**NATIONAL WILMS TUMOR STUDY**
DATA AND STATISTICAL CENTER
FRED HUTCHINSON CANCER RESEARCH CENTER
1100 Fairview Avenue N, M2-A876, 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

Dear NWTS Participant or Partner:

The NWTS has developed several treatment regimens since 1969 for the treatment of Wilms tumor and other kidney tumors of children. All of the regimens have been very effective in preventing the recurrence of kidney tumor, either in the original tumor site or at other sites in the body. To help us determine which treatment regimen should be used in future patients, we need to know if there are side effects of the treatment. Some important side effects may include those of the fertility of our participants and the health of their children. To identify these effects, we would like to obtain detailed records regarding any pregnancy that you have, and detailed records concerning the birth and health of all of your children.

**We request that the attached questionnaire be completed for the biological children of our participants. It would be most helpful if it is completed by the child's biological mother. We would be most appreciative if you would take the time to complete the attached Pregnancy Questionnaire and authorization forms, and mail them to us at the address on the top of this memo.**

With your permission we will use the release to obtain the medical records for the pregnancy and birth of your child/children.

If you have had more than one pregnancy/child, please complete a SEPARATE QUESTIONNAIRE for each pregnancy/child. This applies to all pregnancies and children including abortions, miscarriages, and multiple as well as single births, all of which are very important to the study. (For example, if you have had liveborn twins in addition to one miscarriage, you would fill out one form for the miscarriage and one form each for each twin.) Please also be sure to include these children on the enclosed release form. We may contact you again should we need additional information about a specific pregnancy.

Previous studies of this type have shown that the vast majority of patients treated for Wilms tumor are capable of having normal pregnancies and children. Our current efforts are intended to update earlier studies in order to inform Wilms Tumor survivors about their ability to have children as well as to alert them and their physicians to problems that they might possibly develop. Your participation in this aspect of the study will be invaluable.

With many thanks for your continued participation in this important study.

Yours sincerely,

Wendy Leisenring, Sc.D.
NWTS Statistician

# NATIONAL WILMS TUMOR STUDY - PREGNANCY QUESTIONNAIRE

**(TO BE FILLED OUT BY MOTHER OF CHILD, WHENEVER POSSIBLE)**

Name of NWTS participant: _____ NWTS # (if known): _____

1. You are: (Circle one)
   a. The NWTS participant
   b. The spouse/partner of NWTS participant (Please give your name): _____
2. Date pregnancy ended: ___/___/___
3. Duration of pregnancy (weeks):_____
4. Pregnancy outcome, please circle one of the following:
   a. Single live birth *
   b. Stillbirth
   c. Miscarriage
   d. Ectopic pregnancy
   e. Elective termination of pregnancy
   f. Multiple live birth * (**please circle birth order for the child described on this form: 1 2 3** and include a separate questionnaire for each child)
   g. Therapeutic abortion
   h. Other, please specify:_____

   * May we have your permission to request periodic follow-up on the health status of this child? (Circle one): YES NO
5. Hospital name where delivery or other care was performed: _____

   Hospital address: _____ City/State/Zip: _____
6. Name of obstetrician/midwife: _____

   Address: _____ City/State/Zip: _____
7. Weight of infant at delivery (lb./oz): _____ lbs. _____ ozs. Child's sex: _____
8. Child's full name as recorded on birth certificate:_____
9. Last 4 digits of Child's Social Security Number (Optional): _____
10. Child's mother's date of birth: _____ Child's father's date of birth: _____
11. Please note any birth defects, diseases or handicaps in your child and the date of diagnosis.

| Condition | Date of Diagnosis | Hospital (include city/state) |
|---|---|---|
| _____ | ____/____/____ | _____ |
| _____ | ____/____/____ | _____ |

12. Is this child now living? (Circle one): YES NO

    If not: Date of death: ____/____/____ Cause of death: _____ City/State: _____
13. Please list any complications or diseases you had during this pregnancy:

    _____
14. Did you and your spouse/partner have difficulty becoming pregnant? (Circle one): YES NO

Comments: _____

**********

15. We may contact you if we have more questions. Please provide your telephone numbers and email:

    _____
16. What is your preferred method of contact? _____

Thank you for your cooperation in completing this form.

Signed: _____ Date: _____

# NWTS

## AUTHORIZATION FOR RELEASE OF MEDICAL INFORMATION

A. For research purposes, I hereby authorize the release of all of my prenatal through postpartum records and all of my hospital records for each pregnancy to NWTS investigator, Dr. Daniel Green.

B. I also hereby authorize the release of all of my child(ren)'s hospital and physician birth records listed below to Dr. Daniel Green.

| Child's Name | Child's Birth Date | Last 4 digits of Child's Social Security # (Optional) |
|---|---|---|
| _____ | ____ /____ /____ | _____ |
| _____ | ____ /____ /____ | _____ |
| _____ | ____ /____ /____ | _____ |
| _____ | ____ /____ /____ | _____ |
| _____ | ____ /____ /____ | _____ |
| _____ | ____ /____ /____ | _____ |

I understand that all information obtained will be held strictly confidential and will be used for statistical purposes only.

This authorization(s) will be effective for two years from the date of signature and may be canceled by me in writing at any time. A photocopy of this authorization will be treated in the same manner as the original.

| _____ | _____ | ____/____/____ |
|---|---|---|
| Signature | Relationship | Date |

| ____ /____ /____ | _____ | _____ |
|---|---|---|
| Birth Date | Last 4 digits of Social Security # (Optional) | Other names records may be listed under |

This form should be returned to:

NWTS DSC
FHCRC
1100 Fairview Avenue N, M2-A876
P.O. Box 19024
Seattle, Washington 98109

## National Wilms Tumor Study

## AUTHORIZATION TO USE, CREATE AND SHARE HEALTH INFORMATION FOR RESEARCH

**IR number: 4812** **Protocol number: COG 4941L/9442**

**Title of Research Study: National Wilms Tumor Study Late Effects Study**

By law, we must protect the privacy of health information about you. We may use, create, or share your health information for research **only if you let us**. This form describes what we would do. Please read it carefully. If you agree with it, please sign your name at the bottom.

If you sign this form, information would be shared with the National Wilms Tumor Study and others who work with them. In this form, all these people together are called 'Researchers.' Their names will appear on any Research Consent form that you sign.

The Researchers will use the health information only for the purposes named in this form.

### 1. What 'health information' includes

- All information about you from research studies carried out by the Researchers. These are studies you agreed to join by signing a Research Consent Form. They may also be studies you will agree to join later, by signing a Research Consent Form.
- All health information in your medical records.

### 2. What the Researchers may do with health information

The Researchers may use and create your health information for the Study. They may also share your health information with certain people and groups. These may include:

- The sponsor of the Study: the National Cancer Institute (NCI). The sponsor reviews the Study. By law, Researchers share some information with the sponsor.
- Children's Oncology Group.
- Government agencies, review boards, the NWTS Institutional Review Board and others who watch over the safety, effectiveness and conduct of the research.
- Others, if the law requires.

### 3. Removing your name from health information

The Researchers may remove your name (and other information that could identify you) from your health information. No one would know the information was yours.

If your name is removed, the information may be used, created, and shared by the Researchers and Sponsor as the law allows. (This includes other research purposes.) This form would no longer limit the way the Researchers use, create, and share the information.

**4. How the Researchers and NCI protect health information**

The Researchers and NCI will follow the limits in this form. If they publish the research, they will not identify you unless you allow it in writing. These limitations continue even if you take back this permission.

**5. After the Researchers learn health information**

The limits in this form come from a federal law called the Health Insurance Portability and Accountability Act. This law applies to your doctors and other health care providers, not to the Researchers.

Once the Researchers get your health information, this law may no longer apply. But other privacy protections will still apply.

**6. Storing your health information**

Your health information is part of a database or data repository. This permission will end when the database or data repository is destroyed. Unless you take back your permission, this form does not have an ending date.

**7. Please note**

You do not have to sign this permission ('authorization') form. If you do not, you may not be allowed to join the Study.

You may change your mind and take back your permission anytime. To take back your permission, write to:

**Wendy Leisenring, Sc.D.**
**NWTS Data and Statistical Center**
**Fred Hutchinson Cancer Research Center**
**1100 Fairview Avenue N., M2-A876, PO Box 19024**
**Seattle, WA 98109**

If you do this, you may no longer be allowed to be in the Study. If we have health information by then, it may stay in the Study record.

During the study, you will not be allowed to see your health information that the Researchers create or collect. After the Study is finished, you may see this information.

**Signature**

I, _____, agree to let my doctors and other health care providers use, create, and share health information that identifies me with the Researchers.

| | |
|---|---|
| _____ | _____ |
| Signature of participant or participant's Legal Representative | Date |
| _____ | _____ |
| Printed name of participant or participant's Legal Representative | Representative's relationship to participant |

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**Signature**

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| _____ | _____ |
|---|---|
| Signature of participant or participant's Legal Representative | Date |
| _____ | _____ |
| Printed name of participant or participant's Legal Representative | Representative's relationship to participant |