

Tissue Samples in Clinical Trials

As part of your decision to join this study, we will ask you for **tissue samples**. Tissue samples may help researchers understand diseases and find ways to prevent and treat them in people. Before you decide to let researchers use your samples, we want you to know how and why we collect them.





Types of tissue samples

Tissues are found throughout your body, such as skin, hair, nails, blood, urine or tumors. For the purposes of most studies, tissue samples would include either tumor and/or blood samples.

Researchers may collect new tissue samples or they may ask to use tissue that was collected before.

New tissue samples

Sometimes doctors will ask for your consent to collect a new tissue sample from you. To collect tumor tissue, doctors often do a biopsy, where they take a small amount of tissue from you to study it. If you need a biopsy for the study, your doctor will explain what type of biopsy will be done and any risks. Your doctor may also ask to take a small amount of blood to study.

Stored tissue samples

If you have tissue from a previous procedure, surgery or biopsy, doctors may be able to use that stored tissue instead of taking a new sample.

Blood tissue samples are not commonly stored in this way and must be collected fresh.

Why do researchers collect tissue?

Some clinical studies require tissue samples so researchers can look for “biomarkers” in the tissue. A biomarker is something that can help tell us what is going on in your body. An example may be a molecule or substance made by a tumor. Biomarkers may also be made by the body as a specific response to the presence of cancer.

- Researchers evaluate biomarker results in an effort to:
 - Try to understand if biomarkers can help predict how a body responds to an investigational treatment
 - Help doctors better recommend treatments for future patients
 - Help researchers better understand diseases and disease processes

Storage of your tissue samples for research

The researchers will store any tissue you provide for research related to the study. This stored tissue is for research only and will continue to be tracked according to your study code number.

What are the risks of giving my tissue for research?

If you need to give a new tissue sample, the possible risks depend on the type of biopsy required. Your doctor will discuss the risks in detail with you. Some risks may include:

- Low blood pressure
- Pain
- Bruising
- Redness
- Swelling
- Scarring
- Infection

There are also risks related to data privacy (please see frequently asked questions below) and the release of personal information from your health records.

More information about these risks will be provided as part of the informed consent process for the study.

Frequently asked questions

Will I find out the results of the research using my tissue?

This will depend on the reason for the tissue sample. You may see the results of your biomarker test (such as a biopsy or blood test) if it is required for you to join, or impacts your current participation in, the clinical study. Results of tests performed only for research purposes will generally not be provided.

How is my privacy protected?

To protect your privacy, we take steps to limit the risk of anyone identifying you:

- We label your tissue with a number instead of your name
- We remove your name, address, phone number, social security number, date of birth and anything else that could directly identify you before researchers get access to your records or tissue sample.

If I agree to take part in the study, can I change my mind later?

Yes. You can change your mind about taking part in the study at any time. Here's how:

1. Contact your doctor and tell them you do not want to be in the study anymore.
2. The doctor will contact the study Sponsor.

Tissue samples obtained up until the point of you withdrawing from the study will continue to be retained to support the study research.



If you have any questions,

talk to your doctor, or call the contact person for study-related questions as noted on the informed consent form.

