NATIONAL WILMS TUMOR STUDY

DATA AND STATISTICAL CENTER
FRED HUTCHINSON CANCER RESEARCH CENTER
1100 Fairview Avenue N, M2-B230, P.O. Box 19024, Seattle, Washington 98109
Telephone: (206) 667-4842, Message Line: (800) 553-4878, Fax #: (206) 667-6623, Web: http:www.nwtsg.org

Contact Name:_____ NWTS/Patient ID#:_____
Address:_____
City, State, Zip:_____

Dear:_____

I am the statistician for the National Wilms Tumor Study (NWTS). **Your parents consented for you to be enrolled in our study** when you were diagnosed with the rare childhood kidney disease known as Wilms tumor. Since then, we have received information on your progress from them and from the institution at which you were treated. You and other participants have contributed valuable information about the diagnosis and treatment of Wilms tumor. Today the number of surviving patients is increasing as the overwhelming majority of affected children are cured of their disease.

Now that you are 18 years or older, we are requesting your consent, as an adult, for the NWTS to continue to follow your progress. Accordingly, we are asking you to complete, sign, and return the enclosed consent form to the NWTS at your earliest convenience. In addition, if you would prefer that we contact someone else (i.e. your parent, spouse, etc.), please also indicate that on the back of this cover letter.

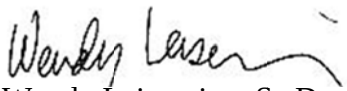
We are requesting your continuing participation in our study so that we may learn more about whether there are long term consequences of childhood cancer treatment. We are happy to make available to you, upon request, any published findings of the NWTS.

We have designed the study to cause you as little inconvenience as possible. We ask that the two forms we will send at five year intervals be filled out and returned to us. In the intervening years we will send you a brief annual mailing to make sure that we have your current address on file. If you or your spouse/partner become pregnant, or if you develop any serious medical problems, we may request additional information at that time. In addition, *some* participants may be contacted occasionally for special studies.

Please feel free to contact us at any time if you have questions, would like a more detailed explanation of the NWTS, or would like to share any new information with us. However, I certainly hope that you will decide to continue in this important study and return the completed consent form.

With many thanks for your past cooperation and best wishes for the future.

Yours sincerely,



Wendy Leisenring, Sc.D.
NWTS Statistician

(optional) The people listed below (for example, parents, spouse, fiancé) may also report my health information to the NWTS. This does not include permission to access my medical records.

Full Name:_____ Relationship:_____

Address:_____

_____ Phone Number:_____

Full Name:_____ Relationship:_____

Address:_____

_____ Phone Number:_____

Full Name:_____ Relationship:_____

Address:_____

_____ Phone Number:_____

Fred Hutchinson Cancer Research Center

Consent to take part in a research study:

National Wilms Tumor Late Effects Study

Principal Investigator:	Wendy Leisenring, ScD 206-667-4842
Co-Investigators:	John Kalapurakal, MD
Research Coordinator:	Susan Peterson 206-667-7251

We would like you to join this research study

If you are serving as a legally authorized representative, a guardian or are providing parental permission for a child in this study, the terms "you" and "your" refer to the person for whom you are providing consent or parental permission .

We are doing a research study to examine the effects of successful treatment for Wilms tumor. 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.

Since you have previously been treated for Wilms tumor on a National Wilms Tumor Late Study protocol, we would like to ask you to join this study. We will enroll at least 5,000 people. Although the study will not benefit you directly, we hope the information we learn will help people who are treated for Wilms tumor in the future.

If you agree to be in this study, you will be asked to do the following:

- **Answer a brief survey:** Every five years we will send a Medical History Form for you to fill out and a Physical Exam Form for your 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. We will always enclose return envelopes for your convenience.

- **Medical records review:** 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.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits for saying no or dropping out. Whatever you decide, your health care will not be affected.

If you leave the study, your test results and information cannot be removed from the study records.

What are the risks?

We respect that each person has a different comfort level with sharing certain aspects of his or her 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.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

Some organizations may need to look at your research records for quality assurance or data analysis. These include:

- Researchers involved with this study.
- Fred Hutchinson Cancer Research Center.
- Institutional Review Boards (IRB), including the Hutchinson Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Children's Oncology Group
- US National Institutes of Health, National Cancer Institute (NCI), Office for Human Research Protections, and other agencies as required.

We will assign a random number to your participation number. The researchers using your data will not have access to your name or other personal information. They will know the random number only. Thus the risk of someone connecting any study information with you as an individual is unlikely.

We will keep your medical records confidential. But we cannot guarantee total confidentiality. Your personal information may be given out if required by law. We will

not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

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 you join the study, the Certificate means that generally we would not have to give out identifying information about you 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 your research information if you give your 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.

As long as the study has continued approval from NCI and the Hutchinson Center IRB, your information will be stored in the study's database. However, if you choose to donate your samples for future research (see below), the identity of your samples and research record will be stored indefinitely.

If you have questions or complaints about this study, please call Dr. Wendy Leisenring at 206-667-4842. If you have questions about your rights as a research participant, call Karen Hansen in the Hutchinson Center's Institutional Review Office at 206-667-4867.

How much will this study cost me?

There are no costs for being in this study.

Do I have to participate in the whole study?

Each part of the study is completely voluntary. You may choose to join all, some, or none of the study activities. You may stop the telephone interview at any time, or choose not to answer some questions.

Will you contact me in the future?

Every year, we will contact you for short surveys so we can keep your address, phone number and health information current.

What will my information and/or biological samples be used for?

As you recall, we may have banked samples when you were treated or as part of one of our substudies. Your information from surveys, medical treatment summaries and any biological samples you donate (such as saliva, blood and tumor cells) will be used for the purposes of ongoing research in this study aimed at understanding health outcomes after Wilms Tumor.

Overall, the researchers may learn new information about disease risks for subgroups of Wilms Tumor survivors in their research. They will not share that information directly with you personally. However, they will publish their study results and send newsletters with important results to you.

In addition, be aware that by agreeing to participate in this study, your information or biological samples could be used for future research studies or sent to other investigators for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board if required by law. The information that identifies you will first be removed from your information or biological samples. If you do not want your information or biological samples to be used for future research studies without your consent, you should not participate in this study.

Signature

If you have read this form (or had it read to you), asked any questions, and agree to participate, please sign:

Participant (age 14+):

Participant / Printed Name, Signature, and Date

Parent or legal guardian:

Printed Name, Signature, and Date

Legally Authorized Representative: Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask questions;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to consent on behalf of the participant for him or her to participate in this study.

Legally authorized representative:

Printed Name, Signature, and Date

Current version date: December 3, 2018

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PLEASE RETAIN THIS COPY FOR YOUR FILES