PARENT/SURROGATE CONSENT FORM TEMPLATE

CHILDREN'S MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD

Permission for a Child to Participate in a Research Project

Investigators at Children's Memorial Hospital invite you to consider having your child participate in a research study entitled:

Analysis of Environmental Chemicals in Dried Blood Spots
(Title of study)

Sponsored by: National Institutes of Health and carried out by Thomas McDade, PhD.

WHY IS THIS STUDY BEING DONE?

The Analysis of Environmental Chemicals in Dried Blood Spots is a sub-study of the National Children's Study, led by the Laboratory for Human Biology Research at Northwestern University. The goal of this study is to find a good way to measure if children come in contact with toxins in their surroundings by measuring what is in their blood. We want to study how easy it is to find toxins in blood by pricking your finger compared to using a needle. It is a lot easier to prick a child's finger than to have to use a needle.

One group of toxins researchers will look at is heavy metals such as lead, mercury, cadmium, and arsenic, which are found in water, air, and soil. A second group of toxins researchers will look at are called chemical proteins, which are found in fuel, wood, and smoke.

WHAT IS INVOLVED IN THE STUDY AND HOW LONG WILL MY CHILD BE IN THE STUDY?

If you agree for your child participate in this study, a nurse will look up the amount of blood your child has already given this month to make sure that they would not give too much blood. If the amount is OK, then your child can participate if you and they agree.

The two ways that this study will take your child's blood are: 1) by taking some extra blood in a tube when they have a blood draw already scheduled, and 2) by pricking your child's finger, or heel if they are an infant, and getting 5 drops of blood on special paper. This will take about five minutes.

You are here today because your child is scheduled to give blood. This study will take an extra tube of blood at the same time that the nurse takes you child's blood during the appointment that they have here today. We will take 2 teaspoons of your child's blood.

Next, your child's finger will be pricked and 5 drops of blood will be dropped onto a special piece of paper.

Finally, your child will be asked to answer 2 questions about how old they are, and if they are male or female.

Participating in the study will take about 15 minutes. Your child will be able to do all of the same activities that they normally do after participating in this study. In the future, the blood we draw from your child today could be analyzed in similar studies.

ARE THERE BENEFITS (GOOD THINGS) TO TAKING PART IN THE STUDY?

You or your child may not personally benefit from participating in this study. Your child's participation may help find an easy way to look at blood and see what is in children's blood. This means that researchers and doctors can understand better what from the environment can make kids sick and unhealthy.

WHAT ARE THE POSSIBLE RISKS OR SIDE EFFECTS (BAD THINGS) OF THE STUDY?

The risks of taking blood include injury to the vein, bleeding into the skin (bruising) and rarely, infection. Study personnel will take care to prevent these or to correct them should they arise.

WHAT OTHER OPTIONS ARE THERE?

You or your child can decide not to participate.

But, if you and your child do decide to participate, you can change your mind at any time and stop.

WHAT ARE THE COSTS?

There will be no costs to participants in this study.

WILL I BE TOLD ABOUT NEW INFORMATION?

You will not receive any health information about your child as a result of this pilot study. The information that we find from this study may be combined and published.

WILL THERE BE COMPENSATION FOR MY CHILD'S PARTICIPATION?

To thank you and your child for your participation, you can choose one of the following:

a $15 gift card; OR

$10 gift card and a book or small toy for your child.

WHAT DO I DO IF MY CHILD IS INJURED?

If your child is injured, medical facilities and treatment will be available. However, you will be required to pay a reasonable fee for such care. Your child can still receive medical benefits if otherwise entitled. If you have any questions or desire further information concerning the availability of medical care, you may contact Dr. Edward Ogata, Chief Medical Officer, The Children's Memorial Hospital, 2300 Children's Plaza, no. 2, Chicago, Illinois, 60614-3363 [773/868-8056].

WHO WILL KNOW ABOUT WHAT MY CHILD DID IN THE STUDY OR HAVE ACCESS TO MY CHILD'S PRIVATE INFORMATION?

This signed consent form will be placed in your child's medical record at Children's Memorial Hospital with a copy placed in the Principal Investigator's research file. If your child does not have a medical record at Children's Memorial Hospital, then this signed consent form will only be kept in the Principal Investigator's locked research file.

Children's Memorial Hospital Institutional Review Board, the committee that is in charge of protecting the rights of all adults and children who participate in research studies at Children's Memorial Hospital, may also have access to your child's consent form. They are required to keep your personal information confidential. However, the staff that work on the study, such as investigators lab personnel, coordinators, and research assistants, will have no access to any of your child's personally identifiable information or medical records.

WHAT ARE MY CHILD'S RIGHTS AS A PARTICIPANT?

By signing this consent form, you agree to have your child take part in this study. You are not giving up any of your or your child's legal rights or releasing this hospital from responsibility for carelessness.

You may cancel your consent and take your child out of this study at any time. Neither you nor your child will be penalized for doing this. Your child's treatment by, and relations with the physician(s) and staff at Children's Memorial Hospital, now and in the future, will not be affected in any way if you do not want your child to take part in this study, or if you enter your child into the study and then withdraw your child from it.

If you have any questions about your child's rights as a research subject, you may take them to Philip V. Spina, Sr. Vice-President and Chief Operating Officer,

Children's Memorial Research Center, 2300 Children's Plaza, no. 205, Chicago, Illinois 60614-3363.
[Ph: 773/755-6301, Fax: 773/755-6533, Email: pspina@childrensmemorial.org].

You will be given a signed and dated copy of this consent form.

SIGNATURES

I have read this consent form, and I agree to have my child, _____ (clearly write the child's name) take part in this study as explained in this consent form.

_____	_____
Date	Signature of Parent(s) or Surrogate(s)
	_____
	Identify the signatory: e.g. Parent, Guardian,

I certify that I have explained the above to the parent(s) and/or surrogate(s) and believe that the signature(s) was affixed freely. I also agree to answer any questions that may arise.

_____	_____
Date	Signature of Person Obtaining Consent
	_____
	Printed Name of Person Obtaining Consent
_____	_____
Date	Signature of Principal Investigator (if not listed above)

Printed Name of Interpreter: _____

Printed Name of Witness: _____

Signature of Witness: _____