consent Template for Adult Cancer Trials

NCI Consent Form Template Version Date: November 27, 2018

**~Notes for Informed Consent Document Authors: ~**

**Purpose:** This document provides a template to follow when writing informed consent documents (ICDs) for many types of oncology trials. It recognizes the significant differences between various types of trials and provides phase-specific examples of suggested ICD language. This ICD template is not meant to be fully comprehensive. However, the lay language used and the format of the information should be followed as closely as possible when applying it to a specific study. In all cases, ICD authors should use clear and concise language.

**Reminder:** The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. The documentation of informed consent must comply with 45 CFR 46.117. These requirements are changed in the Final Revisions to the Common Rule, which are in effect as of January 19, 2018. These regulations are available at: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html>. FDA-regulated clinical investigations must also comply with the requirements for consent at 21 CFR 50 and IRB review at 21 CFR 56.

**Note on Certificate of Confidentiality Issues:** Beginning with the December 12, 2017 version of this template, the new Certificate of Confidentiality protections covering all NIH-funded research are addressed in the “Who will see my medical information?” section. The language in this template has been edited from NIH’s suggested consent language to align with the health literacy and plain language goals of this template.

**These notes and instructions for authors should not be included in the consent form.**

**~Instructions to Informed Consent Document Authors: ~**

* **Document Length and Language:** The NCI strongly recommends that the ICD not exceed 16 pages, excluding the “Optional studies” section. Suggestions for making the informed consent more concise include:

1. Focus on what makes the study different from the care a patient would typically receive. Instead of trying to cover everything that might happen during the trial, limit the information to the research issues.
2. Eliminate repetition of information.
3. Use lay language and explain concepts simply. Consider using shorter words and sentences. Longer words and sentences make the consent form difficult to read. Replace complex medical terminology with common, easily understood words.
4. Use online and/or manual readability tools to assess the reading level of your informed consent document. The 2015 IOM report on “Informed Consent and Health Literacy” recommends an eighth-grade reading level or lower. Information about readability assessments can be downloaded from the CTEP ICD website. If possible, ask patient advocates to review the document before submitting it to the IRB. The advocates can help identify potential comprehension challenges for patients.

* **Use of Example Text:** Edit the text examples as necessary to make the language specific to your study question since many statements throughout the template are generic. Examples are not given for every study situation. Consent authors should review all examples in a section, even if the example is for a different study type, to identify language that may apply to their study.
* **Formatting:**

1. Use 1-inch margins for top, bottom, and sides of the page.
2. Use Times New Roman size 14 font and bold the main section headings.
3. Use Times New Roman size 12 font for the body of the document.
4. Do not use all capital letters or italics to call attention to information. Use other formatting sparingly.

* **Color-Coded Information:**

~Instructions to consent authors for are highlighted in this color and set apart by the tilde symbol, “~”. This text should not be included in the consent form for patients.

Depending on the instructions, the text that follows should either be included in your consent word-for-word or with changes to make the text accurate for your study. ~

#Headers that indicate that the following text includes examples that could be adapted for use in your consent, if appropriate, are highlighted in this color and are set apart by the hash symbol, “#”. This header text should not be included in the consent form for patients. #

Sections where you should enter or modify text are (\*highlighted in yellow and listed between parentheses and asterisks\*). Adapt and enter the text as necessary. Remove the parentheses, asterisks, and highlighting in the consent form for patients.

* **Study Schema:** We encourage you to include a simplified study schema in the consent. The schema should be placed in the section, “What are the study groups?”
* **Use of More Than One Consent in a Single Study**: We encourage you to consider using more than one consent form to improve patient understanding when your study has distinct components (e.g. for multi-phase trials or trials with separate screening and intervention components). In these cases, the consent forms should reference each other appropriately.
* **Patient Educational Attachments:** Recommendations for educational attachments to the consent form may be found in the Attachments document on the CTEP ICD website. We encourage you to attach an easy-to-read-and- understand patient study calendar. Patient study calendars and other supplemental educational materials should not be part of the main consent form. If included, they should be attachments. Highlight the study appointments and procedures on the calendar that are required more frequently than with the usual approach. IRB review of attachments is required as they are considered part of the consent document.

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Research Study Informed Consent Document

~Instructions to ICD authors for the Study Titles:

1. Section length limit: Both titles together should take up no more than one-quarter page.
2. Include 2 titles:
   1. The reader-friendly lay title, which is called the “Study Title for Participants.”
   2. The official title, which can be used by potential study participants for Internet searches and aids in tracking by study administrative personnel.
3. For the lay title:
   1. Provide a brief (about 20 words) title of the study in lay language.
   2. Use general terms.
   3. To make the title concise, list the usual approach generically (e.g., chemotherapy, radiation therapy, surgery) rather than providing specific names (e.g., docetaxel, IMRT, laparoscopy). However, the investigational drug or other investigational item or procedure should be named.
   4. Use bold size 14 font for Study Title for Participants. Then list the actual title using size 14 font without bold. Do not capitalize all letters.
   5. This title should be the same as the lay title that will be used on <http://www.ClinicalTrials.gov>
4. For the official title:
   1. Insert study ID number, e.g., Protocol 0000, and, in quotes, the official study title as provided by the study sponsor.
   2. Use bold size 14 font for Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>. Then list the actual title using size 14 font without bold. Do not capitalize all letters. ~

~Use the following text for all studies: ~

Study Title for Participants: (\*Insert Lay Title here\*)

#Text Example for Lay Title: #

Study Title for Participants: Testing the addition of an anti-cancer drug, triapine, to the usual chemotherapy treatment (cisplatin) during radiation therapy for advanced-stage cervical and vaginal cancers

~Use the following text for all studies: ~

Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>: (\*Insert Study Number, “Insert Official Study Title,” (Insert NCT)\*)

#Text Example for Official Study Title: #

Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>: Protocol NRG-GY006, A Randomized Phase II Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer (NCT02466971)

~Use the following header for all studies: ~

Overview and Key Information

~ Instructions to ICD authors for the new “Overview and Key Information” section:

1. Section length limit: 3.5 pages.
2. This section introduces participants to research and the research study.

Note: This new section complies with new requirements in the Final Revisions to the Common Rule, which are in effect as of July 19, 2018. More information about the revised Final Rule, including more detail about this new requirement on pages 7212-7214 of the January 19, 2017 Federal Register publication, is available at <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>

The Final Rule requires “that the informed consent begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.” This section includes the “five factors” identified in the Final Rule that “would encompass the key information,” including providing a brief description of key foreseeable risks. ~

~Use the following text for all studies: ~

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

~Adapt the following text examples as appropriate for the study. Include type of cancer and, as applicable, relevant targeted mutations or treatment targets: ~

#Text Example for Treatment or Imaging Study #

We are asking you to take part in this research study because you have advanced brain cancer.

#Text Example for Targeted Treatment Study #

We are asking you to take part in this research study because you have non-small cell lung cancer that has spread outside your lungs, and your cancer has a change in the gene called the EGFR (epidermal growth factor receptor) gene.

#Text Example for Prevention Study #

We are asking you to take part in this research study because you have a high risk of developing breast cancer.

#Text Example for Supportive Care Study #

We are asking you to take part in this research study because treatments for your cancer can cause side effects such as nausea and vomiting.

~Use the following text for all studies: ~

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It’s important that you have as much information as you need and that all your questions are answered. See the “Where can I get more information?” section for resources for more clinical trials and general cancer information.

~Use the following text for all studies: ~

Why is this study being done?

This study is being done to answer the following question:

~Adapt the following text for all studies with a simple question summarizing the study’s primary objective: ~

#Text Example: #

Can we lower the chance of your prostate cancer growing or spreading by adding a drug to the usual combination of drugs?

~Use the following text for all studies: ~

We are doing this study because we want to find out if this approach is better or worse than the usual approach for your (\*insert type of cancer or precancerous condition, early detection, prevention of cancer, diagnosis, other\*). The usual approach is defined as care most people get for (\*insert condition\*).

~Adapt the following header for all studies: ~

What is the usual approach to my (\*insert type of cancer, precancerous condition, early detection, prevention of cancer, diagnosis, other\*)?

~ Instructions to ICD authors for the Usual Approach section:

1. Adapt language from the following examples or use other language specific to your study. Provide a brief description of a usual approach, which should not be overly specific or detailed, allowing the research to be placed into context. Indicate whether the usual approach includes FDA-approved treatments. Include an estimate of the expected outcome of the usual approach when/if it is known.
2. For chemoprevention trials, state the precancerous condition or high-risk status (e.g., current or former smoker, oral leukoplakia) and the usual intervention received if not participating in a study.
3. Avoid naming specific drugs as these could change with the availability of new treatments, except where a particular agent is so commonly accepted that it provides the easiest explanation.
4. Use sentences from different examples and add additional sentences or modify the provided examples as necessary to provide an appropriate description of the usual care for these participants. The yellow highlighting indicates sections that may commonly be adapted, but investigators should edit the examples as appropriate for the study. ~

#Text Example for Supportive Care Studies: #

The usual approach for patients who are not in a study is treatment with medications for nausea and vomiting that have been approved by the Food and Drug Administration (FDA).

#Text Example for Behavioral Studies: #

The usual approach for patients who are not in a study is to get advice from their doctor. This advice might include ways to exercise and how to do their daily activities so they are less tired.

#Text Example for Chemoprevention/ Studies: #

The usual approach for patients who are not in a study is to be followed closely by their doctor to watch for the development of cancer. Some patients may receive (\*insert agent; indicate if FDA-approved\*).

#Text Examples for Treatment Studies: #

#Example 1 #

The usual approach for patients who are not in a study is treatment with (\*insert usual treatment modality, e.g., more chemotherapy; indicate if FDA-approved\*). (\*Insert if appropriate: There are no treatments that are proven to help patients with your health condition live longer\*).

#Example 2 #

The usual approach for patients who are not in a study is treatment with surgery, radiation, or drugs (\*indicate if FDA-approved\*). Sometimes, combinations of these treatments are used. Your doctor can explain which treatment may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for a few months or longer. (\*Insert if appropriate: The usual approach is proven to help patients with your health condition live longer\*).

#Example 3 #

The usual approach for patients who are not in a study is treatment with hormonal drugs (\*indicate if FDA-approved\*). If the hormonal drugs stop working against your cancer, then doctors may use chemotherapy. For patients who get the usual approach for this cancer, about (\*insert appropriate number\*) out of 100 are free of cancer after 5 years.

#Example 4 #

The usual approach for patients who are not in a study is treatment with surgery, chemotherapy, and radiation therapy. There are several chemotherapy drugs approved by the Food and Drug Administration (FDA) that are commonly used with the radiation therapy. For patients who get the usual approach for this cancer, about (\*insert appropriate number\*) out of 100 are free of cancer after 5 years.

#Text Examples for Imaging Studies: #

#Text Example for Diagnostic Imaging Studies #

The usual approach for patients who are not in a study is to take a picture of their tumor(s) with a (\*insert as appropriate: CT, MRI, ultrasound, X-ray\*). This picture helps doctors diagnose your cancer. The (\*insert as appropriate, e.g. CT, MRI, ultrasound, X-ray\*) machine uses (\*insert type of mechanism, e.g., radiation, magnets\*) to take this picture.

#Text Example for Imaging Studies that Monitor Response to Treatment #

The usual approach for patients who are not in a study is to monitor the effect of treatment by taking pictures of their tumor(s) with a (\*insert as appropriate, e.g. CT, MRI, ultrasound, X-ray\*) machine over time. This means that you will get more than one (\*insert as appropriate, e.g. CT, MRI, ultrasound, X-ray\*) scan with a machine that uses (\*insert type of mechanism, e.g., radiation, magnets\*).

~Use the following header and text for all studies. Optional bullets should include, when appropriate, alternative procedures or interventions, watchful waiting, and/or palliative care. ~

What are my choices if I decide not to take part in this study?

* You may choose to have the usual approach described above.
* You may choose to take part in a different research study, if one is available.
* ~Consider adding as appropriate: ~ You may choose not to be treated for cancer.
* ~Consider adding as appropriate: ~ You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

~Use the following header for all studies. ~

What will happen if I decide to take part in this study?

~ Instructions to ICD authors for the What Will Happen section:

1. This section should include the length of time that study participants will be on active treatment or receiving the intervention and in follow-up.
2. Adapt the following text examples to appropriately describe the study. The yellow highlighting indicates sections that may commonly be adapted, but investigators should edit the examples as appropriate for the study. ~

#Text Example: Non-Randomized Study #

If you decide to take part in this study, you will get (insert description of intervention, e.g., study drugs or study approach) for up to (insert intervention length).

#Text Example: Randomized Study #

If you decide to take part in this study, you will either get (insert description of intervention, e.g., study drugs or study approach) for up to (insert intervention length), or you will get (insert description of intervention, e.g., study drugs or study approach) for up to (insert intervention length).

#Text Example: #

If you decide to take part in this study, you will either get the study drugs afatinib and cetuximab, or you will get afatinib alone, until your disease gets worse or the side effects become too severe.

~Adapt the following text to describe the length of study follow-up: ~

After you finish (\*insert description of intervention, e.g. your study treatment\*), your doctor will continue to follow your condition for (\*insert study follow-up length\*) and watch you for side effects (\*or insert other purpose\*). (~Include how the follow-up will occur, such as clinic visits or phone calls; how often, such as monthly, quarterly, annually; and how long the follow-up will continue~).

#Text Example: #

After you finish your treatment, your doctor and study team will watch you for side effects. They will check you every 3 months for 2 years after treatment. After that, they will check you every 6 months for 3 years. This means you will keep seeing your doctor for 5 years after treatment.

~Use the following text for all studies: ~

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the “What risks can I expect from taking part in this study?” section.

~Adapt the following text to appropriately describe the key study risks: ~

If you choose to take part in this study, there is a risk that the (\*study drug(s)/study approach\*) may not be as good as (\*the usual approach for your cancer / the other approach or study drug\*) at (\*shrinking or stabilizing your cancer / preventing your cancer from coming back / other explanation of benefit of other approach\*).

There is also a risk that you could have side effects from the (\*study drug(s)/study approach\*). These side effects may be worse and may be different than you would get with the usual approach for (\*you / your cancer\*).

Some of the most common side effects that the study doctors know about are:

* ~In a bulleted list, identify the most important risks, similar to the information that a doctor might deliver in the clinical context in telling a patient how sick the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study. This should be a brief list (generally around 5 although more may be necessary), including the most important reasonably foreseeable risks and discomforts. Note that for investigational agents or combinations, it may be important to highlight that there may be important unknown risks. ~

There may be some risks that the study doctors do not yet know about.

~ Use the following header for all studies: ~

Benefits

~Adapt the following text examples to describe the study benefits, making the language as specific as possible based on the study question. The yellow highlighting indicates sections that may commonly be adapted, but investigators should edit the examples as appropriate for the study. ~

#Text Examples for Treatment Studies: #

#Phase 0 Studies #

This study is not likely to help you. However, it may help the study doctors understand how this study drug works. This study may help the study doctors learn things that may help other people in the future.

#Phase 1 Studies #

There is some evidence (\*select and modify as appropriate: in animals, in living human cells, in living animal cells, in people with another cancer\*) that this treatment can (\*shrink or stabilize\*) cancer (\*insert targeted mutation as appropriate, e.g. with a change in the EGFR gene\*), but we do not know if this will happen in people. It is unlikely that this (\*insert intervention\*) will help you live longer. This study may help the study doctors learn things that may help other people in the future.

#Phase 1 Studies #

There is some evidence (\*select and modify as appropriate: in animals, in living human cells, in living animal cells, in people with another cancer\*) that adding (\*insert investigational drug\*) to the usual approach can (\*shrink or stabilize\*) cancer for longer than the usual approach alone. However, we do not know if this will happen in people. It is unlikely that this (\*insert intervention\*) will help you live longer than the usual approach alone. This study may help the study doctors learn things that may help other people in the future.

#Phase 1 Study Text Example #

There is some evidence in people with blood cancers that adding ruxolitinib to the usual approach can stabilize cancer for longer than the usual approach alone. However, we do not know if this will happen in people with your type of cancer. It is unlikely that adding ruxolitinib to the usual approach will help you live longer than the usual approach alone. This study may help the study doctors learn things that may help other people in the future.

#Phase 2 Non-randomized Studies #

This (\*insert intervention\*) has (\*shrunk or stabilized\*) your type of cancer (\*select and adapt as appropriate: in a limited number of people with your cancer and in animals or in living human or living animal cells\*). It is unlikely that it will work in everyone with your cancer or help you live longer. This study may help the study doctors learn things that may help other people in the future.

#Phase 2 and 3 Randomized Studies #

There is evidence that this (\*insert intervention\*) is effective in (\*shrinking or stabilizing\*) your type of cancer. It is not possible to know now if the (\*study drug(s)/study approach\*) will (\*extend your life / extend your time without disease / other primary endpoint\*) compared to the usual approach. This study will help the study doctors learn things that will help people in the future.

~Use the following text for all studies: ~

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It’s important that you stop safely. (\*Adapt and insert as applicable: This may mean slowly stopping the study drugs so that there is not a sudden unsafe change, risk to your health, etc.\*). If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

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

~Use the following text for all studies: ~

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

* Your health changes and the study is no longer in your best interest.
* New information becomes available and the study is no longer in your best interest.
* You do not follow the study rules.
* (~Include as appropriate. ~) For women: You become pregnant while on the study.
* The study is stopped by the National Cancer Institute (NCI) (~delete if NCI is sponsor ~), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (\*insert sponsor name in parentheses; if NCI delete the earlier mention of NCI\*). The study sponsor is the organization who oversees the study.

~Use the following text for all studies: ~

**It is important that you understand the information in the informed consent before making your decision.** Please read, or have someone read to you, the rest of this document. If there is anything you don’t understand, be sure to ask your study doctor or nurse.

~Use the following header for all studies: ~

What is the purpose of this study?

~ Instructions to ICD authors for the Purpose section:

1. Section length limit: This section should be no more 1/2 of a page.
2. Provide a brief, phase-specific description of why the study is being done.
3. Insert the names and types of investigational drugs/agents/interventions/biomarkers where indicated.
4. Insert the number of study participants taking part in the study.
5. If modifying the template language is necessary, use simple, concise, lay language. ~

~Adapt the following text examples or use other language specific to your study: ~

#Text Examples for Chemoprevention Studies: #

#Phase 1 Dose Escalation Chemoprevention Studies #

The purpose of this study is to test the safety of (\*insert name of study drug or agent\*) at different doses. “Dose” is defined as the amount of drug you get, (\*insert potential dose amounts such as \_\_mg or \_\_mL\*). We want to find out what effects the drug has on people, if any. There will be about (\*insert number\*) people taking part in this study.

#Phase 2 Non-randomized Chemoprevention Studies #

The purpose of this study is to test the safety of (\*insert name of study drug or agent\*) and find out what effect, if any, it has on people’s risk of developing (\*insert type of cancer\*) cancer. (\*Indicate if the drug is FDA-approved or not.\*) There will be about (\*insert number\*) people taking part in this study.

#Randomized Chemoprevention Studies #

The purpose of this study is to compare the safety and effects of (\*insert name of study drug or agent\*) with the safety and effects of (\*insert name of currently-used drug or placebo\*) on people’s risk of developing (\*insert type of cancer\*) cancer. In this study, you will get either (\*insert name of study drug or agent\*) or a placebo. A placebo looks like the study drug, but contains no medication. You will not know if you are getting the study drug or placebo. There will be about (\*insert number\*) people taking part in this study.

#Text Example for Supportive Care Studies #

You will be getting chemotherapy to treat your cancer. This treatment may cause nausea and vomiting. The purpose of this study is to test if (\*insert name of drug/intervention\*) can reduce your nausea and vomiting. The effects of (\*insert name of drug/intervention\*) will be compared to (\*a placebo or the usual approach\*). (~If applicable, include the following sentence.~) A placebo is a (\*insert appropriate description for the placebo, e.g., pill/liquid\*) that looks like the study drug, but contains no medication. There will be about (\*insert number\*) people taking part in this study.

#Text Example for Behavioral Studies #

You will be getting chemotherapy to treat your (\*insert type of cancer\*) cancer. This treatment may cause tiredness. The purpose of this study is to test if (\*insert intervention, e.g., yoga\*) can reduce your tiredness. The effects of (\*insert intervention\*) will be compared to (\*describe comparative intervention, e.g., listening to relaxation tapes, or the usual approach\*).

#Text Examples for Treatment Studies: #

#Phase 1 Dose Escalation Studies #

The purpose of this study is to test the safety of a drug called (\*insert name of study drug, e.g., TST1234\*). (~If applicable, include the following sentence.~) This drug has been tested in animals, but has not been tested in people. This study tests different doses of the drug to see which dose is safer for people. There will be about (\*insert number\*) people taking part in this study.

#Phase 1 Novel Route/Combination Studies #

This study uses a combination of drugs (\*insert names of drugs, e.g., carboplatin and paclitaxel\*). These drugs have already been approved by the FDA to be given through a vein in your arm. The purpose of this study is to test if giving one of the drugs, (\*insert name of drug, e.g., carboplatin\*), through a needle inserted into your belly at the same time that the other drug, (\*insert name of study drug, e.g., paclitaxel\*), is given through the vein in your arm is safe. There will be about (\*insert number\*) people taking part in this study.

#Phase 2 Non-randomized Studies #

The purpose of this study is to test the good and bad effects of the drug called (\*insert name of study drug, e.g., bevacizumab\*). (\*Insert name of study drug(s) or investigational approach\*) could shrink your cancer, but it could also cause side effects, which are described in the risks section below. The study doctors hope to learn if the study drug will (\*insert appropriate study endpoint, e.g., shrink the cancer by at least one quarter compared to its present size\*).

~Include and adapt the following sentence if appropriate. ~ (\*Insert name of drug[s]\*) have already been approved by the FDA to treat other cancers.

~The following sentence should be included only if the agent has not shown evidence of activity in humans. ~ We don’t know if (\*insert name of study drug\*) works to treat cancer in people, but it has shrunk several types of tumors in animals.

There will be about (\*insert number\*) people taking part in this study.

#Phase 2 or 3 Randomized Studies #

The purpose of this study is to compare the usual treatment alone to using (\*specific study drug, surgery, or radiation approach\*) plus the usual treatment. The addition of (\*insert name of study drug(s) or investigational approach\*) to the usual treatment could (\*insert purpose, e.g. shrink your cancer or prevent it from returning\*). But, it could also cause side effects, which are described in the risks section below.

This study will help the study doctors find out if this different approach is (\*adapt and insert as appropriate based on statistical design: better, the same, or worse\*) than the usual approach. To decide if it is better, the study doctors will be looking to see if the (\*study drug(s)/study approach\*) increases the life of patients by 6 months or more compared to the usual approach (\*edit or select other study primary endpoints as appropriate\*).

~The following two sentences should be included if appropriate and modified as necessary. ~ This chemotherapy drug, (\*insert name of drug, e.g., docetaxel\*), is already approved by the FDA for use in (\*insert type of cancer, e.g., prostate\*) cancer. But, most of the time it is not used until (\*e.g., hormone drug\*) stops working. There will be about (\*insert number\*) people taking part in this study.

#Text Examples for Imaging Studies: #

#Diagnostic, staging, response to therapy, or image-guided intervention #

The purpose of this study is to test (\*insert name of study intervention, e.g., PET\*) scans, which are a way to take pictures of your type of cancer. The study doctors want to see if (\*insert name of intervention, e.g., PET, PET-CT, MRI, advanced MRI, ultrasound\*) scans are (\*adapt and insert as appropriate based on statistical design: better, the same, or worse\*) than the (\*insert as appropriate: scans or biopsy or surgery\*) most often used to diagnose or monitor your cancer over time, (\*insert name of usual approach, e.g., CT scans\*). If better, this (\*insert name of intervention, e.g., PET\*) scan should (\*insert description of expected benefit\*). There will be about (\*insert number\*) people taking part in this study.

#Phase 0/First-in-human Imaging Study #

The purpose of this study is to test if (\*insert name of study intervention, e.g., F18-Fluoroglutamine\*) can be used to take pictures of your type of cancer. This will be the first time that (\*insert name of study intervention, e.g., F18-Fluoroglutamine\*) is being tried in people. There will be about (\*insert number\*) people taking part in this study.

#Phase 2 Non-randomized Imaging Agent Studies #

The purpose of this study is to test if an imaging drug called (\*insert name of drug/agent, e.g., 18F-fluoride\*) is useful for (\*diagnosing or monitoring\*) your type of cancer. The study doctors want to see if the (\*insert type of scan, e.g., PET\*) scan, used with the study drug, is better than the scans most often used to (\*diagnose or monitor\*) your type of cancer over time. There will be about (\*insert number\*) people taking part in this study

#Text Examples for Studies with Investigational Integral Biomarker(s) #

~ Instructions to ICD authors for studies with investigational integral biomarker(s):

1. The “what is the purpose of this study?” section should only describe integral biomarkers which are essential for conducting the study (e.g., define eligibility, stratification, disease monitoring, or study endpoints) and are investigational.
2. Do not include integrated biomarkers that are not essential to the primary endpoint or any exploratory biomarkers as these tests must be optional and will be listed in the “Optional studies” section at the end. ~

(\*Insert as appropriate: Another purpose of this study or The purpose of this study\*) is for the study doctors to learn if a (\*insert name of biomarker being tested for\*) test is helpful to decide (\*insert purpose of biomarker test, e.g., which study group you will be in\*). An (\*insert how biomarker sample will be obtained, e.g., extra tube of blood will be drawn or tissue from your surgery will be used\*) for the test. The study doctors do not know if using the test is (\*adapt and insert as appropriate based on statistical design: better, the same, or worse\*) than not using the test. If better, this test should (\*insert description of expected benefit\*). There will be about (\*insert number\*) people taking part in this study.

~Use the following header for all studies: ~

What are the study groups?

~Instructions to ICD authors:

1. Section length limit: This section should be no more than 1 page without a schema, or 2 pages with a schema.
2. Provide a brief, phase-specific description of the study groups.
3. Insert the names and types of the study drugs/agents/interventions, and the route of administration, dosing, where appropriate, and treatment schedule (e.g., how often, duration of infusions, etc.).
4. Clearly identify what intervention(s) are being evaluated.
5. Clearly identify which study drug(s)/arm(s) and study biomarker or imaging screening tests are considered investigational and/or are not FDA-approved in this setting.
6. When applicable, identify whether or not patients will be able to continue receiving study drug after the study or their participation in the study has ended.
7. For studies with multiple groups, indicate how many participants will be in each group, if known.
8. For randomized studies, include the probability of being assigned to each arm. If the assignment is not 1:1, include a brief description of the assignment.
9. If modifying the template language is necessary, use simple, concise, lay language.
10. Use of a simple study schema in this section is strongly encouraged regardless of study design. The schema should not be a duplication of the protocol schema, but should be adapted to highlight the information most relevant to potential study participants, comply with plain language principles, and improve patient comprehension. ~

~Adapt the following text examples or use other language specific to your study. The yellow highlighting indicates sections that may commonly be adapted, but investigators should edit the examples as appropriate for the study. ~

#Text Examples for Chemoprevention Studies #

#Text Example: Phase 1 Dose Escalation Chemoprevention Studies #

Different people taking part in this study will get different doses of the study drug (\*insert name of study drug\*). (\*Insert treatment schedule as appropriate – see text examples in other examples\*.)

Different doses of the study drug (\*insert name of research drug\*) will be given to some study participants. The first (\*input number\*) people taking part in this study will get the lowest dose. If the drug does not cause serious side effects, the next group of people in the study will get a higher dose. The study doctor will watch each group carefully as they increase the dose. The doses will continue to increase for every new group until people have serious side effects that require the dose to be lower. Once this dose is found, the dose escalation is stopped.

Then the study is stopped.

#Text Example: Randomized Phase 2 Chemoprevention Studies #

This study has two study groups. Group 1 will receive the study drug (\*insert name of research drug\*) and Group 2 will receive a placebo. A placebo (\*insert appropriate description for the placebo, e.g., pill/liquid\*) looks like the study drug, but contains no medication. (\*Insert treatment schedule as appropriate – see text examples in other examples\*).

#Text Examples for Studies with Screening Step #

#Studies with a Screening Step (for Intervention or Study Pre-Registration) with Integral Biospecimens #

This study has a screening step. The purpose of this step is to test your tumor to find out if it has a specific (\*gene change, mutation, or other evaluable change, e.g., protein, hormone, receptor, etc.\*). If it does and you meet all the study requirements, then we can assign you to treatment based on these changes. (~Include following sentence if study will screen people out based on test results. ~) If we find that your (\*tumor or other specimen\*) does not have the (\*genetic changes or other results\*) that are needed for this study, then your doctor will discuss other options for your care. (\*If applicable, state if the screening result will assign them to a specific study drug/ treatment or study arm\*). (\*If applicable, state that this screening test is not approved by the FDA in your disease\*).

#Studies with a Screening Step (for Intervention or Study Pre-Registration) with Integral Imaging #

This study has a screening step. The purpose of this step is to find out if your cancer is in specific places in your body (\*or insert other rationale\*). We will review (\*insert type of imaging studies, e.g., CT scans, PET scans, etc.\*) that you have already had. (~Include following sentence if study will screen people out based on test results. ~) If your scans do not show the results needed for this study (\*or specify what is needed for the study\*), your doctor will discuss other options for your care. (\*If applicable, state if the screening scans help assign them to a study group\*). (\*If applicable, state that this screening test is not approved by the FDA in your disease\*).

#Text Examples for Treatment Studies #

#Phase 1 Dose Escalation Studies #

Different people taking part in this study will get different doses of the study drug (\*insert name of study drug\*). (~Insert appropriate description of treatment schedule, including route of administration, e.g. as a pill you take by mouth, through a vein in the arm, or other route; and schedule. ~) Treatment schedule: You will get (\*insert name of study drug\*) through a vein in your arm on the first and eighth day of each cycle. Each cycle lasts 21 days. This study has 4 cycles. (~ Include the following sentence if you are including a study calendar. ~) See the study calendar for more information.

The first (\*insert number\*) people taking part in this study will get the lowest dose. If the drug does not cause serious side effects, the next group of people in the study will get a higher dose. The study doctor will watch each group carefully as they increase the dose. The doses will continue to increase for every new group until people have serious side effects that require the dose to be lower. Once this dose is found, the study is stopped.

(~Include and adapt the following sentences as applicable. ~) You (\*insert appropriate information, e.g., will/will not\*) be able to get additional doses of the drug. This drug is not approved by the FDA for treatment of your disease.

#Phase 1 Dose Escalation and Dose Expansion Studies #

There are two parts in this study, a dose escalation part and a dose expansion part. Your doctor will tell you which part you are in.

In the dose escalation part of this study, different people will get different doses of the study drug (\*insert name of study drug\*). (\*Insert treatment schedule here if different from treatment schedule used in dose expansion – see example below\*).

The first (\*input number\*) people taking part in this study will get the lowest dose. If the drug does not cause serious side effects, the next group of people in the study will get a higher dose. The study doctor will watch each group carefully as they increase the dose. The doses will continue to increase for every new group until people have serious side effects that require the dose to be lower. Once this dose is found, the dose escalation is stopped.

In the dose expansion part of this study, the highest dose with manageable side effects will be given to (\*insert number\*) more people. This will help study doctors better understand the side effects that may happen with this drug.

(~Insert appropriate description of treatment schedule, including route of administration, e.g. as a pill you take by mouth, through a vein in the arm, or other route; and schedule. ~) Treatment schedule: You will get (\*insert name of study drug\*) through a vein in your arm on the first and eighth day of each cycle. Each cycle lasts 21 days. This study has 4 cycles. (~ Include the following sentence if you are including a study calendar. ~) See the study calendar for more information.

(~Include and adapt the following sentences as applicable. ~) You (\*insert appropriate information, e.g., will/will not\*) be able to get additional doses of the drug. This drug is not approved by the FDA for treatment of your disease.

#Phase 2 Non-randomized Studies #

In this study, you will get the usual radiation therapy and chemotherapy (\*insert usual chemotherapeutics, e.g., 5-fluorouracil or capecitabine\*). You also will get the study drug (\*insert name of study drug\*).

(~Insert appropriate description of treatment schedule, including any radiation therapy or surgery, and for drugs include route of administration, e.g. as a pill you take by mouth, through a vein in the arm, or other route; and schedule.~) Treatment schedule: You will get (\*insert name of study drug\*) through a vein in your arm on the first and eighth day of each cycle. Each cycle lasts 21 days. This study has 4 cycles. (~ Include the following sentence if you are including a study calendar. ~) See the study calendar for more information.

(~Include and adapt the following sentences as applicable. ~) You (\*insert appropriate information, e.g., will/will not\*) be able to get additional doses of the drug. This drug is not approved by the FDA for treatment of your disease.

#Phase 2 Novel Route of Administration Study #

This study has 2 study groups.

* **Group 1**  
  If you are in this group, you will get (\*insert name of drug, route of administration [as a pill you take by mouth, through a vein in the arm, or other route], and schedule. For example, “You will get [name of drug] as a pill you take by mouth two times a day for [number of days] days.”\*) (~ Include the following sentence if you are including a study calendar.~) See the study calendar for more information.

(~Include the following sentence as applicable.~) You also will keep a pill diary. This helps you keep track of when you take your pills. The study doctor will show you how to use this diary. Each time you visit the clinic, you must bring the pill diary, any remaining pills, and the pill bottle.  
  
(~Include the following sentence as applicable.~) This drug is not approved by the FDA (\*insert route of administration as appropriate, e.g. “as a pill. However, the FDA has approved this drug to be taken by vein.”\*)   
  
There will be about (\*insert number\*) people in this group.

* **Group 2**If you are in this group, you will get (\*insert name of drug, route of administration [as a pill you take by mouth, through a vein in the arm, or other route], and schedule. For example, “You will get [name of drug] through a vein in the arm on the first and eighth day of each cycle. Each cycle lasts 21 days. This study has 4 cycles”.\*) (~ Include the following sentence if you are including a study calendar.~) See the study calendar for more information.There will be about (\*insert number\*) people in this group.

#Randomized Phase 2 Blinded, Placebo-Controlled Treatment Studies #

This study has 2 study groups. You will not be told which group you are in.

* **Group 1**  
  If you are in this group, you will get the usual drug used to treat this type of cancer, (\*insert name of usual drug\*), plus a study drug called (\*insert name of drug, e.g., docetaxel\*). You will get these drugs (\*insert route of administration [as pills you take by mouth, through a vein in the arm, or other route] and schedule, for example: “as pills you take by mouth two times a day for [number of days] days.”\*) (~ Include the following sentence if you are including a study calendar.~) See the study calendar for more information.  
    
  (~Include and adapt the following sentences as applicable.~) You (\*insert appropriate information, e.g., will/will not\*) be able to get additional doses of the drug. This drug is not approved by the FDA for treatment of your disease.

There will be about (\*insert number\*) people in this group.

* **Group 2**If you are in this group, you will get the usual drug used to treat this type of cancer, (\*insert name of drug[s]\*), plus a placebo. A placebo (\*insert appropriate description for the placebo, e.g., is a pill/liquid that\*) looks like the study drug, but contains no medication.

You will get the drug and placebo (\*insert route of administration [as pills you take by mouth, through a vein in the arm, or other route] and schedule, e.g. as pills you take by mouth two times a day for [number of days] days\*). (~ Include the following sentence if you are including a study calendar. ~) See the study calendar for more information.

There will be about (\*insert number\*) people in this group.

#Phase 3 Randomized Studies #

This study has 2 study groups. You will not be told which group you are in.

* **Group 1**

If you are in this group, you will get the usual drug used to treat this type of cancer (\*insert name of drug\*). You will get this drug (\*insert route of administration [as a pill you take by mouth, through a vein in the arm, or other route] and schedule, e.g. through a vein in the arm on the first and eighth day of each cycle. Each cycle lasts 21 days. This study has 4 cycles\*). (~ Include the following sentence if you are including a study calendar. ~) See the study calendar for more information.

There will be about (\*insert number\*) people in this group.

* **Group 2**

If you are in this group, you will get a study drug called (\*insert drug name, e.g., docetaxel\*) plus the usual drug used to treat this type of cancer, (\*insert name of drug\*). You will get these drugs (\*insert route of administration [as a pill you take by mouth, through a vein in the arm, or other route] and schedule, e.g. through a vein in the arm on the first and eighth day of each cycle. Each cycle lasts 21 days. This study has 4 cycles\*). (~ Include the following sentence if you are including a study calendar. ~) See the study calendar for more information.

(~Include and adapt the following sentences as applicable. ~) You (\*insert appropriate information, e.g., will/will not\*) be able to get additional doses of the drug. This drug is not approved by the FDA for treatment of your disease.

There will be about (\*insert number\*) people in this group.

~Use the following text, adapted as appropriate and including an appropriate probability, when applicable. ~

We will use a computer to assign you to one of the study groups. This process is called “randomization.” It means that your doctor will not choose and you cannot choose which study group you are in. You will be put into a group by chance. You will have (\*insert appropriate probability, e.g. an equal\*) chance of being in Group 1 or Group 2 (\*or insert appropriate description of assignments\*).

~Use and adapt the following text when including a study schema. Use of a simple study schema is strongly encouraged regardless of study design. ~

Another way to find out what will happen to you during this study is to read the chart below. Start reading (\*if using a horizontal schema: at the left side and read across to the right. If using a vertical schema: from the top and read to the bottom\*), following the lines and arrows.

~A very simple schema example is provided below. Additional, more complicated schema examples are provided on the NCI CTEP consent website: <https://ctep.cancer.gov/protocoldevelopment/informed_consent.htm> ~

#Schema Example: Simple Randomization #

Randomize –

The computer will randomly put you in a study group.

**Group 2**

Hormone therapy + Chemotherapy

(Study group)

You agree to take part in the study and sign this consent form.

**Group 1**

Hormone therapy

(Usual approach group)

~Use the following header for all studies. ~

What exams, tests, and procedures are involved in this study?

~ Instructions to ICD authors for the Exams, Tests, and Procedures section:

1. Section length limit: This section should be as brief as possible and take no more than 3/4 of a page. If this section includes a mandatory research procedure, specimen collection, or quality of life study, the length can be expanded to 1 1/2 pages.
2. In this section, it is important to highlight to potential participants what would change in their care if they took part in the study.
   1. Do not list exams, tests, or procedures that are related to the usual approach of cancer care for patients, such as clinically appropriate staging studies, lab tests, and exams.
   2. For optional exams, tests, and procedures, they may be briefly mentioned in this section and then noted that they will be described in the “Optional Studies” section at the end of the consent. This main section should focus on those exams, tests, and procedures that are mandatory for the main study.
3. Indicate whether the exams, tests, or procedures would only happen in certain study groups.
4. Exams, tests, and procedures to monitor patient safety and health: This section should only list those exams, tests, and/or procedures required to prevent complications and/or monitor the effects of the study agent(s), device, or other interventions on patient safety that are:
   1. Done more frequently or on a different schedule than the usual approach; or
   2. Not otherwise needed or necessary for the usual approach.
   3. Note: Any exam, test or procedure listed for (a) and (b) should provide the timing and/or frequency of when they are needed during the study.
5. Exams, tests, and procedures for research: This section should also list any research exams, tests, and/or procedures (including imaging studies or specimen collections) that are not part of clinical management such as those listed above in #4. This includes all mandatory research specimen collections that are considered “integral” to the study.
6. WGS/WES: Section 116(c)(9) of the revised Common Rule (the “Final Rule” released January 2017) requires that informed consents include, when appropriate: “For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).” Authors should be sure that this information is included when the protocol will use WGS/WES. This information should also be included in the optional studies section for any banked specimens.
7. Note: Optional correlative science studies, including specimen collections for integrated and/or exploratory biomarker tests and quality of life/patient-reported outcomes collections may be briefly mentioned here but should be listed as “optional.” They need to be described in detail at the end of the ICD under the “Optional studies” section and provide patients the opportunity to opt in or out.
8. Note: If it is planned to bill insurance for the exams, tests, and procedures being done for the clinical monitoring of the effects of the study drug/agent or treatment (or the prevention of complications), language documenting the clinical rationale for those tests be included in the protocol document, not the ICD.
9. Note: If a study includes the return of secondary or incidental genetic test results, explain what this would involve. However, the risks associated with these test results should be described in the risks section of the ICD.
10. Make sure that all procedures described here align exactly with what is described in the protocol and what is described in other sections of the consent.
11. An attached study calendar is highly recommended. It can be referenced in this section, but should be attached as a supplement to the consent and approved by the IRB as an attachment. ~

~Use the following text for all studies: ~

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

~Use the next paragraph if the study requires tests outside of the usual approach to monitor the effects of the study agent or prevent complications. ~

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

~Only use the next paragraph if the study requires tests outside of the usual approach to monitor the effects of the study agent or prevent complications. Edit the text to include tests as appropriate for the study. The tests should be listed with the timing when they occur in the study. ~

#Text Examples for Exams, Tests, and Procedures That May Be Needed Outside of the Usual Approach to Monitor Patient Safety #

These exams, tests, and procedures to monitor your safety and health include:

* An eye exam before you begin the study.
* Blood counts done weekly during the first cycle of treatment.
* Thyroid testing done every other cycle.
* Physical exams done weekly during the first cycle.

~Only use and adapt the next paragraph if the study will return non-standard secondary or incidental genetic test results. ~

This study will use genetic tests that may identify changes in the genes in your (\*insert either DNA / tumor DNA / other appropriate description\*). Your genes carry information about you and your family, from the color of your eyes to health conditions for which you may be at risk, such as certain kinds of cancer.

Finding these changes would not affect your treatment in this study. However, they could affect your health in other ways. (\*Insert plan for return of results, e.g. If there are changes found that could cause health problems, then your study doctor will discuss your options with you.\*) (\*As appropriate, insert additional information regarding timing, additional confirmatory testing, and availability of genetic counseling.\*)

~Only use the next paragraph of consent text if the study requires additional exams, tests, or procedures for research purposes only. Briefly list any procedures required for research purposes only. Do not include for optional study procedures, which should be included in the “Optional studies” section. ~

Text examples are given for specimen collections for research purposes and mandatory patient-reported outcomes or quality of life assessments, but this section may also include other types of exams, tests and procedures (such as mandatory extra imaging assessments) and the example text should be adapted or changed as appropriate to describe these situations.

It may be helpful to provide headers for timepoints in those studies with many research procedures, e.g. “Before you begin…” followed by a list of procedures required then, “During the study…” and so on. ~

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

~Instructions for mandatory specimen collections for research purposes:

1. Describe when the specimen will be collected.
2. Briefly describe how the specimen will be collected.
3. Briefly describe how the specimen will be used for research purposes.
4. Indicate if any test results will be returned.
5. If applicable, refer to any additional consent forms that may be needed, e.g. for a biopsy.
6. Do not describe any risks associated with the specimen collection here. Risks should be included in the risks section. ~

~Adapt the following text examples or use other language specific to your study. ~

#Text Example for Mandatory Specimen Collection Needed for Research Purposes Only #

You will need to have (\*a biopsy / a blood sample taken\*) for the study. (\*Insert information about when the sample will be taken, for example, before you begin study drug; after the third dose; etc.\*). The study biopsy takes small pieces of cancer tissue from your body. This is like the biopsy you had that helped diagnose your cancer. (\*Include a brief description of how the specimen will be used for research purposes\*). You (\*and/or\*) your study doctor (\*will/will not\*) get the results of this testing. If you agree to take part in the study, you may need to sign a separate consent form for the study biopsy at the hospital or clinic where the biopsy is done.

#Use of Existing Tissue Specimen if Available or a New Specimen Collection if Necessary #

Your study doctor will need to use some of the tissue left over from your biopsy when you were diagnosed with cancer. This sample is a required part of the study. (\*Include a brief description of how the specimen will be used for research purposes\*). You (\*and/or\*) your study doctor (\*will/will not\*) get the results of this testing.

If there is not enough tissue left over from your biopsy, your study doctor will need to do another biopsy to get this tissue. (\*Insert information about when the sample will be taken, for example, before you begin study drug; after the third dose; etc.\*). The study biopsy takes small pieces of cancer tissue from your body. This is like the biopsy you had that helped diagnose your cancer. (\*Include a brief description of how the specimen will be used for research purposes\*). You (\*and/or\*) your study doctor (\*will/will not\*) get the results of this testing. If you agree to take part in the study, you may need to sign a separate consent form for the study biopsy at the hospital or clinic where the biopsy is done.

#Use of Existing Tissue Specimen #

Your study doctor will need to use some of the tissue left over from your biopsy when you were diagnosed with cancer. This sample is a required part of the study. (\*Include a brief description of how the specimen will be used for research purposes\*). You (\*and/or\*) your study doctor (\*will/will not\*) get the results of this testing.

#Text Example for Mandatory Quality of Life or Patient-Reported Outcomes Assessments #

If you (\*briefly describe the languages spoken by patients for whom tools are provided, e.g., are an English or Spanish speaker\*) and choose to take part in this study, you will be asked to fill out a form with questions about (\*briefly state topic, e.g., your physical and emotional well-being\*). Researchers will use this information to (\*briefly describe purpose, e.g., learn more about how cancer and cancer treatment affects people\*).

(~Include and adapt the following two sentences as appropriate. ~) Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.

You will be asked to fill out this form at (\*insert number\*) times:

* (\*insert bulleted list of time indicators, e.g., before surgery, after surgery before chemotherapy, and mode, e.g., inpatient, mail, or phone\*).

Each form will take about (\*insert number\*) minutes to complete. The forms will ask about things like (\*briefly describe, e.g., tiredness, diarrhea\*). You don’t have to answer any question that makes you feel uncomfortable.

#Text Example for Optional Quality of Life or Patient-Reported Outcomes Assessments #

~Optional quality of life or patient-reported outcomes assessments may be briefly mentioned here with a reference to the optional studies section at the end of the consent. However, this is not required. ~

If you (\*briefly describe the languages spoken by patients for whom tools are provided, e.g., are an English or Spanish speaker\*) and choose to take part in this study, you will be asked to answer questions about (\*briefly state topic, e.g., symptoms and side effects you may have during the study\*). Researchers will use this information to (\*briefly describe purpose, e.g., learn more about how cancer and cancer treatment affects people\*). This is an optional part of the study. There is more information about this part of the study at the end of the consent form. You will be asked if you would like to take part in this optional additional study.

~Use and adapt the following statement if you want to include a patient study calendar as an attachment to the ICD. Patient study calendars are strongly recommended, but must be included as IRB-reviewed attachments and must not be incorporated in the ICD. ~

A patient study calendar is attached at the end of this document. It shows how often these (\*insert appropriate words, e.g., exams, tests, and/or procedures\*) will be done.

~Use the following header for all studies. ~

What risks can I expect from taking part in this study?

~Instructions to ICD authors for Risks section:

1. Section length limit: Limit this section to no more than 4 pages. If a study has a very long list of study drugs/treatment side effects and genetic testing risks, it may be up to 6 pages.
2. This section should include all reasonably foreseeable study risks, including those from the investigational drugs, agents, and/or treatments and also risks associated with any mandatory integral biomarkers, investigational biomarkers, research tests, procedures, and exams.
3. This section should focus on what risks might change or be different from what they would be if the individual chose not to participate in the study.
4. Trials that include investigational testing of biospecimens that may have the potential to reveal germline mutations (or suspected germline mutations) should include associated risks to patients and their family members.
5. Note: Risks associated with optional and other non-mandatory tests and procedures should be included in the “Optional studies” section.

Adapt the following text to accurately describe the general risk that the study drug/study approach/study intervention may not be effective:

General Risks

If you choose to take part in this study, there is a risk that the (\*study drug(s)/study approach\*) may not be as good as (\*the usual approach for your cancer or condition / the other approach or study drug\*) at (\*shrinking or stabilizing your cancer / preventing your cancer from coming back\*).

~From the following text, select reasonably foreseeable risks and discomforts and/or add others. Note that physical side effects are described later and should not be duplicated. ~

You also may have the following discomforts:

* Spend more time in the hospital or doctor’s office.
* Be asked sensitive or private questions about things you normally do not discuss.
* May not be able to take part in future studies.

~Use and adapt the following text for all studies as required by the protocol, and include additional detail as required. ~

The (\*specify intervention\*) used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for (\*insert time in months/years\*) after you have completed the study.

~Use and adapt the following text for protocols involving mandatory submission of tissue samples that may be depleted. ~

This study will use a sample of your tissue.  Generally, your hospital will keep some of your tissue.  This tissue may be used to help treat your cancer in the future.  Because this study will need to use some of this tissue, there is a small risk that it could be used up.

~Instructions to ICD authors on how to present risks associated with genetic or other testing that is investigational or non-standard:

1. Risks associated with using investigational genetic or other test results to direct treatment by determining study eligibility or study group assignment:
   1. If the test is investigational as used in this study, describe the risks associated with using the test results for direction of treatment. For studies where the test results will be used to determine patient eligibility in the trial, or for studies where the test results will be used to assign the patient to a study group, these risks include (1) the possibility of incorrectly being found eligible or (2) receiving an incorrect assignment due to an error in the test, and thus, the patient may not receive the best treatment option.
   2. For any study that requires waiting for test results before beginning treatment, there are possible risks to delaying treatment.
2. Risks associated with nonstandard genetic testing (testing not used as part of the usual care in this disease) that might identify mutations that are potentially inheritable:
   1. If the test will only be used on tumor tissue, the test cannot conclusively determine if a mutation is inheritable. This determination would require additional testing and expense outside of the study if a patient wanted to know if the mutation was inheritable.
   2. There may be implications of finding potentially inheritable mutations for the patient and the patient’s family.
3. Risks associated with the potential for secondary/incidental findings that are found using a clinically validated test:
   1. Note: Any plan to return secondary/incidental results should be described in the “What exams, tests, and procedures are involved in this study?” section.
   2. Consider how likely it is that there will be secondary/incidental findings given the planned testing. Secondary/incidental findings are more likely with more extensive testing. The description of the related risks should indicate how likely researchers believe they are to occur.
   3. If the testing is being done in a CLIA-certified lab, investigators will return the results of clinically validated tests and secondary/incidental results will be discussed with the patient.
   4. If the testing is being done in a research lab and the study is designed to return the results to the patient’s study doctor, the doctor would need to discuss with the patient if they are interested in learning more about the results using clinically validated tests. This would entail additional testing and expense outside of the study to confirm any secondary/incidental results in a CLIA-certified lab before they could be provided to the patient.
   5. If the patient chooses to receive information about secondary/incidental results, there may be implications for the patient and the patient’s family and learning this information may cause concern for the patient and their family members.
4. Note: For any study using genetic testing, there is a slight risk that in the future, someone not involved in the research might access and misuse the genetic information of trial participants. This information should be included in the section, “Who will see my medical information?” ~

Genetic Testing Risks

~Adapt the following text examples or use other language specific to your study. ~

#Text Examples for Studies Using Investigational Testing #

~ICD authors will need to carefully revise, add, and tailor the language to best describe the specifics of the study. Language should be adapted for non-genetic investigational testing used for the purposes of study eligibility or group assignment. ~

#Studies Using Investigational Genetic Test Results to Determine Study Eligibility and Assign Patients to Study Groups #

As part of this study, we are also studying a genetic test. The test is designed to find out if your tumor has the genetic changes that are needed for this study. If it does, we will assign you to a study group based on the genetic changes in your tumor.

Because this genetic test is still being studied, there is a risk that the test results may be wrong. If the test results are wrong, you may be included in this study even though it may not offer the best treatment option for you. Or, you may not be included in this study even though it may offer a good treatment option for you.

#Studies Using Genetic Testing of Tumor Tissue Alone to Identify Potentially Inheritable Mutations #

The genetic test used in this study will test your tumor for (\*a genetic change or genetic changes\*), (\*specify which changes, e.g., BRCA1\*). This change also may be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

Since this study is only testing tumor tissue, we will not know if a genetic change in your tumor is also in your normal tissue. If you want to find out if the change is in your normal tissue, then you will need to get other tests done outside of this study.

Genetic tests of normal tissue can reveal information about you and also about your relatives. Your study doctor will talk with you about what testing your normal tissue may mean for you and your family. He or she also may suggest that you talk with a genetics counselor to learn more. You or your insurance plan would have to pay for any genetic tests and visits to a genetic counselor done outside of this study.

#Studies Using Genetic Testing of Tumor Tissue and Normal Tissue to Identify Inheritable Mutations #

The genetic test used in this study will test your tumor and normal tissue for (\*a genetic change or changes\*), (\*specify which changes\*). Changes found in your normal tissue may be passed down in families. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

Genetic tests of normal tissue can reveal information about you and also about your relatives. Your doctor will talk with you about what the tests results may mean for you and your family. He or she also may suggest you talk with a genetics counselor to learn more. You or your insurance plan would have to pay for visits to a genetic counselor.

#Risks of Obtaining a Biopsy (Or Other Mandatory Specimen Collection) for Study #

~If applicable, include risks of research biopsy or other research specimen collection. ~

Biopsy Risks

Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, bruising, and pain at the biopsy site. Pain can be treated with regular pain medications. Rarely, an infection can occur. You may sign a separate consent form for the study biopsy that describes the risks in more detail.

~If there is any leftover specimen that may possibly be stored for biobanking, indicate here that this will be discussed in the section under “Optional studies”. ~

~Use and adapt the following required text describing research side effects for all studies. ~

Side Effect Risks

The (\*specify type(s) of study intervention, such as surgery, radiation therapy, drugs, etc.\*) used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study (\*specify type(s) of study intervention, such as surgery, radiation therapy, drugs, etc.\*).

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. (~Include as appropriate for study and population. ~) Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

* If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
* Your study doctor will work with you to treat your side effects.
* Your study doctor may adjust the study drugs to try to reduce side effects.

(~Include the following two sentences for studies looking at a new combination of drugs and modify if additional details about the interaction are known. ~) This study is looking at a combination of the usual drugs used to treat this type of cancer plus a study drug. This different combination of drugs may increase your side effects or may cause new side effects.

~Use the following required text describing research side effects for all studies. ~

Drug Risks

The tables below show the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

~Instructions to ICD authors on how to present possible side effects:

1. Side effects of study group(s):
   1. For single-arm studies, list all possible side effects of the study drugs per the recommendations below.
   2. For multiple-arm studies with a control arm, the Table(s) of Possible Side Effects for the control arm should appear first and be followed by the Tables of Possible Side Effects for the drugs/agents used in the investigational arm(s).
   3. If the investigational arm consists of the usual treatment drugs/regimens (the control arm) plus investigational agent(s)/drug(s), the Table of Possible Side Effects for the usual treatment should not be repeated.
   4. The following statement should appear before the Table of Possible Side Effects for the investigational drugs/agents: “In addition to side effects listed above for Group 1 and Group 2, people in Group 2 may also have some of the following side effects of (insert name of research drug).”
2. Side effects of procedures:
   1. When describing risks for procedures, describe risks only for procedures that are a change from what would be considered as occurring during the usual treatment approach.
   2. Examples of procedures that are not part of the usual treatment approach could include an unusually large amount of blood to be drawn for PK, central line placement to administer the investigational agent, research biopsy, etc.
3. Side effects of supportive drugs named in the ICD:
   1. Non-experimental supportive drugs should not have their side effects listed unless the treatment they support is the research question tested in the study. For example, side effects of filgrastim need not be listed unless filgrastim is part of the actual study question.
4. Side effects of classes of medications:
   1. If general classes of approved medications, such as a hormonal therapy or anti-emetics – where no specific drug is named – are required by the protocol, these and their related side effects do not need to be listed in the ICD.
   2. Extremely specific possible side effects which are not perceived by the study participant, such as minor changes in lab values, should not be included in the ICD. Lab value changes that could be perceived by the study participant, or could be indicative of harm, should be listed in terms they can understand. For example, the phrase “you could have liver damage,” would be more understandable to the study participant than “you could have elevated liver enzymes” or “you could have an elevation in (such-and-such lab value).”
5. Definitions of frequency categories:
   1. “Common, some may be serious” – There is no standard definition of the frequency of risks included in this category. However, as a guideline, “Common, some may be serious” can be viewed as occurring in greater than 20% and up to 100% of patients receiving the drug/agent.
   2. “Occasional, some may be serious” – There is no standard definition of the frequency of risks included in this category. However, as a guideline, “Occasional, some may be serious” can be viewed as occurring between 4% and 20% of patients.
   3. “Rare, and serious” – Side effects that occur in less than 3% of patients do not have to be listed unless they are serious, in which case they should appear in the “Rare, and serious” category.
   4. “Serious” is defined as side effects that may require hospitalization or may be irreversible, long-term, life-threatening, or result in serious impairment of normal life functions or death.
   5. “Possible, some may be serious” – This is a frequency category that may be used for informing study participants of possible side effects related to IND agents for which the frequency of individual side effects has not yet been determined due to limited experience in humans (fewer than 100 participants).
6. Note on stating possible side effects for imaging agents: Certain FDA regulations will need to be considered when imaging agents are used depending on the imaging agent (IND vs. commercial) and the protocol. Please refer to FDA’s draft guidance for industry standards for clinical trial imaging endpoints, at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM268555.pdf>, and FDA’s resources: “Medical Imaging and Drug Development” at [https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ucm092895 .htm](https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ucm092895%20.htm). Radiation Safety Committees may also require the mention of certain radiation-related information in the informed ICD.
7. Use of CTEP-provided tables:
   1. CTEP maintains tables of possible side effects for its IND agents as well as for many other drugs commonly used in cancer treatment trials. These tables should be inserted as illustrated below for the agents/drugs used in the cancer treatment trial.
   2. Tables of Possible Side Effects for commercial anti-cancer drugs are available on CTEP’s website at: http://ctep.cancer.gov/protocolDevelopment/informed\_consent.htm.
   3. Tables of Possible Side Effects for investigational agents are not posted to this public website. Rather, these tables are sent by CTEP to investigators with approved studies to include in their protocol.
   4. If a study uses a drug for which CTEP has not built a Table of Possible Side Effects, tools and instructions for custom-building a table are provided at <http://ctep.cancer.gov/protocolDevelopment/informed_consent.htm>.
   5. For custom-built tables of possible side effects, the same format and frequency categories should be used.
   6. The following Tables of Possible Side Effects for selected drugs and agents have been supplied as examples of what should be included for the regimens or drugs used in the study. Text and tables are examples for a randomized, phase 3 trial in colorectal cancer with Group 1 consisting of FOLFOX or FOLFIRI and Group 2 consisting of FOLFOX or FOLFIRI plus bevacizumab. These tables are only accurate as of the revision of this template. Up-to-date tables for these regimens should be obtained from the CTEP website. ~

~Use of the following risk tables format with bulleted risks is required for NCI’s Cancer Therapy Evaluation Program (CTEP)-sponsored studies. Consent document authors for studies sponsored by other entities have the option of using these risk tables. ~

#Table Examples for Drug Risks – replace all text through the “Additional Drug Risks” section with the appropriate risk tables. #

**Study Group 1 and Group 2** – Possible side effects of FOLFOX or FOLFIRI are listed in the tables below. These drugs are part of the usual approach for treating this type of cancer:

**Possible Side Effects of FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin)**

(Table Version Date: November 14, 2016)

| **COMMON, SOME MAY BE SERIOUS** In 100 people receiving FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin),  more than 20 and up to 100 may have: |
| --- |
| * Hair loss * Redness, pain or peeling of palms and soles * Rash, increased risk of sunburn, itching * Diarrhea, nausea, vomiting, constipation, loss of appetite * Difficulty swallowing * Sores in mouth * Heartburn * Infection, especially when white blood cell count is low * Anemia which may require a blood transfusion * Bruising, bleeding * Headache * Tiredness * Numbness, tingling or pain, "pins and needles" of the hands, feet, arms and legs * Tingling or a loss of feeling in your hands, feet, nose, or tightness in throat or jaw, or difficulty swallowing or breathing which may be made worse by exposure to cold * Cough * Fever, pain |

| **OCCASIONAL, SOME MAY BE SERIOUS** In 100 people receiving FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin), from 4 to 20 may have: |
| --- |
| * Chest pain * Abnormal heartbeat which may cause fainting * Swelling and redness at the site of the medication injection * Hives * Skin changes * Weight gain, weight loss, belly pain * Internal bleeding which may cause black tarry stool, blood in vomit or urine, or coughing up blood * Changes in taste * Blood clot which may cause swelling, pain, shortness of breath * Bleeding from multiple sites including vaginal bleeding, bleeding of the testis, or bleeding of the brain * Liver damage which may cause yellowing of eyes and skin * Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat * Change in voice * Confusion, dizziness * Muscle weakness * Inability to move shoulder or turn head * Blurred vision, watering eyes * Discomfort from light * Abnormal body movement including the eye and eyelid * Difficulty walking, using your hands, opening mouth, talking, with balance and hearing, smelling, eating, sleeping, emptying the bladder * Hearing loss * Swelling of the body which may cause shortness of breath * Kidney damage which may require dialysis * Scarring of the lungs * Blockage of the airway which may cause shortness of breath, cough, wheezing * Dehydration |

| **RARE, AND SERIOUS** In 100 people receiving FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin), 3 or fewer may have: |
| --- |
| * Damage to the heart which may cause shortness of breath * A new cancer resulting from treatment of a prior cancer * Redness, pain or peeling of palms and soles |

**Possible Side Effects of FOLFIRI (Leucovorin, 5-Fluorouracil, Irinotecan)**

(Table Version Date: November 14, 2016)

| **COMMON, SOME MAY BE SERIOUS** In 100 people receiving FOLFIRI (Leucovorin, 5-Fluorouracil, Irinotecan),  more than 20 and up to 100 may have: |
| --- |
| * Hair loss * Redness, pain or peeling of palms and soles * Rash, increased risk of sunburn, itching * Severe diarrhea, nausea, vomiting, constipation, loss of appetite, weight loss * Difficulty swallowing * Sores in mouth * Heartburn * Infection, especially when white blood cell count is low * Anemia which may require a blood transfusion * Bruising, bleeding * Headache * Tiredness, weakness, dizziness * Cough, shortness of breath * Fever, pain |

| **OCCASIONAL, SOME MAY BE SERIOUS** In 100 people receiving FOLFIRI (Leucovorin, 5-Fluorouracil, Irinotecan), from 4 to 20 may have: |
| --- |
| * Chest pain * Skin changes * Belly pain * Internal bleeding which may cause black tarry stools * Blood clot which may cause swelling, pain, shortness of breath * Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat * Confusion * Difficulty with balancing * Abnormal eye movement, blurred vision, watering eyes * Discomfort from light * Scarring of the lungs |

| **RARE, AND SERIOUS** In 100 people receiving FOLFIRI (Leucovorin, 5-Fluorouracil, Irinotecan), 3 or fewer may have: |
| --- |
| * Damage to the heart which may cause shortness of breath * A new cancer resulting from treatment of a prior cancer |

**Study Group 2** - In addition to side effects listed above, people who are in Group 2 may also have some side effects from bevacizumab. These side effects are listed below.

**Possible Side Effects of Bevacizumab**

(Table Version Date: May 23, 2016)

|  |
| --- |
| **COMMON, SOME MAY BE SERIOUS** In 100 people receiving bevacizumab, more than 20 and up to 100 may have: |
| * High blood pressure which may cause headache or blurred vision |

| **OCCASIONAL, SOME MAY BE SERIOUS** In 100 people receiving bevacizumab, from 4 to 20 may have: |
| --- |
| * Anemia which may require blood transfusion * Low white cell count that may increase the risk of infection * Infection, including collection of pus in the belly or rectum * Abnormal heartbeat which may cause palpitations or fainting * Pain in the belly, rectum, chest, joints, muscles, or tumor * Low appetite, constipation, diarrhea, heartburn, nausea, vomiting, or dehydration * Internal bleeding which may cause black tarry stool, blood in vomit, coughing up blood, or blood in urine * Bleeding from other sites, including the vagina or nose * Blockage of internal organs which may cause vomiting or inability to pass stool * Sores in the mouth * Allergic reaction during or after infusion of bevacizumab which may cause fever, chills, rash, itching, hives, low blood pressure, wheezing, shortness of breath, swelling of the face or throat * Delay in healing of wounds or spontaneous opening of wounds * Weight loss, tiredness, or dizziness * Muscle weakness * Damage to organs which may cause loss of teeth or loss of motion * Headache * Numbness, tingling or pain in the fingers or toes * Hoarseness, stuffy nose, or cough * Dry skin * Swelling and redness of the skin * Blood clot in limbs or lungs which may cause swelling, pain, shortness of breath * Leakage of protein in the urine, which can rarely lead to damage to the kidney |

| **RARE, AND SERIOUS** In 100 people receiving bevacizumab, 3 or fewer may have: |
| --- |
| * Clots in the arteries, causing stroke (which may cause paralysis or weakness) or heart attack (which may cause chest pain or shortness of breath). This risk is significantly increased in patients who are elderly or with history of diabetes. * Heart failure which may cause shortness of breath, swelling of ankles, and tiredness * Bowel perforation (a tear in the bowel) that can cause pain or bleeding and require surgery to repair * A tear or hole (fistula) in internal organs such as the nose, throat, lungs, esophagus, rectum, or vagina. These conditions may cause serious infections or bleeding and require surgery to repair. * Sores in the throat * Flesh-eating bacteria syndrome, an infection in the deep layers of skin * Bleeding in the tumor, brain, belly or lungs which may cause confusion, blood in stool or coughing up blood * Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome) * Kidney damage which may require dialysis * Redness, pain or peeling of palms and soles |

Additional Drug Risks

~Use the following text if drug interaction risks are expected. ~

The study drug could interact with other drugs (\*include if appropriate: and food\*). (\*Insert description of the potential interactions\*). (~Include the following two sentences if appropriate~). Your study doctor will give you a drug information handout and wallet card that lists these possible interactions. Share this information with your family members, caregivers, other health care providers, and pharmacists.

~Use the following text for all drug studies. ~

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

~If applicable, adapt the following text and table examples to describe study risks and side effects of imaging studies. These risks should also be included if there is additional imaging done that is not standard of care to describe the extra research risks involved.~

Imaging Risks

#Text Example of Radiation Risk for Research Imaging Studies #

The (\*insert type of scan, e.g., PET, CT\*) that you get in this study will expose you to low amounts of radiation. Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. This type of radiation is called “background radiation.” No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The (\*insert type of scan, e.g., PET, CT\*) that you get in this study will expose you to more radiation than you get from everyday background radiation. The amount of radiation from this scan is the same as (\*insert estimate, e.g., 2 years’ worth\*) of background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every 1000 people who get a very large amount of extra radiation.

#Text Example of Allergy Risk for Research Imaging Studies #

As part of the (\*insert type of scan, e.g., PET, CT\*) that you get in this study, iodine will be injected into your vein. Some people are allergic to iodine. Let your study doctor know if you have an allergy to iodine or seafood or if you have kidney problems.

~If applicable, adapt the following text and table examples to describe study risks and side effects of radiation therapy studies. Examples should be modified to add possible side effects related to treatment location. ~

#Table Example for Risks of Radiation Therapy Studies #

**Possible Side Effects of Radiation Therapy**

| **COMMON, SOME MAY BE SERIOUS**  In 100 people receiving radiation therapy, 20 to 100 may have: |
| --- |
| * Reddening, tanning, or peeling of the skin * Mild pain * Hair loss * Tiredness * Diarrhea, nausea * Anemia, which may require transfusion * Infection, especially when white blood cell count is low |

| **OCCASIONAL, SOME MAY BE SERIOUS**  In 100 people receiving radiation therapy, 4 to 20 may have: |
| --- |
| * Thickening and numbness of the skin * Sores or ulcers on the skin or near the cancer location * Permanent hair loss * Bleeding from the skin * Sores in mouth which may cause difficulty swallowing |

| **RARE, AND SERIOUS**  In 100 people receiving radiation therapy, 3 or fewer may have: |
| --- |
| * Damage to internal organs * Abnormal opening in internal organs which may cause pain and bleeding |

~Use the following header for all studies. ~

What are my responsibilities in this study?

~Instructions to ICD authors for the Responsibilities section:

1. Section length limit: This section should be no more than 1/2 of a page.
2. This section should include information about the responsibilities of study participants. ~

~Use and adapt the following text for all studies. ~

If you choose to take part in this study you will need to:

* Keep your study appointments.
* Tell your doctor about:
  + all medications and supplements you are taking
  + any side effects
  + any doctors’ visits or hospital stays outside of this study
  + if you have been or are currently in another research study.
* (~Include as appropriate ~) Write down in your medication diary when you take the study drug at home.

~Use and adapt the following text for all studies as required by the protocol, and include additional detail as required. ~

**For women:** Do not get pregnant or breastfeed while taking part in this study. **For men:** Do not father a baby while taking part in this study. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within (\*insert time in months/years\*) after your last dose of study drug (\*or modify for study treatment\*).

~Use the following header for all studies. ~

What are the costs of taking part in this study?

~Instructions to ICD authors for the Costs section:

* + - 1. Section length limit: This section should be no more than 1 page.
      2. If appropriate, state which study agent(s), tests, or procedures are provided free of charge.
      3. We recommend that investigators utilize an insurance coverage analysis of the study to ensure that billable and non-billable costs are appropriately identified. In most cases, all non-billable research costs should be covered by the study and provided free of charge to all participants.
      4. Outline any other pertinent financial impact or support.

1. Make sure that you have committed funding for all costs identified as covered by the study. Make sure that all procedures listed as covered by the study align exactly with what is described in the protocol.

~Use and adapt the following text for all studies. ~

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your (\*cancer/condition\*). This includes:

* the costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
* (~Include as appropriate ~) the costs of getting the (\*insert name of study agent(s)\*) ready and giving it to you.
* your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn’t pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

~Include the following two sentences if study includes exams, tests, and procedures done for research purposes only and paid for by the study.

Change and add to the example bullets to include the exams, tests, and procedures that are covered by the study. Include the time point(s) at which each item is covered. ~

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

#Text example of exams, tests, and procedures that are covered by the study #

* The extra EKGs in this study done at every treatment cycle.
* The blood clot test at the beginning of the study.
* The biopsy for testing (\*insert what is tested on biopsy\*) at the beginning of the study.

~Include and adapt the following text if one or more study agent is provided free to patients. Clearly state if study agent is covered for one group of patients but not others. ~ You or your insurance provider will not have to pay for the (\*insert name of study agent(s)\*) while you take part in this study.

~Use the following text if the study may require more frequent clinic visits than the usual approach. ~

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

* Have more travel costs.
* Need to take more time off work.
* Have other additional personal costs.

~Use the following text for all studies. ~

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment. ~If appropriate, insert a description of any compensation for participation or reimbursement for expenses. ~

~Use the following header for all studies. ~

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

~Instructions to ICD authors for the Injury section:

1. Section length limit: This section should be no more than 1/4 of a page.
2. Include plans for injury and compensation. ~

~Use the following text for all studies: ~

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

~Use the following header for all studies. ~

Who will see my medical information?

~Instructions to ICD authors for the Who Will See section:

1. Section length limit: This section should be no more than 1 page.
2. Note: The list provided below is intended to describe some of the organizations that may see the medical information. It is not intended to be an exhaustive list, as this is not feasible. Please consider limiting the list to key organizations of which a patient should be aware.
3. Additional required text should be included as necessary noting concerns around genetic testing and its potential impact on privacy.
4. Certificate of Confidentiality information is addressed in the first paragraph and further information should generally not be added. ~

~Use the following text for all studies: ~

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

~Modify the following text as necessary for all studies. ~

Some of these organizations are:

* The study sponsor and any company supporting the study (\*or the study agent/treatment\*) now or in the future. This would include any organization helping the company with the study. (~Delete company reference if not applicable. ~)
* The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study. (~Change the name of the IRB if the NCI Central IRB is not the IRB of record for the study. ~)
* The FDA and the groups it works with to review research. (~Add similar regulatory agencies if other countries are involved in the study in the last bullet of this section. Remove this bullet for studies, such as NCORP cancer care delivery research studies, where the FDA will not see study data. ~ )
* The NCI and the groups it works with to review research.
* (~For NCTN trials, add the following language. ~) The NCI’s National Clinical Trials Network and the groups it works with to conduct research (\*insert if appropriate: including the Imaging and Radiation Oncology Core (IROC)\*).
* (~Any other relevant trial organizations should be listed here. ~)

~All NCI studies must use the following two paragraphs of required text. ~

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people’s health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don’t know what research may be done in the future using your information. This means that:

~All NCI studies must use the following required text. Only the third bullet point may be modified. ~

* You will not be asked if you agree to take part in the specific future research studies using your health information.
* You and your study doctor will not be told when or what type of research will be done.
* (~ If some information may be given to study doctors, include appropriate information. ~) You will not get reports or other information about any (\*or some\*) research that is done using your information.

~Use the following required text when conducting genetic testing as part of the study. ~

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

~Use the following header for all studies. ~

Where can I get more information?

~Instructions to ICD authors for the More Information section:

1. Section length limit: This section should be no more than 1/2 of a page.
2. The second paragraph below complies with the FDA regulation found at 21 CFR 50.25(c) and must be included verbatim in all consent forms for any applicable trial under the regulation. The text in this paragraph cannot be revised. ~

~Use and adapt the following text for all studies. ~

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor (\*insert name of study doctor[s]\*) at (\*insert telephone number, and email address if appropriate\*).

For questions about your rights while in this study, call the (\*insert name of organization or center\*) Institutional Review Board at (\*insert telephone number\*).

~Use the following header and adapt the following text for all studies with additional optional studies. ~

Optional studies that you can choose to take part in

~Instructions to ICD authors for the Optional Studies section:

1. Section length limit: If the study mandates that any of these optional studies be included, the text should be as brief as possible and take up no more than 5 pages.
2. All the regulatory elements of consent included in the primary consent form pertain to the embedded optional studies. If any do not apply, they must be addressed in the discussion of the optional studies.
3. Provide yes/no options at each decision point and do not require initials.
4. After choosing which optional studies included below pertain to your specific research, delete the studies that do not pertain.
5. If modifying the Template language to include other studies is necessary, use simple, concise, lay language.
6. If participation in some optional studies will be limited (e.g. to certain institutions) make sure that this is clearly noted in instructions for the local sites. ~

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading (\*this optional study / these optional studies\*) hope the results will help other people with (\*cancer / your condition\*) in the future. (~ Include the following sentence if appropriate. ~) The results (\*will/ will not\*) be added to your medical records and you or your study doctor (\*will/will not\*) know the results.

Taking part in (\*this optional study / these optional studies\*) is your choice. You can still take part in the main study even if you say “no” to (\*this study / any or all of these studies\*). There is no penalty for saying “no.” You and your insurance company will not be billed for (\*this optional study / these optional studies\*). If you sign up for, but cannot complete (\*this study / any of these studies\*) for any reason, you can still take part in the main study.

Circle your choice of “yes” or “no” for (\*the following study / each of the following studies\*).

Optional imaging study – extra scan

~Adapt this example as needed to describe an extra scan for research purposes. ~

If you choose to take part in this study, you will have an extra (\*insert name of standard clinical imaging procedure, e.g., PET scan\*). This scan is already used in medical care. But, in this study, the scan would be done at a different time in your treatment than it would be if you were getting usual care. Researchers would use this scan to (\*briefly describe purpose, e.g., try to learn more about how treatment works on cancer\*). (~Include and adapt one of the two following sentences as appropriate, depending on whether the scan may be used to guide care. ~) The scan (\*may or would\*) be used to guide your medical care. (~If scan will not guide care, use the following sentence instead. ~) The scan would only be used for research and not to guide your medical care.

If you agree to have this extra scan, it would involve (\*briefly describe procedures, e.g., blood draw, contrast agent, time\*). The risks would be (\*briefly describe risks, focusing on risks of extra scan, e.g., additional radiation risk, risk of contrast\*). Ask your study doctor if you would like to learn more about this type of scan.

Please circle your answer: I choose to take part in the imaging study and will have the extra (\*insert name of procedure, e.g., PET scan\*):

YES NO

Optional imaging study – research scan or procedure

~Adapt this example as needed to describe an investigational scan or procedure. ~

If you choose to take part in this study, you will have an extra (\*insert name of standard clinical imaging procedure, e.g., PET scan\*). This scan is already used in medical care. In this study, the scan will be done at another time in your treatment than with the usual care. Researchers would use this scan to (\*briefly describe purpose, e.g., try to learn more about how treatment works on cancer\*). (~Include and adapt one of the two following sentences as appropriate, depending on whether the scan may be used to guide care. ~) The scan (\*may or would\*) be used to guide your medical care. (~If scan will not guide care, use the following sentence instead. ~) The scan would only be used for research and not to guide your medical care.

If you agree to have this extra scan, it would involve (\*briefly describe procedures, e.g., blood draw, contrast agent, more time\*). The risks would be (\*briefly describe, focusing on risks of extra scan, e.g., additional radiation risk, risk of contrast\*). Ask your study doctor if you would like to learn more about this type of scan.

Please circle your answer: I choose to take part in the imaging study and will have the (\*insert name of scan or procedure\*):

YES NO

Optional quality of life study

~Adapt this example as needed to describe an optional quality of life study embedded in the main study. ~

If you (\*briefly describe the languages spoken by patients for whom tools are provided, e.g., are an English or Spanish speaker\*) and choose to take part in this study, you will be asked to fill out a form with questions about (\*briefly state topic, e.g., your physical and emotional well-being\*). Researchers will use this information to (\*briefly describe purpose, e.g., learn more about how cancer and cancer treatment affects people\*).

(~Include and adapt the following two sentences as appropriate. ~) Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.

You will be asked to fill out this form at (\*insert number\*) times:

* (\*insert bulleted list of time indicators, e.g., before surgery, after surgery before chemotherapy, and mode, e.g., inpatient, mail, or phone\*).

Each form will take about (\*insert number\*) minutes to complete. The forms will ask about things like (\*briefly describe, e.g., tiredness, diarrhea\*). You don’t have to answer any question that makes you feel uncomfortable.

Please circle your answer: I choose to take part in the quality of life study and will fill out these forms:

YES NO

Optional sample collections for known laboratory studies and/or storage for possible future studies

~Instructions to ICD authors for optional sample collections:

1. Section title and content should be modified as applicable based on whether the study has optional collections and/or biobanking.
2. WGS/WES: Section 116(c)(9) of the revised Common Rule (the “Final Rule” released January 2017) requires that informed consents include, when appropriate: “For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).” Authors should be sure that this information is included when known future studies will use WGS/WES. This information should also be included for any protocols where specimens are banked for future unspecified research.
3. Some content for the biobanking consent has been adapted with the consent of the author, L. M. Beskow, from a simplified consent available as a supplementary appendix at: Beskow LM, Lin L, Dombeck CB, Gao E, Weinfurt KP. Improving biobank consent comprehension: a national randomized survey to assess the effect of a simplified form and review/retest intervention. Genet Med. 2016. ~

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person’s response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

~Adapt the examples below based on whether there are “Defined/Known Lab Study(ies)” or “Future Unspecified Research”. Include both types if appropriate per the protocol. Include information about all specimens to be collected and all known future studies. Make sure that all optional collections described here align with what is described in the protocol and study calendar. ~

#Text Example for Defined/Known Lab Study(ies) #

Known future studies

If you choose to take part in this optional study, researchers will collect (\*insert specimen to be collected, e.g., blood\*) for research on (\*briefly describe purpose\*). (\*Insert additional sentences describing in plain language the specimen to be collected, the research purpose, and planned analyses such as genetic sequencing for each known study.\*)

#Text Example for a Specimen Collected for Future Unspecified Research #

~Include the information below as appropriate, for instance with modifications if they will be contacted for additional consent. ~

Unknown future studies

~All information in this section is required if specimens are being banked for unknown future studies. This section may only be adapted as specifically noted. ~

If you choose to take part in this optional study, (\*insert specimen to be collected, e.g., a sample of tissue from your previous biopsy\*) will be collected and stored. Storing samples for future studies is called “biobanking.” The biobank is being run by (\*insert name of clinical trials organization\*) and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people’s health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don’t know what research may be done in the future using your (\*blood and/or tissue\*) samples. This means that:

* You will not be asked if you agree to take part in the future research studies.
* You and your study doctor will not be told when or what type of research will be done.
* (~If some information may be given to study doctors, include appropriate information. ~) You will not get reports or other information about any (\*or some\*) research that is done using your samples.

~All NCI studies banking specimens for future unknown studies are required to use one of the next two text examples. Select the appropriate text example based on whether you are collecting tumor tissue or not. ~

#Text Example for Study Collecting Tumor Tissue – Required to select this or one below#

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes. If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

#Text Example for Study Not Collecting Tumor Tissue # Required to select this or one above#

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may be passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes.

~Adapt the text below based on the study. The entire section should not be repeated for each sample collection; instead, describe all sample collections – for both known and unknown future research – in item 1 of the “What is involved” section below.

For Item 1 of the “What is involved” section, choose the appropriate information from the sentences that follow or add other information as necessary. Describe all study sample(s) and all collection time points. Note if the sample is drawn at same time as other draws, is residual material from embedded correlative, or already exists (archived tissue). ~

What is involved in this optional sample collection?

If you agree to take part, here is what will happen next:

1. (~Text example for blood sample. ~) About (\*insert number\*) tablespoons of blood will be collected from a vein in your arm. (~Text example for archival tissue sample. ~) A sample from the tissue that was collected at the time of (\*insert such as your surgery or your procedure\*) will be sent to the biobank. (~Text example for new tissue sample. ~) A sample of tissue will be collected from an optional extra biopsy.
2. (~Include or adapt the following sentences as appropriate. ~) Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. (~Include or adapt the following sentence as appropriate. ~) Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

* (~Adapt the following sentence as appropriate to describe risks from the study sample collection. ~) The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
* (~Include and adapt the following sentence as appropriate to describe risks from optional tissue submissions as appropriate for the study. ~) Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future.  There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
* Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
* In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. (~For non-US participants, adapt the following two sentences as needed. ~) There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

You will not benefit from taking part. (~If information may be given to the study participant’s physician for use in their care, insert appropriate information about the return of results. ~)

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this optional sample collection?

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?

If you decide you no longer want your samples to be used, you can call the study doctor, (\*insert name of study doctor for main trial\*), at (\*insert telephone number of study doctor for main trial\*), who will let the biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor, (\*insert name of study doctor for main trial\*), at (\*insert telephone number of study doctor for main trial\*).

~Use the following sentence if optional studies have been included. ~

Please circle your answer below to show if you would or would not like to take part in each optional study:

~Include the following statements as applicable. ~

Samples for known future studies:

I agree that my samples and related health information may be used for the laboratory (\*study or studies\*) described above.

YES NO

(~Include or adapt the following sentence if appropriate. ~) I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to learn about results from (\*this study or these studies\*).

YES NO

Samples for unknown future studies:

I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES NO

~Use the following text for any studies where patients may be contacted in the future. ~

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES NO

~Use the following sentence if optional studies have been included. ~

This is the end of the section about optional studies.

My signature agreeing to take part in the study

~Instructions to ICD authors for Signature section.

1. Section length limit: This section should be no more than 1/2 of a page.
2. Use the following text for all studies. Note that the signature of person(s) conducting the informed consent discussion is required for CTEP-sponsored studies. ~

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. (~Include the following sentence if appropriate. ~) I also agree to take part in any additional studies where I circled “yes”.

Participant’s signature

Date of signature

Signature of person(s) conducting the informed consent discussion

Date of signature