

Informed Consent Form for Adult Participants

Sponsor / Study Title: National Cancer Institute / “Cancer Moonshot Biobank Research Protocol”

Protocol Number: 10323

Principal Investigator: «PiFullName»
(Study Doctor)

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Overview and Key Information

- This is a consent form for a research project.
- Research is voluntary and you can decide whether to take part or not.
- This project is about collecting blood and tissue samples, and medical information for cancer research.
- The samples and information will be collected over the course of your cancer treatment so that researchers can study questions such as how cancer changes during treatment.
- You’ll be in the study starting now and for up to five years.
- The Biobank will collect some samples, like blood and cancer tissue from you.
- The Biobank will collect health and medical information about you for research.
- The Biobank will do a biomarker test on your cancer tissue and give you and your doctor the results.
- There is a risk that you may learn information about your or your family member’s cancer risks that is unexpected or disturbing.
- The main risk to this study is the small chance your private information could be released.

What am I being asked to do?

We are asking you to take part in a research study called the Cancer Moonshot Biobank (“Biobank”) because you have cancer. You are being asked to donate some of your tumor tissue and some blood samples for research. This study doesn’t involve any special cancer treatment other than what your doctor would usually recommend to you. 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.

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 clinical trials and general cancer information.

Why is this study being done?

This study is being done to learn more about how cancer changes and responds to treatment over time. To do this, researchers need tissue and blood samples that are collected over the whole course of a patient's cancer treatment, along with medical information. With time, researchers hope to develop better cancer drugs and diagnostic tests by studying samples and medical information from people with cancer.

A biobank collects and stores samples - like blood and tissue - and patients' medical information, so researchers can do research with them in the future. The Cancer Moonshot Biobank is asking cancer patients to give some blood and small pieces of tissue for research. The tissue will be removed during medical procedures such as biopsies and surgeries, at several times during patients' cancer treatment. The Biobank will also ask patients to share their medical information. The Biobank will collect samples and medical information from many different people because cancer grows and changes in people in different ways.

The purpose of this study is to collect multiple tumor tissue samples and blood samples, along with medical information, over the course of your treatment. The Biobank will store the samples and medical information and distribute them to approved researchers.

The Biobank is a longitudinal study. This means it will collect samples and information over time, throughout the course of a patient's cancer treatment, to help researchers better understand and treat cancer. By looking at samples and information collected from the same people over time, researchers hope to better understand how cancer changes over time and over the course of medical treatments.

About 1000 cancer patients ages 13 and older, from all parts of the United States will be asked to take part in the Biobank. People from all racial and ethnic groups will be asked to participate in the Biobank, so that all communities may benefit from the research.

What is the usual approach to my cancer?

The usual approach for patients who don't participate in a study is treatment without donating tissue and blood for research.

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

This study is for research purposes only. You can say ‘no’ and choose to not be in this study. If you say no, the Biobank will not collect anything from you for future cancer research. If you say no, you’ll still receive your medical care at the study site. You may choose to participate in another study, if one is available, or choose not to participate in any study.

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

If you decide to be in this study, you’re giving consent for the study site to collect samples and medical information from you before and during your cancer treatment. If you want to be in the Biobank study, sign and date this consent form, and the following things will happen:

You’ll set up an account on the Biobank Website. The Biobank study has a website called MoonshotBiobank.cancer.gov. On the public part of the website, you can learn about research that will use Biobank samples. This website has helpful information for you and your family about cancer and cancer treatment. The Biobank study team at the study site will help you set up a private online account using your email address. You may receive copies of documents such as your signed and dated consent form and updates about your participation through your private account. You may be asked to participate in surveys about your cancer and your health in your private online account.

The Biobank study will collect samples from you. The study site will ask for your donations of tissues and blood. This is explained more in the section below called “What exams, tests and procedures are involved in this study?”

The Biobank study will collect information about you and your health. The study site will ask for some information from you like name, age, sex, race or ethnic group. The study site will check your medical record from time to time to collect your medical information for 10 years or longer. The medical information includes things like your test results, procedures, X-rays, scans, and the medicines you take.

The Biobank may do a biomarker test on your cancer tissue and return the results to you and your doctor. The biomarker test for the Biobank study will look for cancer genes in your cancer tissue. The test results may or may not help you and your doctor decide about choices for your medical treatment. If the Biobank can run the test, they’ll send the test results to both you and your doctor. You’ll be able to see your test results using your private account on the website, MoonshotBiobank.cancer.gov. You can learn more about the type of biomarker test used by the Biobank study, on the Biobank website.

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’s important for you to think carefully about these as you make your decision. They are:

Physical risks:

The most common side effects that doctors know about from their experience taking tissue and blood samples are:

- You may bleed or have pain, swelling, and infection from the biopsy site.
- Your biopsy may take longer depending on the type of cancer you have and the type of procedure your doctor orders.
- You may have mild pain, get light headed, or experience inflammation of the vein, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection from taking blood from your arm.

Unexpected results of the biomarker test:

The biomarker test only looks for cancer genes that are found in your cancer tissue. This biomarker test is different from genetic tests that look at genes you get from your parents. But the results from the biomarker test might suggest that you should get additional tests to look at genes you may have been born with that put you at risk for cancer or otherwise affect your health or your medical care. You should talk to your doctor about this. The Biobank will not arrange for additional tests.

New information about the genes that you were born with may mean something about your family members too, since you share some of the same genes with your blood relatives. The genes you share with family members may affect things like hair and eye color, and certain health conditions that are passed down in families. If there is information from the biomarker test about genes you were born with, it may be helpful but may also cause you or your family concern. You should ask your doctor about this.

There's a small risk that the biomarker test may incorrectly detect a biomarker that's not part of your cancer tissue. On the other hand, there's a small risk that the biomarker test results may not detect a biomarker that's part of your cancer tissue. This may or may not influence what you and your doctor decide about your choices for medical treatment based on the test results.

Privacy Risks: The Biobank will do everything it can to protect your privacy. But there's a small chance that your private information could be released. If your genetic information is released, it could be misused.

A federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

The law doesn't protect you against discrimination by companies that sell life and disability insurance, or long-term care insurance. However, many states have other laws that protect against genetic discrimination.

Please see "How will information about me be kept private?" for more information about how the Biobank protects your privacy.

Benefits:

The results of the biomarker test done on your cancer tissue may be a benefit. But we can't know for sure if the results will help you and your doctor decide about your choices for medical treatment.

The information that researchers learn may help you, your family or other people in the future. Your samples may help researchers find new ways to prevent, find, and treat cancer and other diseases. You may feel good about participating in the study and helping cancer research.

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 leave the Biobank study, you can contact your doctor, or you can login to your private online account on the website, MoonshotBiobank.cancer.gov, to leave (withdraw) from the study. If you decide to leave the study, the Biobank will not send your samples or information to researchers. If some of your samples and medical information have already been given to researchers, the Biobank can't get them back. And the Biobank can't destroy results from studies that have already used your samples and medical information.

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

Yes, your doctor may take you off the study if:

- Your health changes and being in the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You don't follow the study rules.

- The study is stopped by the National Cancer Institute (NCI) or the Institutional Review Board (IRB).

It's 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's anything you don't understand, be sure to ask your doctor or nurse.

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

The study site will collect some blood from you for the Biobank. The study site will take about 3 tablespoons of blood at a time from you, usually when you're already having blood drawn for your medical care. Sometimes, the nurse may need to take blood for the Biobank with a separate needle stick. The study site will collect blood from you at least three times while you're in the Biobank study.

The study site will take some small pieces of tissue from you for the Biobank. Some of the tissue for the Biobank may come from surgeries you may have during treatment. Some of the tissue may come from biopsies where extra tissue will be taken just for the Biobank.

- **Tissue taken during surgery:** You may already have had a biopsy (removal of a small piece of tissue) or surgery where tissue was saved. The study site will send some of that tissue to the Biobank. In the future, if you have surgery for your cancer, the study site will send some of the tissue to the Biobank. The study site will only send tissue to the Biobank if your doctor doesn't need it for your health care.
- **Tissue taken during regular biopsies:** Your doctor may do biopsies to check if your cancer has changed. Your doctor uses the results from the biopsy to plan your care. When your doctor orders a biopsy, the study site may take some more tissue at the same time for the Biobank. This means the biopsy may take a few minutes longer, which could be tiring or uncomfortable. Your doctor will only take more tissue for the Biobank if it doesn't significantly increase the risk to you.
- **Tissue taken during extra research biopsies:** Your doctor may plan one or two extra biopsies just to send to the Biobank. The tissue taken at these biopsies may be used for the biomarker test and for research. The study site will only ask you to have an extra biopsy if it won't significantly increase the risk to you. You will not have to pay extra for these extra biopsies. You can stay in the Biobank study even if you miss some biopsy procedures. If you agree to take part in the study, you may need to sign and date a separate consent form for the study biopsy at the hospital or clinic where the biopsy is done.

The Biobank may do a biomarker test on your cancer tissue and return the results to you and your doctor. The results of biomarker tests on cancer tissue can sometimes be important in deciding about particular cancer treatments. The biomarker test for the Biobank study will look for cancer genes in your cancer tissue. If the Biobank can run the test, they will send the test results to both you and your doctor. You'll be able to see your test results using your private

account on the website, MoonshotBiobank.cancer.gov. The biomarker test results will be put into your hospital medical record. The test results may or may not help you and your doctor decide about your choices for medical treatment. Sometimes it will not be possible to run the test because there's not enough tissue, or for other reasons. You can learn more about the type of biomarker test used by the Biobank study, on the Biobank website.

What are my responsibilities in this study?

If you choose to take part in this study, you'll need to tell your doctor about:

- Any side effects from the biopsy, and
- If you have been or are currently in another research study.

The Biobank study is asking you to stay in the study during the whole time of your cancer treatment.

The study site will plan to draw your blood when you come in for your other regular appointments, but if that doesn't happen you may need to come in for a research blood draw.

When the study site takes extra tissue for the biobank during your regular biopsies, the biopsy procedure will last a little longer. If you have any extra research biopsies, you will need to make time to come to the study site for the appointment.

What are the costs of taking part in this study?

You won't have to pay any extra costs if you take part in the Biobank study. You won't be charged for the biomarker test that the Biobank study will do on your cancer tissue and you won't be charged for procedures that are just for the Biobank study.

You or your health insurance will need to pay for tests and procedures that your doctor orders as part of your regular medical care. If you decide to get extra tests based on information you get from the biomarker test, you may have to pay for those if they're not covered by your health insurance.

If you have extra research biopsies, you may have more travel costs, you may need to take more time off work, or have other additional personal costs.

You won't be paid to take part in the Biobank. Your doctors and the study site may get paid for their work for the Biobank. Some studies that use your samples and medical information may lead to the invention of new drugs or tests. Companies that sell these drugs or tests may make a profit, but you won't get any of those profits. The Biobank won't get any of those profits either.

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

If you're injured as a result of taking part in this study and need medical treatment, please talk to your doctor about your treatment options. The study sponsor (NCI) 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 don't have insurance, you'll be responsible for any costs.

If you feel this injury was a result of medical error, you have legal rights to receive payment for this injury even though you are in this study. Agreeing to take part in this study does not mean you give up these rights.

Who will use my samples and see my medical information?

The goal of the Biobank study is to collect samples and medical information, and get the samples and medical information to approved researchers so that they can do cancer research studies. The Biobank will make every effort to protect your privacy so that any information that goes out to others will not identify who you are. Your privacy is very important to us. The Biobank has a **Certificate of Confidentiality** from the National Institutes of Health to help protect your records; 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.

These are the ways the Certificate protects your private research records: the Certificate says that the Biobank doesn't have to give out your personal information, even if ordered to by a judge or court. The Certificate means that courts can't get research records from the Biobank that name you, unless you ask the Biobank in writing to hand over those records.

These are the ways the Certificate does not protect your private research records. Even with a Certificate, the Biobank may need to give your personal information to the government if they need your records for the purpose of reviewing this research. It could happen if the government needed to know how the Biobank spent the research money from the government. This rarely happens.

The Biobank will release information about you if the information is something that the law says must be reported to state officials.

You can still give out your own information. The Certificate doesn't stop you from giving out information about yourself or your part in this project. If you give the Biobank the written okay to give your research information to someone else, then the Certificate doesn't stop the Biobank from doing so.

Use of medical information for research:

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 NCI in a central research database. However, your name and contact information will not be put in the database. NCI will make the information available for research that may improve people's health. Some types of future research may include looking at your records and those of other patients to see who did or did not respond to cancer treatments across many studies or comparing new study results with older study results. The researchers have to apply for permission to use the medical information, they will not be given your name and contact information, and they have to promise that they won't try to identify you or other Biobank participants.

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. Some of these organizations are:

- The Institutional Review Board, called Advarra IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study
- The National Cancer Institute (NCI)
- The NCI Community Oncology Research Program (NCORP)

Use of samples for research:

Researchers will request to study the Biobank samples that were donated from the many patients who participate in the Biobank, including you. An expert committee will review each request from researchers. The committee will make sure the plan for the research on the samples is ethical, useful, and based on good science. If a request is approved, the NCI will give some of your samples to the researchers. The researchers will not get your name or other personal information about you. The Biobank will only give samples to researchers who show that they need the samples for important research. The researchers may be from any country in the world. Researchers may work at universities, at non-profit research institutions, or at for-profit companies that make new drugs or tests for diseases.

One type of research may use cells grown from your cancer tissue. Sometimes these cancer cells are grown for a very long time, well into the future. Researchers can also make cancer cells grow in lab animals like mice, making what's called patient derived models. Researchers can use cells, or models, to test new cancer drugs and do other types of medical research. In some cases, the results from this type of research will be put on a public website available to all researchers. Your name and other information that could easily identify you won't be on the website.

Another type of research that may be done on your samples is the study of the entire genetic code (DNA) of a tumor, called whole genome sequencing. Researchers in the future may use whole genome sequencing and other technologies, such as exome and RNA sequencing, to study your cancer tissue and your medical information to better understand how cancer develops and changes, how cancer drugs work, and other medical research questions. These results won't be given to you. Researchers may also study the genetic code that you were born with, by studying

your blood samples in addition to your tumor samples. This might be done to study how the genetic code you were born with is the same or different from the genetic code seen in the tumor, or to look for changes in the genetic code that may cause health problems. If any type of genome sequencing is done on your samples in the future, the sequencing will be done in a research lab and the researchers will not know who you are. The only results you may receive in this study are the results of the biomarker test that may be done on your tumor tissue.

Future use of samples and medical information:

We do not know all the kinds of research that may be done in the future using your samples and information. This means that:

- In the future, you won't be asked if you agree to take part in the specific research studies using your samples and health information.
- You and your doctor won't be told when or what type of specific research will be done with your samples or information.
- You won't get reports or other information when your specific samples and information are used for research.
- However, the website MoonshotBiobank.cancer.gov will have general information about some of the studies that will be done with the samples and medical information that you, and patients like you, have donated to the Biobank.

How long will my samples and medical information be in the Biobank?

The Biobank plans to keep your samples and medical information for as long as they're useful for research, or until the samples are used up. The Biobank may decide to destroy samples in some situations, for example if the Biobank must close. If you change your mind about being in the Biobank study, you can ask the Biobank to destroy your stored samples. But the Biobank will not be able to destroy samples that were already shared with researchers.

How will information about me be kept private?

Your privacy is very important to the Biobank. Here are just a few of the steps the Biobank and researchers will take to protect your privacy:

Your samples and medical information will be securely stored. Your medical information will be stored in computers at the Biobank. The study site will send your blood and tissue samples to the Biobank where they will be stored in locked freezers and cabinets.

Your samples and medical information will be shared with researchers. Your samples along with medical information and the results from the cancer biomarker test will be shared with researchers.

Things like your name and date of birth won't be on your samples. Each sample will be labeled with a code, such as "30992871". The key that links your name to the code will be kept separate from the samples. For example:

Your name	becomes	The code
Mary Jones		30992871

The key that links your name to the code will be stored on secure, password-locked computers. Only a few people at the study site will know the key and they will agree to keep it private. The study site needs to keep the link so it can contact the Biobank about your medical information or if you decide to stop taking part in the Biobank. Biobank study staff will take yearly training on how to keep information safe and private

Researchers won't get your name or be told who you are, and researchers who use your samples and medical information must promise that they won't try to find out who you are.

Where can I get more information?

You can visit several websites to learn more about this study:

MoonshotBiobank.cancer.gov has information about the Biobank study.

The NCI web site www.cancer.gov has information about other cancer studies and general information about cancer. You may also call the NCI Cancer Information Service to get information at: 1-800-4-CANCER (1-800-422-6237).

A description of this study will be available on <http://www.ClinicalTrials.gov>. 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.

You can talk to your doctor about any questions or concerns you have about this study or to report side effects or injuries.

Whom to contact about this study

During the study, if you have any medical problems, or have a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
Study Subject Adviser
Advarra IRB
6940 Columbia Gateway Drive, Suite 110
Columbia, MD 21046
- or call **toll free**: 877-992-4724

- or by **email:** adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser:
Pro00041631.

My signature agreeing to take part in the study

I have read this consent form, or had it read to me. I've discussed it with my doctor and my questions have been answered. I'll be given a signed and dated copy of this form. I agree to take part in this study.

We'll give you a copy of this signed and dated consent form.

Email of Adult Participant (for use in the website private online account)

Signature of Adult Participant / Date

Print name of Adult Participant

Signature of Legally Authorized Representative / Date (For Adults Not Capable of Giving Consent)

Print name of Legally Authorized Representative

Description of Representative's Legal Authority to Act for Participant

Signature of Person Taking Consent / Date

Print Name of Person Taking Consent

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

Signature of Impartial Witness / Date

Print name of Impartial Witness