



caHUB The Cancer Human Biobank

BSS Name and Number	
IRB #	
Consent form approved	
This consent valid through	

What is the cancer Human Biobank (caHUB)?

The caHUB is a research biobank created by the National Cancer Institute (NCI). A biobank is a place where small amounts or "samples" of tissue, blood, and other human material, and related medical information, are collected and stored for future use in medical research. The caHUB will collect and store samples and information from people across the United States, and send them to research scientists.

[INSERT INSTITUTION NAME] collects samples and related medical information for the caHUB and is asking you to donate your samples and related medical information for future medical research. It is up to you whether or not to donate to the caHUB. Saying no will not affect your medical treatment or insurance benefits at [INSERT INSTITUTION NAME].

This form explains what will happen if you say yes. You can learn more about this project by first reading the fact sheet "Questions and Answers About the caHUB." Please ask questions if something is not clear or if you would like more information.

Why are you asking me to donate to the caHUB?

[INSERT INSTITUTION NAME] is asking you to donate to the caHUB because your tissue samples could help scientists find, prevent, and treat cancer and other diseases. You need to have tissue removed for medical reasons. Your doctor will examine the tissue samples removed and keep what is needed for your medical care. The tissue samples not needed by your doctor are the ones you can now choose to donate to the caHUB.

What will happen if I say yes?

Note: Specific details in this section may vary by institution and may require modification if additional biospecimens (i.e., urine, saliva) are collected or additional collection procedures (i.e., extra blood draw) are undertaken.

If you say yes, you are giving permission for [INSERT INSTITUTION NAME] to:

- **Send your samples to the caHUB.** Samples may include small amounts of healthy as well as diseased tissue removed by your doctor for medical reasons.
- **Send about 3 tablespoons of your blood to the caHUB.** The blood will be collected during your procedure. You will not have any additional needle sticks to obtain this blood.

- **Send information from your medical record to the caHUB.** This information may include your age, ethnic background, diagnosis, disease history, family medical history, medical treatment, and response to treatment. It will not include your name, social security number, or other information that could identify you.

How will the caHUB respect my privacy and confidentiality?

The caHUB values your contribution to research. The caHUB will take several steps to respect your privacy and keep your information confidential.

- **[INSERT INSTITUTION NAME]** will label your samples and information using a code number instead of your name. For example:

Mary Jones becomes 30992871

- The caHUB will use this code to keep track of your samples and information and will not know your name, address, social security number, or other information that identifies you or your family.
- Only a few people at **[INSERT INSTITUTION NAME]** will be able to link your code to your name. **[INSERT INSTITUTION NAME]** needs to keep the link so it can contact the caHUB to update your medical information or to let them know if you decide to stop participating in the caHUB. The link between your code and your name will be stored on secure, password-protected computers at **[INSERT INSTITUTION NAME]**.
- The caHUB will ensure that your samples are stored in a locked freezer in a secure building.
- Information about you and your samples will be stored in a secure database.
- The caHUB is sponsored by the NCI and must follow federal rules and laws to protect your privacy. A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect you from being treated unfairly because of the kinds of genes you have.

Who can use the samples and information in the caHUB?

The caHUB will give samples and related information only to researchers who need high-quality samples for medical research. The researchers may be from any country in the world. They could be doctors, scientists in universities, or researchers from companies that make new drugs or tests for diseases.

Researchers will need to get approval to use samples and information from the caHUB. A committee of experts and patient advocates will review each request to make sure the proposed research is ethical, useful, and based on good science.

After a project is approved, the caHUB will give researchers samples and related information from one or more people. You will not be contacted when your samples or information are sent to researchers.

How will my samples and information be used?

Researchers will use your samples and information to study cancer and other diseases. You should not donate to caHUB unless you are willing to allow your samples and information to be used for all types of medical research. Scientists may use the samples and information to study how genes affect human health. Genes are instruction manuals for our bodies. Genes carry information about diseases and medical conditions that run in families, like diabetes or Alzheimer's disease. Some tissue samples may be treated so that they grow forever and can be studied for many years.

Researchers who receive samples and medical information from the caHUB are asked to share their research results with other scientists so that research moves forward as quickly as possible. The caHUB will store your samples and information safely and confidentially, and send them out to researchers for approved studies. Since the caHUB does not know your name or contact information, it cannot give them to researchers. Many samples will be used right away but there is no limit on how long the caHUB may store your samples and information for research.

Will the researchers tell me if they learn something about my health?

Research using your samples and information is not likely to show anything about your disease. You will not receive the results of studies that use your samples and information. But you may visit the caHUB Web site at <http://cahub.cancer.gov/> to learn about the kinds of research being done.

In the unlikely event that a researcher found something directly relevant to your medical care, [INSERT INSTITUTION NAME] would contact you. The caHUB researchers will never contact you directly.

Can anything bad happen if I say yes?

[IF ADDITIONAL BLOOD DRAWS ARE COLLECTED FOR THE CAHUB, ADD THE TEXT IN RED BELOW.]

Blood draw risk

The risks of drawing additional blood include pain, bruising, or infection at the site of the needle stick. These are the same risks you face any time you have blood drawn in a doctor's office.

Privacy risks

Although the caHUB will take all measures to protect your private medical information, there is a very small risk that private information could be disclosed outside [INSERT INSTITUTION NAME]. The caHUB will not release your private medical information to employers or insurers.

Will donating to the caHUB help me in any way?

You will not personally benefit from donating samples and medical information to the caHUB.

You should not donate to try to learn information about your own health. But your samples and medical information might help future patients.

Will there be a cost to donating to the caHUB?

No.

Will I be paid for donating to the caHUB?

No. You will not be paid to donate to the caHUB. Your samples and medical information will be used only for medical research and will not be sold for profit. It is possible that research using your samples or information could lead to new tests, drugs, or other commercial products. The caHUB was developed to support medical research and will not reimburse donors whose samples were used to develop a commercial product.

Do I have to donate to the caHUB?

No. It is your choice to donate or not. No matter what you decide, your care at [INSERT INSTITUTION NAME] will not change. You will still be able to join other research studies in the future.

If I say yes now, can I change my mind later?

Yes. You have the right to stop participating in the caHUB. You may do so by sending a letter to:

[NAME
INSTITUTION
ADDRESS]

[INSERT INSTITUTION NAME] will notify the caHUB of your request. The caHUB will stop using the samples and information you have left in the bank. This means your samples and information will no longer be available for future studies.

If you decide to leave the project, please note that:

- You cannot stop your samples and information from being used in studies that have already started.
- caHUB staff cannot get back samples or information already shared with other researchers. Results from studies that used your samples and information will not be destroyed.

Who can answer my questions?

[INSERT NAME OF LOCAL CONTACT]
[INSERT NAME OF CAHUB CONTACT]

You can learn more about the caHUB in the fact sheet “Questions and Answers about the cancer Human Biobank” which is available at [\[INSERT LOCATION AT INSTITUTION\]](#) and at [\[INSERT WEB SITE URL\]](#).

Summary and consent statement

You have been asked to donate samples and related information to the caHUB. This form describes the caHUB and the risks and benefits of donating samples and information for research. Its purpose is to help you decide if you want to donate. You will only be able to donate to the caHUB if you sign this form.

Participant’s Consent Statement

By signing this form, I confirm that:

- I know enough about the caHUB and the risks and benefits involved to decide that I want to donate.
- I know that giving samples and related information to the caHUB is voluntary, and I agree to do so.
- I know that the caHUB cannot predict all future research that will use my samples and information. Research topics are likely to include cancer and other diseases.
- I know that future studies may include genetic research.
- I know that I can always ask to stop participating in the caHUB by writing to the address listed in this form.
- I have read this form and received a copy of “Questions and Answers About the caHUB.” I have had a chance to ask questions, and they have been answered to my satisfaction. I know who to contact for any questions I might have in the future.

(Date/Time)

(Printed Name of Participant)

(BSS Number)

(Signature of Participant)

(Date/Time)

(Printed Name of Individual Obtaining Consent)

(Signature of Individual Obtaining Consent)