

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>

Patient: _____

Patient ID # _____

Institution: _____

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 Adult Consent Form to the NWTs at the above address 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 enclosed form.

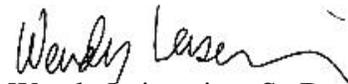
We are requesting your continuing participation in our study so that we may learn more about whether there are long term consequences of childhood cancer treatment. We are happy to make available to you, upon request, any published findings of the NWTs.

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 (800) 553-4878 or email nwtsg@fredhutch.org 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. **If you should decide to discontinue your participation**, check the second box on the form, sign and return it and we will send you no further correspondence. However, I certainly hope that you will decide to continue in this important study and return the completed adult consent form.

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

Yours sincerely,



Wendy Leisenring, Sc.D.
NWTs Statistician

LATE EFFECTS STUDY ADULT CONSENT FORM

1. I, _____, (Birth Date: _____), consent to participate in this study and authorize the National Wilms Tumor Study to continue contacting me to obtain further updates regarding my health status and significant life events. *(using my contact information given below).*

Please remove my name from your mailing list and discontinue contacting me about the National Wilms Tumor Study.

Full Name: _____

Address: _____

_____ Phone Number: _____

Last 4 digits of Social Security # (Optional): _____

2. *(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: _____

If more than three, please continue on the back.

3. _____
Signature of participant **Date**

I retained a copy of this form.
 Please send me a copy of this form.

LATE EFFECTS STUDY ADULT CONSENT FORM

You are being asked to continue participation in this study because you were previously treated for Wilms tumor on a National Wilms Tumor Study 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 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 I AM 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 ability to be seen by a health care provider.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to continue participation in this study you 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 you 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 current health and the health of your children we hope to learn about any risks associated with treatment for Wilms tumor.

LATE EFFECTS STUDY ADULT CONSENT FORM

WHAT ARE THE RISKS OF THE STUDY?

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.

HOW LONG WILL I BE IN THE STUDY?

We would like you 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 participate in the study, we encourage you to talk to your 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 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 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 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 RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or 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>.