PATIENT CONSENT FORM
National Wilms Tumor Late Effects Study

NWTS #_____

CONSENT FORM: UNDER 18 YEARS OF AGE

I, _____, willingly agree to allow my child to participate in this investigation, which has been explained to me by _____. This research study is being conducted by the National Wilms Tumor Study (NWTS) and by _____.
(Institution)

The purpose of this research is to learn more about the possible causes of Wilms tumor and the effects of successful treatment for Wilms tumor. I have been asked to be in this voluntary study because my child had a Wilms tumor and has completed therapy for the tumor. I have read and understand the two-page explanation of the purpose of this research study, and of the potential risks and benefits of participation, which is attached to this consent form. To determine the long-term effects of the treatment which has been given to my child, s/he will be evaluated once per year by her/his own physician or, if my child doesn't have a physician, by completing a brief questionnaire. This research study involves the completion of several forms requiring information about my child's family and my child's current state of health. Depending upon my child's health status, I may also be asked to allow copies of my child's past medical records to be sent to the NWTS Data and Statistical Center. This study does not specifically involve obtaining any blood tests. These will be obtained at the discretion of my child's doctor.

POTENTIAL BENEFITS: Although there may be no direct benefit to my child through participation in this study, other children who need treatment for Wilms tumor, the children's parents, and the health care professionals who take care of those children may benefit from increased knowledge about the children with Wilms tumor.

I understand that I will not be charged additional expenses for my child's participation in this study. I also understand that I will not receive money for participation in this study. I understand that I am free to withdraw my consent to allow my child to participate in this study. I may withdraw consent at any time and this decision will not adversely affect my child's care at this institution or cause a loss of benefits to which my child might be otherwise entitled.

All data obtained from this research will remain confidential and will only be used for biomedical research. The confidentiality of this document and all records from this research will be protected to the extent provided by law. Neither my child's name nor any other family member's name will be used in any report.

My signature below indicates that I have read all the above information, received answers concerning areas I do not understand, and am willingly giving my consent for my child to participate in this program. On signing this form, I will receive a copy.

_____	_____
Parent, Guardian	Date
_____	_____
Patient	Date
_____	_____
Witness	Date
_____	_____
Physician	Date

CONSENT FORM PAGE 2: UNDER 18 YEARS OF AGE

You are being asked to allow your child to continue participation in this study because your child was previously treated for Wilms tumor on the NWTS-5 protocol. This research project includes only people who choose to take part in it. Please consider the following information and take your time in making your decision.

WHY IS THIS STUDY BEING DONE?

The Late Effects Study is being conducted in order to answer scientific questions and to serve as a resource for Wilms tumor patients and their families. Although most people in this study enjoy good health, some may be at risk for certain health conditions. We are collecting information from as many participants as possible in order to determine if they or their offspring are at risk for adverse medical conditions. If there is more than one case of Wilms tumor in a given family, we plan to work with geneticists to try to estimate heritability and recurrence risks. We would like to answer your questions about possible long-term effects of treatment for Wilms tumor. This is why we are collecting information on health issues and pregnancies.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Over 5,000 people have chosen to participate in this study. We expect that more people will enroll as we contact them to continue participation, at least 1,500 between September 2012 and July 2018.

WHAT DOES PARTICIPATION INVOLVE?

Every five years we will send a Medical History Form for you to fill out and a Physical Exam Form for your child's physician to complete and return. In each of the intervening four years we send an annual request. This Annual Status Report asks about significant health events and confirms your most recent address.

Reports of conditions of particular interest are followed up with requests for consent to obtain confirming medical records. Current conditions of interest include pregnancy in participant or partner, heart, kidney or lung conditions, the development of other cancers, and the diagnosis of Wilms tumor in a family member.

We will always enclose return envelopes for your convenience.

WHAT IF MY CHILD IS NOT SEEING A PHYSICIAN?

When we send the Physical Exam Form every five years we understand that a visit to a health care provider may be a prohibitive expense for some. Completion of this form is not a requirement for participation. Although we recommend continued medical care, we would like to continue hearing from you regardless of your child's ability to be seen by a health care provider.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to allow your child to continue participation in this study your family may not personally experience any medical benefits. However, you may benefit by the resources we provide when you contact us for information or advice. Members of our national committee stand ready to answer, as knowledgeably as possible, any questions you may have.

We believe that the information we collect about your child and other participants will benefit other people diagnosed with or touched by Wilms tumor. Already people entered on the NWTS protocols have contributed enormously to our ability to successfully treat a new generation of children with Wilms tumor. By continuing to gather information on your child's current health we hope to learn about any risks associated with treatment for Wilms tumor.

CONSENT FORM PAGE 3: UNDER 18 YEARS OF AGE

WHAT ARE THE RISKS OF THE STUDY?

We respect that parents have different comfort levels with sharing certain aspects of their children's medical history. This discomfort is the primary risk of participation. However, we ask that you let us know if there is a particular part of our study for which you would rather not provide information. When we ask for annual updates you may decline to provide answers or releases for medical records if you are uncomfortable in sharing this information. Please let us know if you do not want to answer a particular question.

HOW LONG WILL MY CHILD BE IN THE STUDY?

We would like your family to participate in this study until the research is completed. However, you may withdraw at any time. We hope that you decide to continue participating and help us with this important research. However, if you decide to withdraw your consent to allow your child to participate in the study, we encourage you to talk to your child's regular doctor first and to retain the information in this document so that you may contact us in the future. We remain available to you as a resource regardless of your participation status.

WHAT ABOUT CONFIDENTIALITY?

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If your child joins the study, the Certificate means that generally we would not have to give out identifying information about them even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

In order to ensure compliance with the laws that govern research, the Fred Hutchinson Cancer Research Center (FHCRC) Institutional Review Board (IRB) will periodically audit studies. As part of their audit process, the IRB may review your child's medical records as they pertain to this protocol to ensure that the informed consent process was conducted properly. If you have any questions about this review process, you may call Karen Hansen, Director of the FHCRC Institutional Review Office at (206) 667-4867.

WHAT ARE THE COSTS?

This study makes no payments to participants for taking part in the study. We are also unable to provide any money for medical examinations or treatment.

WHAT ARE MY CHILD'S RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or your child may leave the study at any time. Again, you may contact Karen Hansen at the phone number above regarding your rights as a research participant.

WHOM DO I CALL FOR MORE INFORMATION OR IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study please call Dr. Wendy Leisenring at (800) 553-4878. Dr. Leisenring is the Principal Investigator of the Late Effects Study, and the NWTS Statistician. You may also visit the website of the Data and Statistical Center at http://www.nwtsg.org.