**INFORMED CONSENT FORM TEMPLATE**

This document provides a template to follow when writing informed consent (IC) documents for cancer prevention trials in ULACNet. This IC 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, IC authors should use clear, concise language.

Italicized text is instructional and should be removed. Edit the text examples as necessary to make the language specific to your study question. Additional elements from your institute can be added as needed.

**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 (also known as the Federal Policy for the Protection of Human Subjects), 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.

**Document Length and Language:** The NCI strongly recommends that the IC not exceed 16 pages, excluding the “Optional Studies” section. Suggestions for making the IC 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 IC. The 2015 IOM report on “Informed Consent and Health Literacy” recommends an eighth grade reading level or lower. If possible, ask patient advocates to review the document before submitting it to the IRB.

**Formatting:**

1. Use 1-inch margins for top, bottom, and sides of the page.
2. Use Times New Roman size 12 font and bold the main section headings.
3. Use Times New Roman size 11 font for the body of the document.
4. Do not use all capital letters or italics to call attention to information.

**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 participant understanding when your study has distinct populations (e.g., HPV vaccine for children living with HIV and HIV negative children, men and women groups) or components (e.g., eligibility determining biopsy or screening, followed by therapeutic vaccine administration). In these cases, the consent forms should reference each other appropriately.

**Participant Educational Attachments:** We encourage you to attach an easy-to-read-and-understand participant study calendar. Highlight the study appointments and procedures on the calendar that are required more frequently than with the usual approach. If included, participant study calendars and other supplemental educational materials should be attachments.

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***Study Title for Study Participants*** *(in lay language)*

***Official Study Title for Internet Search on*** [***http://www.ClinicalTrials.gov***](http://www.ClinicalTrials.gov)

# Overview and Key Information:

## 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.

We are asking you take part in this research study because…*insert appropriate reason for participant in the study.*

## 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 your access to medical care or any legal rights.

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

## Why is this study being done?

This study is being done to answer the following question: *Write the study question in plain language.*

*Text example: We are doing this study because we want to find out if this approach is better or worse than the usual approach for…. The term “usual approach” means the kind of care most people get for…*

## What is the usual approach to ………?

*Text example: The usual approach for patients who are at increased risk for cancer is to be followed closely by their doctor to watch for the development of cancer.*

*Text example: The usual approach for patients who have been detected with HPV infection is …*

## What are my choices if I do not 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 condition.*

# Study Details

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

*This section should include a brief description of the length of time that study participants will be on active treatment or receiving the intervention and in follow-up.*

## 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 will give you more information about study-specific risks in a later section.

*Text example: If you choose to take part in this study, there is a risk that the (study intervention(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).*

*There is also a risk that you could have side effects from the (study intervention(s)/study approach). These side effects may be worse than you might have with the usual approach for (you/your condition)*

Some of the most common side effects that researchers 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 participant about the usual approach to treatment, 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 risks) including the most important reasonably foreseeable risks and discomforts.*

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

* + **Benefits**

*Text example: Participating in this study may or may not help you because we do not know how the study approach will compare to the usual approach for your condition. This study may help us learn things that could help people in the future.*

## 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. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study. Your decision will not affect whether you can participate in the study, and it will not affect your relationship with your doctor or the study staff.

## 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 sinformation becomes available and the study is no longer in your best interest.
  + You do not follow the study rules.
  + The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (*insert US Lead Academic Organization name in parentheses*). The study sponsor is the organization that oversees the study.
  + *Include as appropriate. For women: You become pregnant while on the study.*

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.

## What is the purpose of this study?

*-Provide a brief, phase-specific description of why the study is being done. (3-5 sentences)*

*-Include the names and types of investigational drugs/agents/interventions/biomarkers.*

*-Include the number of study participants taking part in the study.*

*-Use simple, concise, lay language.*

## What are the study groups?

*-Provide a brief, phase-specific description of the study groups. Include simple schema if possible.*

*-Include the names and types of the study drugs/agents/interventions, and the route of administration, dosing (where appropriate), and treatment schedule per group.*

*-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.*

*-Indicate how many participants will be in each group, if known.*

*-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.*

* + *Text example: We will use a computer to assign you to one of the study groups. This process is called “randomization.” This is like tossing a coin. It means that neither you nor your doctor can choose which study group you are in. You will be put into a group by chance. You will have an equal (insert appropriate probability) chance of being in Group 1 or Group 2 (or insert appropriate description of assignments). Neither you nor your study doctor will know the group you are assigned to.*

*Example schema:*

Randomize –

The computer will randomly put you in a study group.

**Group 2**

Placebo

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

**Group 1**

Study Drug or Agent

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

*-In this section, outline the exams, tests, or procedures in each study visit. It is important to highlight for potential participants what would change in their care if they take part in the study.*

*-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.*

*-Indicate whether the exams, tests, or procedures would only happen in certain study groups.*

*-Describe when and how the specimen(s) will be collected and how the specimen(s) will be used for research purposes. Indicate if any test results will be provided to the participant.*

*-If applicable, refer to any additional consent forms that may be needed (e.g., for a biopsy).*

*-Do not describe any risks associated with the specimen collection here. Risks should be included in the “Risks” section.*

*Text example: Before you begin the study, you may need to have the following extra tests, and/or procedures in a Screening Visit to find out if you can be in the study. The study staff will discuss the consent form with you and answer any questions you may have. Once you have signed it, the following procedures will be done:*

* + *List screening tests/procedures*

*Text example: 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 may have more exams, tests, and procedures during the study to closely monitor your safety and health.*

*List the exams and procedures that will take place at each study visit. Include a simplified study calendar or chart if possible.*

*Section 116(c)(9) of the revised Common Rule requires that informed consents include whether research involving biospecimens will or might include whole genome sequencing or whole exome sequencing.*

*This information should also be included in the “Optional Studies” section for any banked specimens. The NIH Genomic Data Sharing policy can be found here:* [*https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/*](https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/)

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

If you choose to take part in this study, there is a risk that you may:

* Lose time at work or home and spend more time in the hospital or doctor’s office than usual.
* Be asked sensitive or private questions which you normally do not discuss, for example *……..*
* *(Insert if applicable) There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. The researchers believe the chance these things will happen is very small but cannot promise that they will not occur.*

There is also a risk that you could have side effects.

Here are important points about side effects:

* The study doctors do not know who will or will not have side effects.
* Some side effects may go away soon, some may last a long time, or some may never go away.
* Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

* Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
* The study doctor may be able to treat some side effects.
* The study doctor may adjust the schedule of study drugs application to try to reduce side effects.

*Medication Name if applicable:*

| **Common, some may be serious**  In 100 people receiving study drug, more than 20 may have: |
| --- |
|  |

| **Common, some may be serious**  In 100 people receiving study drug, more than 20 may have: |
| --- |
|  |
| **Occasional, some may be serious**  In 100 people receiving study drug, from 4 to 20 may have: |
|  |

*(If relevant)* Reproductive risks:

*(female participants) You should not get pregnant or breastfeed while in this study. The drugs used in this study could be very damaging to an unborn baby. You must use two forms of contraception while participating in sexual activity throughout the study. For example, use birth control pills and condoms, intrauterine device (IUD) and condoms, tubal ligation and condoms. If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your study doctor right away. Getting pregnant will result in your removal from this study.*

*(male participants) Do not father a baby while taking part in this study. The drug used in this study could be very harmful to an unborn or newborn baby. There may be some risks that researchers 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 up to X months after you have completed the study.*

*(If relevant) Risks related to blood tests: Blood tests can cause mild discomfort, bruising and/or bleeding at the blood draw site. Less likely is the possibility of significant bleeding or infection.*

*(If relevant) Risks from biopsy: describe risks*

## What are my responsibilities in this study?

If you choose to take part in this study, you will need to: *adapt as applicable*

* Keep your study appointments.
* Tell your doctor about:
  + medications you are taking
  + any side effects
  + any doctors’ visits or hospital stays outside of this study
  + your current or past enrollment in another research study

## What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights. For questions about your rights while in this study, call the (*insert name of center*) Institutional Review Board at (*insert telephone number*).

## What are the costs of taking part in this study?

*-Outline any pertinent financial impact or support including insurance coverage and costs identified as covered by the study.*

*-If appropriate, insert a description of any compensation for participation or reimbursement for expenses.*

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

If you feel you have been injured or hurt as a result of taking part in the study, it is important that you tell the study doctor immediately. You will get medical treatment if you are injured or hurt as a result of taking part in this study.

*Sample text: The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance coverage, you would be responsible for any costs. Even though you are in a study, you keep all of your legal rights to receive payment for injury caused by medical errors.*

## Who will see my medical information?

Your privacy is very important to us and we will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, we will do our best to make sure that any information that is released will not be able to identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private. Some of these organizations are: *list as applicable*

* The study sponsor (*insert US Lead Academic Organization name in parentheses*)
* The funding sponsor, the US National Cancer Institute (NCI) and their agents and partners.
* The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
* The US Food and Drug Administration (FDA)
* Every health care personnel who provides services to you in connection with this study.
* Any laboratories, other individuals/organizations that analyze your health information in connection with this study as defined by protocol.

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:

* You will not be asked if you agree to take part in the 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.
* *(Include the following sentence if true, or if the statement is not accurate and information may be given to study doctors, include appropriate information.)* You will not get reports or other information about any research that is done using your information.

*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.*

***Adapt the below text for appropriate studies as required by the protocol***

*As part of this study, we will collect information from an application downloaded from the Internet and/or from a [insert type of device here, e.g., fitness tracker, smart watch].*

*[insert information about the specific device to be used (e.g. brand name), whether the study team will provide the device, and whether participants will be asked to return the device at the end of the study.]*

*The maker of the application and/or device may collect and store personal information, such as health information, location data, and internet usage. A complete description of what data will be collected and what the company will do with it can be found in the Terms of Service. You will need to agree to the Terms of Service to participate in this study.*

*The researchers in this study may not have any control over what the company does with your information. The application and/or device may collect and transmit more information to the company than is needed for this study.*

## Where can I get more information?

The National Cancer Institute will obtain information from this clinical trial under data collection authority Title 42 U.S.C. 285.

You may visit the NCI website 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](http://www.clinicaltrials.gov/), as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

## Who can answer my questions about this study?

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).*

# Optional Sample Collections for Laboratory Studies and/or Storage for Possible Future Studies

This section is about optional studies you can choose to take part in. *If required locally, this section can be written as a separate consent form.*

*For future studies that are already planned, explain which collected specimens will be used, how the specimens will be used, and the research purpose.*

*For unknown future research, sample text: There may be some specimens collected for unknown future research or specimens remaining once the study is complete. The researchers would like to store and use your samples for future medical research. The research that may be done is unknown at this time but your samples could help researchers to find new ways to prevent, detect, treat, or cure health problems, including (insert disease). Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment. You can take part in the main research study described above without giving your consent for your samples to be stored.*

If you choose to take part in this optional study, (*list all types of specimens to be collected*) will be collected and stored. Any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, may be stored for future use. Storing samples for future studies is called “biobanking.” Samples from biobanks may be shared with other researchers to make more research possible that may improve people’s health. Researchers who want to get samples and data from the biobank 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.

Since the future research using your specimens is unknown:

* 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.
* You will not get reports or other information about any research that is done using your samples. *If some information may be given to study doctors, include appropriate information.*

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.

## What is involved in this optional sample collection?

If you agree to take part, here is what will happen next: (*Edit as appropriate per institutional norm)*

1. Your remaining samples will be stored at the study institution until the end of the study.
2. After study completion, your remaining samples and some related information may be transferred to a central facility (Biobank) supported by the National Institutes of Health and stored in the Biobank along with samples and information from other people who take part.
3. Qualified researchers can submit a request to use the materials stored. A research committee will review each request.There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
4. Neither you nor your study doctor will be notified if/when research is conducted using your samples.
5. You will not get reports or other information about any research that is done using your samples.
6. Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

## What are the possible risks in this optional sample collection?

*-Describe risks from the study sample collection. Sample text: 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. Sample text: 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 researchers and they will make every effort to protect it. Here are just a few of the steps they will take: (*edit as appropriate per institutional and country norms)*

1. When your sample(s) is sent to the researchers, no information identifying you (such as your name or social security number) will be sent. Samples will be identified by a unique study code only.
2. The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and the study team with access to the list must sign an agreement to keep your identity confidential.
3. Researchers to whom the study team sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4. Information that identifies you will not be given to anyone, unless required by law.
5. If research results are published, your name and other personal information will not be used.

## What are the benefits of 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?

*Edit as appropriate:* There are no costs to you or your insurance. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

## 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 researchers know. Then, any sample that remains in the bank will no longer be used. Samples or related information that have already been given to or used by researchers will not be returned.

## What if I have more 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)*.

*If applicable:*

**Samples and Information for Future Research Studies:**

Indicate your choice of “yes” or “no” for each of the following studies.

1.  My remaining samples and related health information may be kept in a Biobank for use in future health research.

Yes    No

2. I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

Yes    No

3. My genetic data and health information can be released, with no direct identifiers, into scientific databases.

Yes    No

This is the end of the section about optional studies.

**My Signature Agreeing to Take Part in the Main Study**

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 copy of this form. I agree to take part in the main study and 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_