CHILDREN'S ONCOLOGY GROUP

The world's childhood cancer experts

North American Wilms Tumor Study

CONSENT FORM

North American Wilms Tumor Study (NAWTS)

AEPI10N4 Molecular and Genomic Epidemiology of Wilms Tumor

Rayjean J. Hung, Ph.D., M.S. – Principal Investigator
Mount Sinai Hospital
Dalla Lana School of Public Health, University of Toronto
Hospital of Sick Children

The Mount Sinai Hospital and the Hospital for Sick Children, along with the Children's Oncology Group, a cooperative group of hospitals in the United States and Canada including the institution where your child's cancer care was received, is conducting a study of genetic factors affecting the health of children and their families. Rayjean J. Hung, Ph.D., M.S., of the Mount Sinai Hospital and a COG member of the Hospital for Sick Children, is responsible for this study. Your child was selected as a possible participant because he or she was diagnosed with Wilms tumor and was registered with the Children's Cancer Research Network (CCRN) of the Children's Oncology Group.

You are being asked to participate in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Study purpose

While we know that genetic and environmental factors have a role in cancer development, there is still very little known about the causes of cancer in infants and children. The purpose of this study is to obtain health and lifestyle information about children who have been diagnosed with Wilms tumor and their parents, and to compare this to information from children without cancer in order to identify risk factors for childhood cancer. Although cancer in children is rare, research on childhood cancer could have an impact on the years and quality of life of affected children. This research study is being conducted by the Children's Oncology Group, the Mount Sinai Hospital, and the International Agency for Research on Cancer, a research institute of the World Health Organization. The overall purpose is to find possible causes, including genetic or environmental factors and medical conditions that may increase the risk of Wilms tumor. Wilms tumor is a type of cancer in the kidney that occurs in very young children. By possible causes, we mean things in the environment, genetics, or certain medical conditions that may be related to the development of embryonal tumors.

Study procedures

If you decide to allow your child to participate in this study the following will occur:

1) An interviewer will administer the questionnaire over the phone with each parent/guardian separately at a time of your choice. The interview will take about 1.5 hours and it consists of questions related to lifestyle, environment and health history.
2) If you are willing to donate a saliva sample, you will follow the instructions provided in the collection kit and spit into a plastic container.
3) We will request from the Childhood Oncology Group Renal Tumor Biology and Biobanking Study, a small sample of DNA and tumor tissue from your child.
4) If your child has a twin, we will ask that you answer some questions about him or her too. We would also like to collect some saliva from him or her.
5) Any information obtained will only be used for the purposes of this study. Information which may identify you or your child will be destroyed within 5 years after the study is complete.

Each of these procedures is described in detail below. Please note that component number 2 (saliva sample) is only applicable to biological parents.

- *Survey*

We will ask each parent/guardian to complete a questionnaire related to your lifestyle, environment and health history. The primary care taker of the child will also complete a questionnaire about the child's growth, development, and health. The questionnaires will be completed over the phone with a trained interviewer at a time of your choice.

- *DNA collection*

We will ask you to donate a sample of saliva. The saliva sample will be collected by having you spit into a sample container. Samples can be returned to us using the pre-paid mailer. This part of the study takes about 10 minutes. If we find out that your saliva sample does not have enough DNA to be useful, we may call you for a replacement sample. We will request from the Childhood Oncology Group Renal Tumor Biology and Biobanking Study, a small sample of DNA from your child.

Why are we looking at DNA and Wilms tumor?
The saliva sample we collect will be used to study your DNA. DNA is the genetic material in a person's cells that makes them unique. In each cell, there are thousands of genes that are made up of DNA. By studying DNA, scientists can discover what genes might be involved in the development of Wilms tumor.

Biological samples obtained will be used for research purposes only. The research results are not likely to be suitable for use as clinical tests for you or your child's medical care. Therefore, the results will not be available to you and your health care provider. The findings of the study will be available to the public through publications in scientific journals. If you wish, we can inform you of the overall findings from the study once the study has been completed.

How will the DNA be used and stored?
Saliva samples will be shipped to a laboratory at Mount Sinai Hospital for storage and analysis. These samples will be used for biochemical and genetic analysis in this study, and they will be tested for genetic and molecular characteristics that may be related to developing cancer or protecting against it. Any material not immediately used will continue to be stored to be used in the future to help scientists learn more about environment, genetic changes and health. By agreeing to participate in the biological sampling component of this study, you are granting

consent now for future uses of these samples that relate to the purposes of this study. None of these samples will be tested for illegal drugs. All results will remain anonymous. In some cases, your saliva DNA sample could be sent to other research groups for analysis. You would not be notified, but any samples we send to another researcher would be identified only with a number and will not be able to be traced back to you. You or your child will not be identified in any publication or reports from this study.

If you initially decide to give permission to have saliva DNA samples stored for future research purposes, but later change your mind, whatever remains of your biologic samples will then be destroyed.

You will be asked at the end of this document about giving your permission to store and use left over DNA from you for future research. DNA from your child's Wilms tumor and blood has already been stored in the Children's Oncology Group (COG) Biological Samples Bank because you took part in the COG AREN03B2 study. For the purposes of the AEPI10N4 study, we will obtain DNA and blood samples from the COG samples bank. Any unused material will be returned to the COG bank.

- *Tumor sample*

We will contact the Children's Oncology Group Wilms Tumor Biology and Biobanking Study for the tumor samples. We would request that they send us a small amount of DNA to be used to look at changes in the tumor. No additional tumor samples would be requested from you.

There are laws that require that research records that have your child's name on them be shown to people who make sure that the research is being done right. These are the only people, besides Dr. Hung and her associates, who would be able to trace the cells or DNA back to you.

- *Medical records*

We would ask that you grant us access to your child's medical records related to growth. If your child has been diagnosed with a genetic condition we would also ask for records related to the condition. You will need to sign separate authorization forms for release of your child's medical records.

Study Size and Duration

A total of 2200 families will be included in this research internationally. About 840 will come from North America.

Your participation in this study will last until your saliva samples have been collected, the questionnaire information has been obtained, and your child's DNA and tumor sample is obtained. You can stop participating at any time. Your child's doctor, or the study investigator, may decide to take you off this study, if they feel it is in your best interest not to continue.

Risks of Study Participation

The risks of this study are minor. There is a risk that your personal information could accidentally be released to someone other than study staff. We would keep all personal information in locked file cabinets or in computer databases protected by passwords. Only study staff would have access to these documents and files.

Because we are getting DNA from parents and child, we may be able to tell if someone was adopted or if their father is different than they think. Our policy is to not reveal this information.

Research on the biological samples is **very unlikely** to discover results that are important to your child's current or future health. However, if it does, we will try to contact your child's doctor as listed with COG about what the research tests might mean. Only the doctor will be notified and the information will not become part of your child's medical record. Your doctor will decide whether to discuss the results with you. Your doctor may recommend repeat testing, meeting with a genetic counselor, or no further action.

In addition to the risks described above, there may be unknown risks, or risks that we did not anticipate, associated with being in this study.

Benefits of Study Participation

To individual subjects: You (your child) will not benefit directly from participating in this study. To society: However, information learned from this study may help other children diagnosed with cancer and help to prevent the development of cancer in the future. Your participation is very important to the success of this scientific research.

Other Options

Instead of being in this study, you have the option not to take part.

Study Costs/Compensation

There is no cost to you for participating in this study. Your family will receive $25 gift card to thank you for participating in this study.

Research Related Injury

As this is an observational study, it is very unlikely that there will be any harm or injury caused by study participation. In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form. If you think that you have suffered a research related injury, let the study staff know right away.

Confidentiality

The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you or your child as a subject. Your and your child's record for the study may, however, be reviewed by Mount Sinai Hospital Research

Ethics Board that makes sure research is done right. Your child's participation in this study will not be noted in his or her medical record. To these extents, confidentiality is not absolute.

The risks to you and your family from genetic research are very low. Your samples will be identified only with your study code number. In the event of an unexpected breach of confidentiality, a recent US federal law (Genetic Information Non-Discrimination Act, GINA) and other similar federal regulations and laws in North America will help protect you from health insurance or employment discrimination based on genetic information obtained about you through research such as this. If you have questions about GINA or the risks of research on genetic information, please ask study staff.

The Children's Oncology Group has received a Certificate of Confidentiality from the federal government, which will help us protect the privacy of our research subjects. Information about the certificate is included in **Attachment #1**.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- **Children's Oncology Group**
- **Representatives of the National Cancer Institute (NCI), Food and Drug Administration (FDA), and other U.S. and international governmental regulatory agencies involved in keeping research safe for people**
- **Mount Sinai Hospital Research Ethics Board**

Protected Health Information (PHI)

Your child's PHI created or received for the purposes of this study is protected under the federal regulation known as Health Insurance Portability and Accountability Act (HIPAA) in the U.S. or Personal Information Protection and Electronic Documents Act (PIPEDA) in Canada.

Voluntary Nature of the Study

Participation in this study is up to you. If you choose to let your child take part in this study you can take your child out of the study at any time. If your child is able to provide assent to participate, this will also be required from him/her. The care your child will not be affected in any way by whether your child takes part in this study.

New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the study.

Contacts and Questions

The researchers conducting this study are Rayjean J. Hung and her associates in the Mount Sinai Hospital. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact them at 1-416-586-4800 ext8118. If your phone carrier/plan does not have long-distance calling option, please call the study toll-free number at 1-855-586-8815.

If you have any questions about your rights as a research participant or have concerns about this study, call Ronald Heslegrave, Ph. D., Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics office number at 1-416-586-4875. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

You will be given a copy of this form to keep for your records.

Summary

If you consent to participate, this is what it means:

1) You have had the opportunity to discuss this study with anyone you desire. You have had the opportunity to ask any questions you may have regarding participation.
2) You have read and understand the possible harms and benefits (if any) of this study.
3) You understand that you have the right to refuse to let your child take part in the study. You also have the right to take your child out of the study at any time. Your decision about your child taking part in the study will not affect your child's health care.
4) You are free now, and in the future, to ask questions about the study.
5) You understand that your child's medical records will be kept private except as described in this consent form.
6) You understand that no information about your child will be given to anyone or be published without first asking your permission.
7) You agree, or consent, that your child may take part in this study."

If you have any questions about this study, please contact Research Assistant, Laura Adams at 416-586-4800 x8118 or adams@lunenfeld.ca or the Principal Investigator, Dr. Rayjean Hung at Rayjean.Hung@lunenfeld.ca.

If you have questions about your rights as a subject in a study, please call the Research Ethics Manager at 416-813-5718.

Statement of Consent (Only 1 parent required to consent for self and child.)

I have Read and Understood this Consent to Participate Form and agree with the Conditions Included. **I consent to participate in the study on behalf of myself and my child.**

Signature of Parent/Guardian _____Date _____

Printed Name of Parent/Legal Guardian_____

Signature of Parent/Guardian***** _____Date _____

Printed Name of Parent/Legal Guardian_____

*If Applicable (only 1 parent is required to consent)

Level of Participation

Please initial the boxes to indicate your level of participation:

	Mother		Father	
	Yes	No	Yes	No
1. I give permission to the research staff working on the above project to have access to: (a) my child's medical records.				
(b) my medical records				
2. I agree that tissue samples removed from my child at operation may be used in the study. I understand that I will not be given the results of these tissue samples by the study team.				
3. I agree to give a saliva sample for research purposes. I understand that I will not be given the results on the saliva sample by the study team.				
4. I agree to have my left over DNA stored for future research				
5. I agree that a saliva sample may be taken from my child if a blood sample cannot be obtained from a sample taken for other medical reasons. I understand that I will not be given the results on the saliva sample by the study team.				
6. I give permission to the research staff working on this project to contact me if questions arise, such as clarification of survey responses or additional biosamples are required. If yes, please provide daytime telephone number or e-mail address: _____.				
7. I am willing to be contacted for future research projects.				

If you have any questions about this study, please contact Research Assistant, Laura Adams at 416-586-4800 x8118 or adams@lunenfeld.ca or the Principal Investigator, Dr. Rayjean Hung at Rayjean.Hung@lunenfeld.ca.

If you have questions about your rights as a subject in a study, please call the Research Ethics Manager at 416-813-5718.

Attachment #1 Information about the Certificate of Confidentiality

The Children's Oncology Group has received a Certificate of Confidentiality from the federal government, which will help us protect the privacy of our research subjects. The Certificate protects against the involuntary release of information about your subjects collected during the course of our covered studies. The researchers involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, the subject or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the subject or his/her guardian requests the release of information in writing, the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act. The Certificate of Confidentiality will not protect against mandatory disclosure by the researchers of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.