Better Outcomes for Children Project

Cincinnati Children's Hospital Medical Center (CCHMC) works to improve child health by finding new ways to prevent, identify and treat diseases and conditions. "Better Outcomes for Children" uses information and leftover biological samples collected during you/your child's visits. We will "de-identify" this information and your samples. This means that the researchers at CCHMC and their partners will be able to use the information and the samples, but will not know who you/your child is.

Will we want more samples from you/your child for this project? No.

What samples will we study? We may use for research any leftover samples that we do not need for your/your child's medical care. Examples are blood, urine, and solid tissues. We may separate out parts of the samples such as DNA.

Will you study my DNA? Yes, we may study your/your child's DNA if the research requires it. We will study other things within your/your child's samples.

Will this cost me anything extra? No.

Will my insurance company find out about my participation in this project? CCHMC will not tell your insurance company.

If I choose to be a part of this project, will it affect my/my child's care? No.

Can I choose NOT to have my/my child's information and remaining samples used for this project? Yes. Let the registrar know that is what you want.

What research might we do on the samples? We would like your permission to use the samples and information to do any research that we believe will benefit children or other patients. This may include research on: allergies, arthritis, asthma, cancer, genetic diseases, heart disease, human development, infectious diseases, injuries, mental health, premature births, sports medicine, or surgery.

Who will study these samples? Doctors and scientists at CCHMC and their partners may use the samples.

Are we going to share your samples with researchers outside of CCHMC? CCHMC may have partners outside of the medical center, including commercial partners, with whom we may share your/your child's samples.

Will researchers share information from the study of these samples? Researchers will probably publish the results of their research in places such as medical journals. The National Institutes of Health (NIH) and other agencies may make some of this information public through their databases. It may then be used for more research. No one will be able to tie this information to you or your child's name.

Will researchers be able to identify me or my child? The doctors and nurses taking care of you will know who you are. We will not tell researchers using your samples who you are without proper approval from the Institutional Review Board (IRB).

How long will you keep my/my child's samples and information? We will keep the samples until we use them up. This could be years or decades. We will keep the information from the visits and samples indefinitely.

How long is this consent valid? If you sign the consent for yourself, it will remain valid until you withdraw it. If you do not withdraw it, it will remain valid indefinitely. If you sign the consent for your child, it will be valid until your child is 18 or until you withdraw your permission. Once your child turns 18, we will ask for his or her consent.

Will I be paid for my samples? No. These are leftover samples. You will not be paid even if our commercial partners make money from products developed from your/your child's samples.

Can I change my mind later? Yes. If you change your mind, you can visit http://www.cincinnatichildrens.org/patients/visit/during/stay/better-outcomes-for-children for information on how to leave the project or call a member of the project team at 513.636.8695.

Who should I contact if I have more questions? Please call a member of the project team at 513.636.8695. If you leave a message, we will call you back within two business days. You may also email questions to BetterOutcomesforChildren@cchmc.org

If you have questions about your rights as a participant in this project, or you have questions, concerns or complaints about the project that you don't want to share with the project team, you may contact the Institutional Review Board at 513.636.8039.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must give your permission for the researchers to use and share you/your child's "protected health information" (called PHI for short) with you/your child's samples. Your child's name and identity will be removed from this information for this study.

What protected health information will be used and shared during this study?

CCHMC will need to use and share you/your child's PHI as part of this study. You/your child's name and identity will not be attached to this information. This PHI will come from:

- CCHMC medical records
- Research records

The types of information that will be used and shared from these records include:

- Laboratory test results, genetic test results, diagnosis, and medications
- Reports and notes from clinical and research visits
- Imaging reports (like CT scans, MRI scans, x-rays, etc.)

Who will share, receive and/or use your child's protected health information in this study?

- Researchers at CCHMC and its study partners, which may include outside study sponsors.
- The members of the CCHMC Institutional Review Board and the staff of (and those working with) CCHMC's Office of Research Compliance and Regulatory Affairs.

How will you know that your/your child's PHI is not misused? Any researchers that receive your child's PHI as part of this research are limited in how they can use the information. Federal privacy laws also require most people who receive your child's PHI to protect it. Your child's name and identity will not be attached to the samples or PHI. However, some people that may receive your child's PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind? Yes. You may cancel your permission at any time. Information on how to do this is in the first part of this document. If you cancel your permission to use and share your/your child's PHI, we will not do any new research using your/your child's samples. We will destroy your/your child's samples. If you cancel your permission, no new PHI about your child will be used or shared. However, the following uses of your/your child's PHI may occur:

- Use or sharing of PHI that happened or was in process before you cancelled your permission.
- Use or sharing of PHI that is needed to ensure the accuracy of the research.

Will my permission expire? Unless you withdraw it, your permission will not expire.

Will my/my child's other medical care be affected? By signing this document, you agree for you/your child to be in this research study. You also give permission to CCHMC and its partners to use and share you/your child's PHI for this research study. If you don't sign this document, you/your child will not be in the research study. However, you/your child's rights arising from any treatment that is not related to this study, payment for services, enrollment in a health plan, or qualification for benefits will not be affected.

BETTER OUTCOMES FOR CHILDREN

Please sign only ONE section of this document. If you are the parent of a child age 11 or older, please discuss participation in this research with your child.

Statement of Agreement (with re-contact)

By signing below, I AGREE to allow CCHMC, as a part of the Better Outcomes for Children Project, to keep and use leftover samples from me/my child. CCHMC may link the sample to clinical information about me/my child, but not my/my child's identity. I WISH TO BE RE-CONTACTED IF CCHMC FINDS IMPORTANT INFORMATION THAT WOULD AFFECT MY/MY CHILD'S MEDICAL CARE. In general, CCHMC will not tell me individual results from this testing. But if CCHMC finds important information about a major disease that can be prevented or treated, CCHMC would then link the information to my/my child's name. Approved staff will then try to contact me to talk about what could happen if CCHMC tells me the results. If I/my child is receiving regular medical care anyway, I may already know about these results.

Patient/Parent/Guardian Signature: _____ **Relationship:** _____

Patient/Parent/Guardian Printed Name: _____ **Date:** _____

Statement of Agreement (without re-contact)

By signing below, I AGREE to allow CCHMC, as a part of the Better Outcomes for Children Project, to keep and use leftover samples from me/my child. CCHMC may link the sample to clinical information about me/my child, by not to my/my child's identity. I DO NOT WISH TO BE RE-CONTACTED IF CCHMC FINDS IMPORTANT INFORMATION THAT WOULD AFFECT MY/MY CHILD'S MEDICAL CARE. In general, CCHMC will not tell me individual results from this testing. But if CCHMC finds important information about a major disease that can be prevented or treated, CCHMC would then link the information to my child's name. By signing on the line below, I request that staff from CCHMC NOT try to contact me to discuss what it could mean if CCHMC tells me the results. If I/my child is receiving regular medical care anyway, I may already know about these results.

Patient/Parent/Guardian Signature: _____ **Relationship:** _____

Patient/Parent/Guardian Printed Name: _____ **Date:** _____