INFORMED CONSENT STATEMENT

PROTOCOL FOR COLLECTING DATA ON PATIENTS WITH CHILDHOOD CANCER

NOTE: *When we say "you" throughout this document, we mean "you or your child."*

You are invited to take part in a research study of the effects of treatment for childhood cancer. You were selected to take part in this study because you were treated, are being treated or followed after treatment for childhood cancer at St. Jude Children's Research Hospital.

This consent gives you information about the study, which will be discussed with you. Once you understand the study, and if you agree to take part, you will be asked to sign this consent form. You will be given a copy to keep.

Before you learn about the study, it is important that you know the following:

- Whether or not you take part in this study is entirely up to you.
- If you decide not to be in the study, or withdraw from the study at any time, you will not lose the benefits of routine medical care.
- This study is being sponsored by St. Jude Children's Research Hospital.
- The principal investigator (researcher) of this study is Dr. Melissa Hudson, who can be reached at 901/595-3300.

Why is this study being done?

The purpose of this study is to collect information about the effects of childhood cancer and its treatment on the patients who are treated or followed after treatment for childhood cancer at St. Jude.

How many patients will take part in this study?

All St. Jude patients will be invited to take part in the study. Currently, this includes about 7274 patients. That number will continue to grow as more childhood cancer patients are referred to St. Jude for treatment and followed by St. Jude.

What is involved in the study?

We are asking permission to collect medical information about your treatment and disease. This information will be updated every year as part of the treatment follow-up.

We will be collecting medical information on four groups of St. Jude patients. You will fall into one of these groups.

Group 1 are patients followed by an Active treatment clinic as described below:
These patients are receiving treatment for cancer or are being followed after completing treatment for cancer in the Leukemia/Lymphoma, Solid Tumor, Brain Tumor or Bone Marrow Transplant Clinics. Medical information is collected by the doctor and clinic staff responsible for treating or following patients in these clinics.

Group 2 are patients followed by the After Completion of Therapy (ACT) clinic as described below:
These patients are 5 or more years from cancer diagnosis. They will be invited to return to the St. Jude After Completion of Therapy Clinic (ACT clinic) once a year for a general check-up. During this visit, the St. Jude doctors get a detailed medical history, perform a thorough physical exam, and do blood tests and x-rays to screen for late effects related to cancer treatment. Patients in the ACT clinic are also asked to complete a survey about over-all health and give information about changes in their health that took place over the year. This questionnaire also asks about health behaviors (such as smoking, drinking, and physical activity) thought to have an effect on a person's over-all health, school and/or work progress, problems getting insurance, and quality of life. Patients are discharged from pediatric follow-up in the ACT Clinic when they are at least 18 years of age and 10 years from diagnosis.

Group 3 are patients followed by the Cancer Registry as described below:
These patients have completed cancer therapy and are no longer coming back to St. Jude for check-ups. Patients in Group 3 are followed by the St. Jude Cancer Registry. The Registry mails a short set of questions every year that ask about changes in health, late effects from the cancer and its treatment, and health behaviors. The St. Jude Cancer Registry follows these patients every year for life.

Group 4 are patients enrolled in the St Jude Life study as described below:
These patients are adult childhood cancer survivors who were treated at St. Jude Children's Research Hospital. The patients in Group 4 were either formally in Group 3 or enrolled in the St. Jude Life protocol at the time of discharge from the After Completion of Therapy Clinic. They are returning to St Jude for a one-time comprehensive health evaluation in the After Completion of Therapy Clinic. The purpose is to study health outcomes in aging adults surviving pediatric cancer.

All information collected about the outcome and effects of cancer treatment may be used for research purposes in talks and articles about childhood cancer survivors. This information will not include specific details that will make it possible to identify you personally.

What are the risks of the study?

One possible risk is the release of information from your health records. St. Jude will protect your records so that your information will be kept private. The chance that this information will be given to someone else is very small.

The yearly evaluations will be done to monitor for late effects caused by treatment for childhood cancer. If any of the medical questions or evaluations make you uncomfortable, you may choose not to answer the question(s) or have the test(s) done.

What are the benefits of the study?

Taking part in this study may help doctors identify what types of problems patients can develop after childhood cancer treatment, and learn better how to take care of these problems, or prevent them from happening. You will not be paid to take part in this study.

What are the options to taking part in the study?

You may choose not to take part in the study.

What about confidentiality?

Your medical records will be kept confidential to the degree allowed by law. Information from your medical records will not be given to anyone outside the hospital unless you agree. You will not be identified in any publication about this study.

Government agencies oversee research studies involving people. Your medical records may be reviewed by such agencies if you take part in this research study. These agencies include the Food and Drug Administration (FDA) and the National Cancer Institute (NCI). By signing this consent form, you are allowing your medical records to be reviewed by these persons.

It may be necessary to check parts of your medical record to be sure that the study data are correct and complete. Such a check might be done by the following groups:

1. A federal agency such as the Food and Drug Administration (FDA) or the National Cancer Institute (NCI).
2. The St. Jude Institutional Review Board (IRB), a committee which reviews the ethics of studies

No information other than what is needed for the study is recorded. Every effort is made to protect your privacy.

SUMMARY OF RESEARCH AND PRIVACY RIGHTS

IRB Approved Version: April 23, 2013

The following statement describes your rights as a research participant in this study:

1) You may refuse to be in this research study or stop at any time. This decision will not affect your care or your relationship with your doctor or St. Jude. If available, you may receive routine medical care at St. Jude Children's Research Hospital.

2) You will not be charged for being in this research study. If you have insurance, TennCare or Medicaid, they will be billed for many of the services we provide. However, we do not bill patients or their families for the cost of medical care not covered by their health plan, this includes research costs.

3) Your samples and information may be used to develop a new product or medical test, which may be sold. If this happens, you will not receive any payments for these new products.

4) A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most the Website will include a summary of the results. You can search this Website at any time. A decision to take part in this research means that you agree to let the research team use and share your health information also called protected health information (PHI) for the study explained above. This information will be kept indefinitely. You have the right to see, copy, and ask for changes to your protected health information that will be used or given out. However, research information may not be seen until the end of the study.

5) When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI may be used or given to someone outside the hospital. You have the right to read the Notice of Privacy Practices before you sign this form. You can find it at the bottom of every page on the St. Jude Internet website: *www.stjude.org*.

6) Federal agencies such as the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP) or the National Institutes of Health (NIH), St. Jude Children's Research Hospital Institutional Review Board (IRB), your insurance company (if charges are billed to insurance), as well as other regulatory agencies, committees, or persons involved in overseeing research studies may review your research and medical record. Information about you that may be given out includes your complete medical records, including details about diagnosis, illness, treatment, and information that may be recorded about past diagnosis or treatment and information taken as a part of this research study as explained in this informed consent.
7) After your records are given to or used by others, St. Jude Children's Research Hospital cannot promise that information will not be given out again. Also, the information given out may no longer be protected by federal privacy laws.

8) St. Jude uses reasonable safeguards and means to protect your private information. However,

St. Jude cannot guarantee the security and confidentiality of e-mail, text messages, fax communications or mail.

9) Your permission to use and give out your child's protected health information will end when your child turns 18 years of age. At that time, we may contact your child for his or her permission to continue using it.

10) You may take back permission for your records to be used or given out at any time, for any reason, except when that information has already been given out or used for the study based on your permission. To take back your permission, please fill out a form called a Revocation of Release of Authorization. You may ask for this form by calling the St. Jude Privacy Officer at 901-595-6141. You must mail the form or hand it to:

    HIPAA Privacy Officer
    St. Jude Children's Research Hospital
    262 Danny Thomas Place
    Memphis, TN 38105

11) You can get more details about your rights as a research participant by calling the St. Jude Institutional Review Board at 901-595-4357 or the Research Participant Advocate at 901-595-4644. If you are outside of the Memphis area, please call toll-free 1-866-583-3472 (1-866-JUDE IRB).

12) The St. Jude Research Participant Advocate is an individual who is not part of the research study team and is available to you to discuss problems, concerns, and questions. The Advocate can help you obtain information and can relay any input you may have concerning the research to the research study team. You can reach the Advocate by calling 901-595-4644, or if you are outside of the Memphis area, call toll free at 1-866-583-3472 (1-866-JUDE-IRB).

13) You will be given a copy of this signed consent form.

RESEARCH PARTICIPANT STATEMENT (14–17 years old and Adult Participants 18 years and older):

I have read this document or it was read to me. I have been encouraged to ask questions and all my questions were answered. I agree to take part in this research study.

_____	_____	_____ AM/PM
Research Participant Signature	Date	Time (circle one)

PARENT/GUARDIAN STATEMENT (Required for participants younger than 18 years):

I have read this document or it was read to me. I have been encouraged to ask questions and all my questions have been answered. I give permission for my child to be in this research study.

_____	_____	_____ AM/PM
Parent/Legal Guardian Signature	Date	Time (circle one)

ASSENT DISCUSSION (Required for participants 7–13 years old)

☐ The research was explained to the minor participant in age-appropriate terms and the minor verbally agreed to take part in the study.

☐ An assent discussion was not initiated with the minor for the following reason(s):
- ☐ Minor is under 7 years of age.
- ☐ Minor is incapacitated.
- ☐ Minor refused to take part in the discussion.
- ☐ Minor declined to take part in the study. The minor declined for the following reason(s):

  _____

- ☐ Other_____

RESEARCHER/DESIGNEE STATEMENT: I hereby certify that I have discussed the research project with the research participant and his/her parent(s) or legal guardian(s). I have explained all the information contained in the informed consent document, including any risks that may be reasonably expected to occur. I further certify that the research participant was encouraged to ask questions and that all questions were answered.

_____	_____	_____ AM/PM
Researcher/Designee	Date	Time (circle one)

RESEARCH PARTICIPANT ADVOCATE STATEMENT (If interpreter is required)

I observed the informed consent process. The research study, intervention/observation, risks, benefits, and alternatives were presented to the research participant and/or legal guardian(s). They were encouraged to ask questions, and research team members answered all their questions. The participant/parent(s) indicated that they: 1) understood the information presented; and 2) voluntarily consented /agreed to take part in the research.

_____	_____	_____ AM/PM
Interpreter (if needed)	Date	Time (circle one)

PLEASE FAX CONSENT FORM TO THE PROTOCOL OFFICE #6265