Informed Consent Form for Parent/Legal Guardian of Minor Participant

Sponsor / Study Title:	**National Cancer Institute / "Cancer Moonshot Biobank Research Protocol"**
Protocol Number:	**10323**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Overview and Key Information

- This is a consent form for a research project.
- Research is voluntary and you can decide whether your child takes 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 child's cancer treatment so that researchers can study questions such as how cancer changes during treatment.
- Your child will be in the study starting now and up to five years.
- The Biobank will collect some samples, like blood and cancer tissue from your child.
- The Biobank will collect health and medical information about your child for research.
- The Biobank will do a biomarker test on your child's cancer tissue and give you and your child's doctor the results.
- There is a risk that you and your child 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 child's private information could be released.

What is my child being asked to do?

We're asking for you to allow your child to take part in a research study called the Cancer Moonshot Biobank ("Biobank") because your child has cancer. Your child is being asked to donate some of their tumor tissue and some blood samples for research. This study doesn't involve any special cancer treatments other than what your child's doctor would usually recommend. 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 and your child's choice

You and your child can choose to take part or choose not to take part in this study. You and your child also can change your minds at any time. Whatever choice you and your child make, your child won't lose access to their medical care or give up any legal rights or benefits.

This document has important information to help you and your child make your choice. Take time to read it. Talk to your child's 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.

What is the purpose of this study?

The purpose of this study is to collect multiple tumor tissue and blood samples over the course of your child's 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 the course of patients' 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 child's 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 child's choices if we decide not to take part in this study?

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

What will happen if my child decides to take part in this study?

If your child decides to be in this study, you're giving consent for the study site to collect samples and medical information from your child before and during their cancer treatment. Once you sign and date this parental permission form and your child signs the assent form, 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 and your child 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 on the website using your email address. You may receive copies of documents such as this signed and dated consent form, your child's signed and dated assent form, and updates about your child's participation through your private online account. You may be asked to participate in surveys about your child's cancer and their health in your private online account.

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

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

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

Physical risks:

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

- Your child may bleed or have pain, swelling, and infection from the biopsy site.
- Your child's biopsy may take longer depending on the type of cancer they have and the type of procedure their doctor orders.
- Your child may have mild pain, get lightheaded, 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 their arm.

Unexpected results of the biomarker test:

The biomarker test only looks for cancer genes that are found in your child's cancer tissue. This biomarker test is different from genetic tests that look at genes your child gets from their parents. But the results from the biomarker test might suggest that your child should get additional tests to look at genes they may have been born with that put them at risk for cancer or otherwise affect their health or their medical care. You should talk to your child's doctor about this. The Biobank will not arrange for additional tests. If your child has additional tests to look at the genes they were born with, those tests may give new information about the genes that your child was born with may mean something about your child's family members too, since they share some of the same genes with their blood relatives. The genes that your child shares with family members may affect things like hair and eye color, and certain health conditions that are passed down in families. That information may be helpful but may also cause you or your family concern. You should ask your child's doctor about this.

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

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

This law generally will protect your child in the following ways:

- Health insurance companies and group health plans may not request your child's genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your child's genetic information when making decisions regarding your child's eligibility or premiums.
- Employers with 15 or more employees may not use your child's genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire your child or when setting the terms of their 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 your child 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 my child be kept private?"" for more information about how the Biobank protects your child's privacy.

Benefits:

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

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

If my child decides to take part in this study, can they stop later?

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

If your child decides to leave the Biobank study, you can contact your child's doctor, or you can login to your private online account on the website, MoonshotBiobank.cancer.gov, to leave (withdraw) from the study. If your child decides to leave the study, the Biobank will not send their samples or information to researchers. If some of their 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 child's samples and medical information.

If your child turns 18 while still in the study, we'll ask them at that time if they still want to be in the study. When your child turns 18, even if they aren't still in the study, we'll try to contact them to ask them if their samples and information can still be used for research.

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

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

- Your child's health changes and being in the study is no longer in their best interest.
- New information becomes available and the study is no longer in their best interest.
- Your child doesn'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 child's study doctor or nurse.

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

The study site will collect some blood from your child for the Biobank. The study site will take about 3 tablespoons of blood at a time from your child, usually when your child is already having blood drawn for their 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 your child at least three times while they're in the Biobank study.

The study site will take some small pieces of tissue from your child for the Biobank. Some of the tissue for the Biobank may come from surgeries your child 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:** Your child 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 your child has surgery for their 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 child's doctor doesn't need it for their health care.
- **Tissue taken during regular biopsies:** Your child's doctor may do biopsies to check if their cancer has changed. Your child's doctor uses the results from the biopsy to plan their care. When your child's 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 child's doctor will only take more tissue for the Biobank if it doesn't significantly increase the risk to your child.

The Biobank may do a biomarker test on your child's cancer tissue and return the results to you and your child's 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 child's cancer tissue. If the Biobank can run the test, they will send the test results to both you and your child's doctor. You'll be able to see your child's test results using your private online account on the website, MoonshotBiobank.cancer.gov. The biomarker test results will be put into your child's hospital medical record. Talk with your child's doctor about the biomarker test results. The test results may or may not help you and your child's doctor decide about choices for your child's 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 website.

What are my child's responsibilities in this study?

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

- Any side effects from the biopsy, and
- If your child has been or is currently in another research study.

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

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

When the study site takes extra tissue for the biobank during your child's regular biopsies, the biopsy procedure will last a little longer.

What are the costs of taking part in this study?

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

You or your child's health insurance will need to pay for tests and procedures that your child's doctor orders as part of your child's 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 child's health insurance.

Your child won't be paid to take part in the Biobank. Your child's doctors and the study site may get paid for their work for the Biobank. Some studies that use your child's 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 and your child won't get any of those profits. The Biobank won't get any of those profits either.

What happens if my child is injured because they took part in this study?

If your child is injured as a result of taking part in this study and needs medical treatment, please talk to your child's doctor about their treatment options. The study sponsor (NCI) will not offer to pay for medical treatment for injury. Your child's insurance company may not be willing to pay for study-related injury. Ask them if they will pay. If your child doesn't have insurance, you'll be responsible for any costs.

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

Who will use my child's samples and see their 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 researcher studies. The Biobank will make every effort to protect your child's privacy so that any information that goes out to others will not identify who they are. Your child's privacy is very important to us. The Biobank has a **Certificate of Confidentiality** from the National Institutes of Health to help protect your child's records; however, some of their 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 your child is.

These are the ways the Certificate protects your child's private research records: the Certificate says that the Biobank doesn't have to give out your child's 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 your child, unless you ask the Biobank in writing to hand over those records.

These are the ways the Certificate does not protect your child's private research records. Even with a Certificate, the Biobank may need to give your child's 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 your child if the information is something that the law says must be reported to state officials.

You and your child can still give out your child's information. The Certificate doesn't stop you or your child from giving out information about your child or their part in this project. If you give the Biobank the written okay to give your child's 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 child's health information, such as their response to cancer treatment, results of study tests, and medicines they took, will be kept by the NCI in a central research database. However, your child's 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 child's 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 child's name and contact information, and they have to promise that they won't try to identify your child or other Biobank participants.

There are organizations that may look at or receive copies of some of the information in your child's study records. Your child's health information in the research database also may be shared with these organizations. They must keep their 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)
- The Imaging and Radiation Oncology Core (IROC)

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 your child. 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 their samples to the researchers. The researchers will not get your child's name or other personal information about them. The Biobank will only give samples and medical information 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 child's cancer tissue. Sometimes these cancer cells are grown for a very long time, well into the future. Researchers may 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 child's name and other information that could easily identify them won't be on the website.

Another type of research that may be done on your child's 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 child's cancer tissue and their 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 or your child. Researchers may also study the genetic code that your child was born with, by studying your child's blood samples in addition to their tumor samples. This might be done to study how the genetic code they were born with is the same or different from the genetic code seen in their 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 child's tumor in the future, the sequencing will be done in a research lab and the researchers will not know who your child is. These results won't be given to you or your child. The only results you may receive in this study are the results of the biomarker test that may be done on your child's 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 child's samples and information. This means that:

- In the future you and your child won't be asked if you agree to take part in specific research studies using your child's samples and health information.
- You, your child and your child's study doctor won't be told when or what type of specific research will be done with their samples or information.
- You and your child won't get reports or other information when their 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 your child, and patients like your child, have donated to the Biobank

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

The Biobank plans to keep your child's samples and medical information them 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 or your child change your mind about being in the Biobank study, you can ask the Biobank to destroy your child's stored samples. But the Biobank will not be able to destroy samples that were already shared with researchers.

How will information about my child be kept private?

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

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

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

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

Your child's name		The code
Mary Jones	becomes	30992871

The key that links your child's 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 child's medical information or if your child decides 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 child's name or be told who they are, and researchers who use your child's samples and medical information must promise that they won't try to find out who your child is.

Where can I get more information?

You and your child 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 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 your child's 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 your child experiences any medical problems, or has a research-related injury, or you 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 child's 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 child's doctor and my questions have been answered. I'll be given a signed and dated copy of this form. I agree to let my child take part in this study.

This research study has been explained to my child in my presence in a language my child can understand. They've been encouraged to ask questions about the study now and at any time in the future.

For children aged 13 to 17 years old: confirm that signed and dated assent has been obtained.

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

____
Email of Parent/Legal Guardian (for use in the website private online account)

____
Print Child's Name

____
Print Name of Parent/Legal Guardian

____
Signature of Parent/Legal Guardian / Date

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Print Name of Person Obtaining Consent

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Signature of Person Obtaining Consent / Date

WITNESS SIGNATURE FOR PARENTS/LEGAL GUARDIANS WHO CANNOT READ

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

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Signature of Impartial Witness / Date

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Print name of Impartial Witness