

Assent Form for Participants Ages 13 to the Age of Majority

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

Protocol Number: 10323

Principal Investigator: «PiFullName»
(Study Doctor)

Telephone: «IcfPhoneNumber»

Address: «PiLocations»

What is this project about?

This paper talks about the Cancer Moonshot Biobank (“Biobank”) and the choice that you have to be part of it, if you want to. A biobank is a place where blood and cancer tissue along with medical information is stored for researchers to study new treatments for cancer. The Biobank is funded by the National Cancer Institute and will help scientists do research to learn more about cancer and about treatments to help patients.

Important things to know...

- You get to decide if you want to take part.
- You can take your time to decide.
- You can say ‘No’ even if your parents say ‘Yes’.
- If you say ‘Yes’ now but change your mind, you can stop later.
- Your doctors and nurses will still take good care of you even if you say ‘No’.

1. Why are you doing the Cancer Moonshot Biobank project?

We are doing this research to find out more about how cancer grows and how to fight it. We are collecting samples, like blood and tissue samples, from medical procedures from kids and adults across the United States to try to speed up progress in cancer research. The samples and medical information will be used by scientists who study cancer. The Biobank needs to collect samples over the time that you have cancer and are getting treatment, to help researchers learn how cancer grows and changes in people, and to find new cancer treatments.

2. What will happen if I say NO?

If you say no, the Biobank will not collect anything from you. If you decide not to join the Biobank, your doctors and nurses at study site will still take care of you, and no one will be mad at you.

3. What will happen if I say YES?

If you say yes, then the Biobank project will stay in touch with you and your family while you are getting treatment for cancer. The Biobank project has a website called MoonshotBiobank.cancer.gov. You can use the website to get answers to questions that you or your family members may have about the Biobank. You can also find information about the research projects that are using your samples as well as samples from other research participants.

Medical Information: Your study site will collect some information about your health, such as test results and medicines you take and update the information from time to time for 10 years or longer. We will look at notes and information from your doctor visits in your medical record and use them for this research project.

Blood: When you are already having some blood collected, we will take a little extra blood for cancer research. However, sometimes a separate needle stick will be needed to collect blood for the Biobank, but you can say no to that if you want to.

Cancer Tissue: If you have surgery for your cancer, we will also take some of the cancer tissue that your doctor removes during the surgery for the Biobank. Depending on your cancer treatment, your doctor may take a small sample of your cancer tissue to test it. Whenever your doctor does this, the study site will collect a little bit of tissue at the same time for the Biobank. To collect the extra tissue may take a few minutes longer. You can say no to this if you want to.

Perform a Biomarker Test: Researchers may do a biomarker test on some of your cancer tissue. This test looks for abnormal genes that are sometimes found in cancer. The test results will be given back to your parent and your doctor and the results may help your doctor plan your care.

4. Could I get hurt in this research project?

Some of the procedures your doctor orders may hurt or be uncomfortable, but the doctors will do their best to make sure you are okay. You may bleed or have pain, swelling, and infection from the biopsy site. A needle stick to get blood may hurt a bit. We'll try to only collect some blood in a tube when your doctor has already ordered a blood test.

5. Could the research done on my samples help me?

This research may not help you directly. Your samples may help researchers find new ways to prevent, find, and treat cancer and other diseases. The information that researchers learn may help other cancer patients in the future. You may feel good about participating in the project and helping cancer research.

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

Your samples and information will be in the Biobank as long as they are useful for research or until they are used up, which could be many years.

7. Who will know I'm in the Biobank project?

The people who work on the Biobank project and your parents will know that you joined the Biobank. You can tell anyone you want to that you are in the Biobank project. Researchers who look at your blood and cancer tissue and medical information will not know who you are.

8. Where can I get more information?

You and your parents can use the MoonshotBiobank.cancer.gov to find more information about the Biobank project. You can also learn on the website about the research projects that are using the samples from the project. You can also call the NCI Cancer Information Service to get information at: 1-800-4-CANCER (1-800-422-6237).

9. What about payments?

You will not be paid to be to take part in the Biobank, and it will not cost you any money to be in the Biobank. It is possible that some research on your sample may lead to companies making new drugs or tests for cancer. Even if these companies sell the drugs or tests and make a profit, you will not be paid. The Biobank won't get any of those profits either.

10. What if I have more questions?

You can ask questions any time. You can talk to the study doctor and ask any questions you have.

11. If I say yes now can I change my mind later?

Yes, you can stop being in the project anytime you want. When you turn 18 years old, we will try to contact you and ask you if it is OK for us to keep using your samples and information if they are still in the Biobank.

If you want to be in the Biobank project after we talk, please write your name below. We will write our name too. This shows that we talked about the project, you understand everything and that you want to take part.

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

Print Name of Child

Signature of Child / Date

Printed name of Person Taking Assent

Signature of Person Taking Assent / Date