

LEFTOVER TISSUE STORAGE DISCLOSURE

If you/your child is having a clinical test or procedure in which tissue will be taken, your/your child's leftover tissue sample(s) may be kept indefinitely. It is standard clinical practice to keep leftover tissue samples in the event that clinical tests need to be repeated or new clinical tests need to be done on the tissue samples.

Your/your child's leftover tissue samples can lead to new discoveries in medicine that help us diagnose, treat and prevent diseases. After at least three months, these stored tissue sample(s) may be used for de-identified research, coordinated by Cincinnati Children's Discover Together Biobank. "De-identified" means that your/your child's personal identifiers – like name or date of birth- will not be attached to the tissue sample(s) used in the research.

If your/your child's leftover tissue sample(s) qualifies for a research study in which personal identifiers and/or genetics are involved, you may be contacted to discuss the study and your/your child's potential participation in the research.

You can opt out of having your/your child's tissue samples being used for research. Please see the Frequently Asked Questions below or contact 513-803-7107 or DiscoverTogetherBiobank@cchmc.org for any questions or to opt out. For translated versions of this document, please visit our website at www.cincinnatichildrens.org/dtbiobank-tissuedisclosure.

FREQUENTLY ASKED QUESTIONS

What is a tissue sample? A tissue sample could be a piece of skin or even a piece of a certain organ, such as a liver. When a piece of tissue is taken from a living person, it's called a biopsy. Biopsies can help doctors and researchers discover the presence, cause, or extent of diseases.

Why does Cincinnati Children's store leftover tissue samples? Leftover tissues are stored in case a clinical test needs to be done again or a new clinical test needs to be done on the tissue(s). Rather than taking another piece of tissue from a patient, the stored tissue can be used for the testing. Even if your/your child's leftover tissue is stored, there is a chance that as part of your/your child's clinical care you/your child may need to have tissue collected again. After at least three months, the stored tissue samples may be used for approved research.

Can I opt out of my/my child's tissue being stored? No. It is standard clinical practice that leftover tissues be stored in case a clinical test needs to be repeated. You can contact us and tell us that you do not want research to be done on your/your child's tissue sample.

What kind of research could be done on my/my child's samples? Samples are used in many different types of research, such as studies to better understand the causes of disease, the way diseases happen, and how to best treat diseases.

Why is biobank research important? Biobanks help scientists make discoveries faster and more efficiently. Rather than taking a lot of time to recruit research participants, they can request samples from the biobank that fit their research study. For example, if they want to study 12-year-olds with Type 1 diabetes or study a rare disease, they can quickly and easily ask for those samples from the biobank.

What is Discover Together Biobank? Discover Together Biobank is Cincinnati Children's research biobank. "Bio" means life. Think of biology, which is the study of life. "Bank" means a safe and protected place to keep valuables. Therefore, a biobank is a "bank of life." The Discover Together Biobank is a secure place where we keep our research valuables – the samples (blood, saliva, tissues) and the information that goes along with those samples – so that our researchers and their collaborators can work with these samples and data to find treatments and cures for diseases. If you/your child have questions about Discover Together Biobank, you can contact 513-803-7107 or DiscoverTogetherBiobank@cchmc.org.

If my/my child’s leftover clinical tissue sample is running low, is the tissue not given to researchers?

We do our best to never run out of a leftover tissue sample. If a tissue sample is running low, we typically would not hand out this sample for research and would instead try to find a different sample that meets the needs of the researcher.

Am I giving consent for research studies by reading this disclosure? We are notifying you that your/your child’s leftover samples may be stored and used for de-identified research. If certain studies ask to use your/your child’s leftover samples where they are asking for identifiable information, or genetic/genomic testing is involved, we may try to contact you to see if you are OK with giving consent to participate in that study. We may try to contact you over phone, email, mail or in some cases in person if you are at Cincinnati Children’s. If we do contact you to get your/your child’s consent and you say/your child says “No,” we will not use your/your child’s leftover tissue sample for that study. If you say “No” to the research, it will not impact your/your child’s care at Cincinnati Children’s.

What does “de-identified” research mean? De-identified research means that personal identifiers, such as name, address, and dates of appointments/procedures, are not included with the information provided to the researchers to answer their research questions. For a full list of Health Insurance Portability and Accountability Act (HIPAA) identifiers, visit the Discover Together Biobank at www.cincinnatichildrens.org/dtbiobank-tissuedisclosure.

Will Cincinnati Children’s ever sell my/my child’s tissue samples? No, Cincinnati Children’s will never simply exchange your/your child’s tissue samples for money. However, researchers at Cincinnati Children’s may share samples with collaborators outside of Cincinnati Children’s to complete the goals of a research project, and Cincinnati Children’s may be paid for the work to transfer samples or for its costs of the research collaboration. Cincinnati Children’s collaborators may work at a university or another hospital, or they may work at a for-profit company, like a drug company. When Cincinnati Children’s researchers share samples with researchers at for-profit companies, those companies will use the samples to develop new drugs or medical treatments and may profit from new products developed. Sometimes, academic collaborations may also lead to new products, and Cincinnati Children’s or its academic collaborators could profit.

Does Cincinnati Children’s ever receive money from research done on these samples? Yes, it is possible that discoveries can be made from these samples that could lead to new products – such as new medicines. If this happens, Cincinnati Children’s could receive money from these new medicines or treatments. Also, if samples are shared with outside collaborators to conduct a research project, the outside collaborators may pay Cincinnati Children’s for our costs to conduct the research project. Money received is used to support the mission of Cincinnati Children’s, so more children can be cared for and our researchers can continue making breakthrough discoveries. You will not be paid if research done on your/your child’s samples lead to new products.

Why and how might I be contacted if research is being done on my/my child’s samples? If researchers ask to use your/your child’s tissue samples for research that involves genetic/genomic testing or identifiable information, you may be contacted to learn about the project and to give your consent, if you are interested. You could be contacted by phone, mail, email, or approached in person at Cincinnati Children’s. In this case, if you decide you do not want to consent to participate in the project, your/your child’s samples will not be used for that project.

Whom do I contact with questions, concerns, or to opt out of research on my/my child’s leftover tissue sample? You can contact 513-803-7107 or DiscoverTogetherBiobank@cchmc.org. For translated versions of this document, please visit our website at www.cincinnatichildrens.org/dtbiobank-tissuedisclosure.