

National Children's Study Authorization to Obtain Bodily Fluids and Tissues

Name of health care provider _____

Facility _____

Street address _____

City _____

State Zip

Phone number --

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Centers for Disease Control and Prevention
U.S. ENVIRONMENTAL PROTECTION AGENCY

This form is a permission form called an Authorization to Obtain Bodily Fluids and Tissues. Some institutions require this form as part of compliance with the Health Insurance Portability and Accountability Act of 1996 (known as HIPAA) in order to collect protected health information from your medical and health records to use in the National Children's Study. Protected health information (PHI) is any identifiable health information about your past, present, or future physical or mental health condition or payment for health care. Examples of PHI are medical and dental records, billing records, x-rays, and laboratory reports.

If you sign this form, you authorize the health care provider identified above to allow the National Children's Study research team to obtain and/or collect samples, such as blood, from you as well as samples from your child(ren) such as your child(ren)'s blood, umbilical cord, umbilical cord blood, and placenta. The specific samples that we plan to collect are described in the National Children's Study informed consent forms. This authorization form covers the period of time when you or your child(ren) receive care at this facility for labor, delivery, and/or perinatal services during and following your current pregnancy.

This authorization form covers any care you or your child(ren) received from other health care providers associated with the above identified health care provider or facility who provided care to you or your child(ren), such as laboratories and diagnostic centers who may have taken part in analyzing or evaluating your or your child(ren)'s biological samples.

The National Children's Study and its contractors will use these samples and information for research purposes only and to supplement the information you have already given to the research team. Once your information is released to the National Children's Study, it is no longer covered by HIPAA but is covered by the Privacy Act of 1974, Titles II and III of the E-Government Act (FISMA) and the Public Health Service Act⁽²⁾, which prohibits the release of information that would identify you and your child(ren) or your health care providers outside the sponsoring agency and its contractors without your permission or that of your health care providers.

Any National Children's Study generated information incorporated into your medical record maintained at the facility mentioned above will be covered by the same HIPAA privacy laws as the rest of your medical information.

Your decision to sign or not to sign this authorization form will have no effect on your eligibility for treatment with the health care provider or facility identified above. In addition, it will have no effect on payment, enrollment, or eligibility for any benefits to which you are entitled. You have the right to stop this HIPAA authorization at any time. You must do so in writing by sending a letter to the Study representative as indicated below. Stopping this HIPAA authorization will not stop information sharing that has already happened. Otherwise, this authorization does not have an expiration date.

You will be given a copy of this Authorization to Obtain Bodily Fluids and Tissues Form.

Printed name of participant (first, middle, last) _____

Other names under which records may be filed _____

Signature of participant _____

Date of birth: //
m m d d y y y y

Date signed: //
m m d d y y y y

If the participant is a non emancipated minor, according to state law, a parent/guardian must sign and date.

Signature of parent/guardian _____

Date signed: //
m m d d y y y y

1. Health Insurance Portability and Accountability Act: 42 U.S.C. 1320d-2 and 1320d-4 and the implementing regulation, 45 CFR 164.508, require a detailed authorization for your health care provider to disclose health information from your records for research purposes.
2. Public Health Service (PHS) Act: 42 U.S.C. 242m(d) protects the confidentiality of data collected under the research authorities of the National Institutes of Health. The National Children's Study will be carried out in compliance with these provisions as well as those in the Children's Health Act of 2000 (Public Law 106-310 Sec. 1004).

Affix label with local contacts:
1. Rights as a Human Subject
2. Local Office

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.