ADULT CONSENT FORM TEMPLATE

CHILDREN'S MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD

Adult Consent to Participate in a Research Project

Investigators at Children's Memorial Hospital invite you to consider participating 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 I BE IN THE STUDY?

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

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

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

Next, your finger will be pricked and 5 drops of blood will be dropped onto a special piece of paper.
Finally, you will be asked to answer 2 questions about how old you are, and if you are male or female.

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

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

You may not personally benefit from participating in this study. Your 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 great care to prevent these or to correct them should they happen.

WHAT OTHER OPTIONS ARE THERE?

You can decide not to participate.

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

WHAT ARE THE COSTS?

There will be no cost to you for participating in this study.

WILL I BE TOLD ABOUT NEW INFORMATION?
You will not receive any health information as a result of this pilot study. The information that we find from this study may be combined and published.

WILL I BE COMPENSATED FOR MY PARTICIPATION?

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

a $15 gift card; OR

$10 gift card and a book or small toy.

WHAT DO I DO IF I AM INJURED?

If you are injured, medical facilities and treatment will be available. However, you may be required to pay a reasonable fee for such care if you have no medical insurance. You have medical insurance; you can still receive this care 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 I DID IN THE STUDY OR HAVE ACCESS TO MY PRIVATE INFORMATION?

This signed consent form will be placed in your medical record at Children's Memorial Hospital with a copy placed in the Principal Investigator's research file. If you do 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 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 personally identifiable information or medical records.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

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

You may stop participating in this study at any time without penalty or loss of benefits. Your treatment by, and relations with the doctor(s) and staff at Children's Memorial Hospital, now and in the future, will not be affected in any way if you refuse to take part or if you enter into the study and then decide not to participate.

If you have any questions about your rights as a participant in a research study (research subject), you may take them to Philip V. Spina, Sr. Vice-President and Chief Operating Office, 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 take part in this study as explained in this consent form.

_____	_____
Date	Signature of Research Subject (subject is ≥18 years)
	_____
	Printed Name of Research Subject

I certify that I have explained the above to this research subject and believe that the signature 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: _____