

# 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 Parent of Participant,

Thank you for taking the time to sign the release authorization and HIPAA form allowing us to obtain copies of medical records to document the diagnosis you have reported to us. This diagnosis may be related to your child's treatment for Wilms tumor, and the documentation will enable us to update earlier studies in order to possibly improve or reduce treatment in newly diagnosed Wilms tumor patients as well as to alert study participants to problems that might possibly develop as a result of their treatment.

For each type of condition reported to us, we request copies of specific records. For the condition you have reported please find below a list of the records we will request.

## CARDIAC

Hospital discharge summary  
Report of EKG  
Report of MUGA scan  
Path report on biopsies  
Report of chest x-ray

## RELAPSE

Operative and pathology reports  
Treatment summaries

## KIDNEY

Hospital discharge summary  
BUN, creatinine, urinalysis reports  
Biopsy pathology reports  
Report of late nephrectomy  
Report of renal dialysis  
Report of renal transplantation

## PULMONARY

Hospital discharge summary  
Record of outpatient visit  
Pulmonary function test reports  
Chest X-ray/CT scan reports  
Pulmonary consultants reports

Again, thank you for your cooperation with our request. We appreciate it very much.

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## AUTHORIZATION FOR RELEASE OF MEDICAL INFORMATION

For research purposes, I hereby authorize the release of medical records for documentation of a diagnosis of \_\_\_\_\_ which occurred on or about \_\_\_\_/\_\_\_\_/\_\_\_\_ (mm/dd/yy).

Attached is a table detailing which records I authorize you to send to the National Wilms Tumor Study.

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

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

Hospital or clinic where diagnosis was made: \_\_\_\_\_

Hospital or clinic address: \_\_\_\_\_ City/State/ZIP: \_\_\_\_\_

Name of physician: \_\_\_\_\_

Address: \_\_\_\_\_ City/State/ZIP: \_\_\_\_\_

My Name: \_\_\_\_\_

\_\_\_\_\_  
Birth Date

\_\_\_\_\_  
Last 4 digits of Social Security # (Optional)

\_\_\_\_\_  
Other names records may be listed under

\_\_\_\_\_  
Authorizing Signature

\_\_\_\_\_  
Relationship to participant (parent, guardian, etc.)

\_\_\_\_\_  
Date

## 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 your child. We may use, create, or share your child's 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 your child 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 child's medical records.

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

The Researchers may use and create your child's health information for the Study. They may also share your child's 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 child's name from health information**

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

If your child's 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 your child 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 child's doctors and other health care providers, not to the Researchers.

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

**6. Storing your child's health information**

Your child's 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, your child 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, your child 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 child's health information that the Researchers create or collect. After the Study is finished, you may see this information.

**Signature**

I, \_\_\_\_\_, agree to let my child's doctors and other health care providers use, create, and share health information that identifies my child 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