LTFU

Long-Term Follow-Up Study
Home Survey

St. Jude Children's Research Hospital
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Children's Hospital at Stanford
Children's Hospital Colorado
Children's Hospital of Orange County
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Children's Medical Center of Dallas
Children's National Medical Center
City of Hope National Medical Center
Cook Children's Hematology-Oncology Center
Dana-Farber Cancer Institute/ Children's Hospital Boston
Mattel Children's Hospital at UCLA
Mayo Clinic
Memorial Sloan-Kettering Cancer Center
Miller Children's Hospital
Nationwide Children's Hospital
Riley Hospital for Children - Indiana University
Roswell Park Cancer Institute
Seattle Children's Hospital
St. Louis Children's Hospital
Texas Children's Hospital
Toronto Hospital for Sick Children
UAB/The Children's Hospital of Alabama
University of California at San Francisco
University of Chicago Comer Children's Hospital
University of Michigan - Mott Children's Hospital
University of Minnesota
U.T.M.D. Anderson Cancer Center

Our mailing address is:
Long-Term Follow-Up Study
St. Jude Children's Research Hospital
Department of Epidemiology
Mail Stop 735
262 Danny Thomas Place
Memphis, TN 38105-3678

St. Jude toll-free phone number:
1-800-775-2167

St. Jude e-mail: LTFU@stjude.org

ltfu.stjude.org

St. Jude Children's Research Hospital
ALSAC • Danny Thomas, Founder
Finding cures. Saving children.

Thank you for your continued participation in the Long-Term Follow-Up study. Your participation helps to provide us with valuable information in the fight against serious illnesses of childhood and adolescence.

You can be assured that we will respect your privacy at all times. Your name or other identifiers will not be used in any report of our findings, or released to any person or agency, except study investigators.

Your generosity in participating is greatly appreciated.

Sincerely,

The LTFU study staff

Person completing this questionnaire is (please print):

Your relationship to study participant:

☐ Self ☐ Parent ☐ Other: _____

Today's date: ☐☐ / ☐☐ / ☐☐☐☐
m m d d y y y y

Study ID: ☐☐☐☐☐☐☐☐

Please! Do not mark below this line

Survey #161

0072631335

LTFU Consent Form

This form is an informed consent statement that requires your signature if you wish to participate in the study. Please review the following four pages and sign and date at the yellow arrows.

! Watch for this symbol - it indicates that you need to do something at this point in the consent.

INFORMED CONSENT STATEMENT

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

LONG-TERM FOLLOW-UP STUDY

As a participant in the Long-Term Follow-Up (LTFU) Study, a research study being conducted by St. Jude Children's Research Hospital, you are invited to participate in a research project to help us obtain direct measures of important health outcomes. This research project will collect a blood sample, some physical measurements, and a brief questionnaire. This information will be an important addition to the "self-reported" survey data that the LTFU study has collected.

This consent form gives you information about the study. If you agree to take part in this study, please sign this consent document and return it in the postage paid envelope you received. The second consent document is a copy for you 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 to withdraw from the study at any time, it will not affect your relationship with St. Jude or the institution where you received treatment for your childhood illness.
- This study is being sponsored by the National Cancer Institute, which will provide financial support for a portion of the costs of the study.
- The principal investigator (researcher) of this study is Dr. Leslie Robison, who can be reached at 800-775-2167.
- Your study information will be shared with researchers at St. Jude Children's Research Hospital, the LTFU Biopathology Center (Columbus, OH), LTFU Laboratory (Cincinnati, OH), LTFU Statistical Center (Seattle, WA), LTFU Radiation Physics Center (Houston, TX) and LTFU collaborating researchers.

Why is this study being done?

The LTFU study has previously collected survey-based information from all participants. We would like to add to this self-reported information with direct measures of important health indicators such as blood sugar and cholesterol levels, blood pressure, and liver and kidney function.

How many patients will take part in the study?

About 200 people from around the United States, who were treated as children for cancer or a similar illness, will take part in this initial study to determine if survivors are willing to participate.

What is involved in this study?

We would like to collect a blood sample, a brief questionnaire about your health, and some physical measurements specifically: height, weight, blood pressure, and your waist size. A trained laboratory technician will call you and arrange to come to your home, office, or other convenient location to take the blood specimen and measurements.

The blood specimens collected will be analyzed to look at sugar level, kidney and liver function, and cholesterol levels.

Study procedures:

If you agree to participate, four things will be asked of you:

1) Fast (no food or drink) for 8 hours before your blood sample is collected.

2) Allow a sample of blood to be taken from you. This would be done by a trained technician who will come to your home, office, or other site you select to draw the blood. You will not have to go to a doctor's office or hospital. The sample will be sent to St. Jude Children's Research Hospital in Memphis, TN.

3) Allow the trained technician to collect physical measurements: height, weight, blood pressure, and your waist size.

4) Complete a brief questionnaire about your health.

Duration of study:

Your participation will involve a one-time visit that will last about 30 minutes. Your blood sample will be analyzed and then the results will be sent to you within 4-8 weeks of your appointment. Your results will also be used for research purposes as part of the LTFU study. Your name or other identifiers will not be linked to your results when used for research.

Compensation:

There is no cost to participate in this study. If you choose to provide a blood specimen, measurements, and questionnaire, you will receive a $50 gift card. You will also receive the results of your lab work within 4-8 weeks of your appointment.

What are the consequences of withdrawing from this study?

Participating in this study is voluntary. You can stop taking part in this study at any time. Whether or not you take part in the study will not affect your relationship with St. Jude. No matter what you decide to do, it will not affect the care that you will be given or your relationship with the Long-Term Follow-up Study being conducted by St. Jude Children's Research Hospital.

If you decide not to participate in this project, you may still participate in the Long-Term Follow-Up Study.

What are the risks of the study?

Very rarely, personal information from your records could be given out by accident. Only very few, authorized people, who have specifically agreed to protect your identity, will have access to this information. To prevent this from happening, electronic data is stored on password protected computers. Only study team members work with the data, and study results are reported on the whole group, never identifying one individual in reports.

Having a needle put into a vein for blood drawing may cause a feeling of faintness, pain, bruising, or a minimal chance of infection.

There also may be other privacy risks that we have not foreseen.

What are the benefits of the study?

The research that may be done with your blood may benefit you by providing laboratory results for tests routinely used by your doctor for health screening. It is also our hope that research using your information will help researchers learn more about the health status of childhood cancer survivors. This research might help people in the future who have cancer or other diseases.

What other options are there?

Your participation in this study is voluntary. You may choose not to take part in this study.

What about new information?

You will receive a Long-Term Follow-Up Study Newsletter every six months that contains a study update and other health information that may be helpful to yourself and others treated for cancer or similar illness. You have the right to learn about the results of the study. If you are interested in learning more about when and how to get the results of this research study, you may contact the study Principal Investigator, Dr. Leslie Robison or Dr. Greg Armstrong, Project Director, at St. Jude Children's Research Hospital at 1-800-775-2167.

What about privacy?
All identifiable information that is obtained in connection with your sample and health-related information will remain confidential.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the federal government. With this Certificate, the researchers cannot be forced to give out your personal information, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other process. The researchers will use the Certificate to block any demands for information that would identify you, except in the cases listed below.

The Certificate cannot be used to resist a demand for information from the United States Government, if that information is used to audit or check federally funded projects or to meet the needs of the U.S. Food and Drug Administration (FDA).

You should know that a Certificate of Confidentiality does not keep you or a member of your family from choosing to give out information about you or your part in this research. If an insurer, employer, or other person gets your written consent to receive research information, then the researchers cannot use the Certificate to keep that information private.

The Certificate of Confidentiality will not keep researchers or hospital staff from making reports required of them. These include reports about suspected child abuse, about disease that spread from person to person, or about possible threat of harm to yourself or others.

Your medical records will be kept confidential to the degree allowed by law. Steps taken to prevent breach of confidentiality include: storing records separately from names or other personal information in a locked file cabinet, limiting access to members of the study team, storing electronic data only on password-protected computers and reporting study results on the whole group and never identifying individuals in any reports.
Government agencies oversee research studies involving people. Your research record and medical record information may be reviewed by other agencies as required by state or federal laws.

These agencies include:

- Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Office for Human Research Protection (OHRP)
- St. Jude Children's Research Hospital Institutional Review Board, a committee that reviews the ethics and safety of research studies

By signing this consent form, you are allowing your medical records to be reviewed by these persons.

Where can I get more information?

If you have questions about the study, you may contact the St. Jude Principal Investigator for this study, Dr. Leslie Robison toll-free at 1-800-775-2167. If you have questions or concerns regarding the study or your rights as a research subject and would like to talk to someone other than the researcher(s), contact the Chairman of the Institutional Review Board at 1-901-595-4357 or the Research Participant Advocate (Ombudsman) at 901-595-4644. If you are outside of the Memphis area, you may call 1-866-583-3472 (866-JUDE IRB). This is a toll-free call.

IRB Approved Version: July 19, 2011
The following statement describes your rights as a research participant:

1) You may talk as much as you want with the researchers about the reasons for this study and about its risks.

2) This study may have risks that the researchers or other doctors do not know about now.

3) We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.

4) You will not be charged for being in this research study.

5) If you decide not to be in this study, or to withdraw from the study at any time, it will not affect your relationship with St. Jude or the institution where you received treatment. You can leave this study at any time.

6) The St. Jude Notice of Privacy tells how your medical information 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.

7) You have the right to see, copy, and ask for changes to your protected health information that will be used or given out. This consent form describes any limits to this right, such as research information that you will not see until the end of the study or that will only be used for research.

8) 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.

9) 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), as well as other regulatory agencies, committees, or persons involved in overseeing research studies, may review your research and medical record.

10) Information about you that may be given out includes the following:
- Complete medical records, including details about diagnosis, illness, treatment, and information that may be recorded about past diagnosis or treatment.
- Information taken as a part of this research study as explained in this informed consent.

11) 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.

12) St. Jude uses reasonable safeguards and means to protect the security and confidentiality of e-mail/text messaging, fax information or mail sent to and received from you. However, St. Jude cannot guarantee the security and confidentiality of e-mail or text messaging or fax communications or mail. Despite the best efforts of St. Jude to protect private information, e-mails/text messaging or fax can be electronically taken by other users, changed, forwarded, or used without permission or detection. Possible risks include e-mail/text messaging, fax or mail senders can type the wrong address for an email or mail or dial a wrong phone number. Backup copies of an e-mail/ text messaging or fax may exist after the sender or receiver has deleted a copy.

13) If applicable, 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, researchers may get your child's consent if they wish to keep using or giving out your child's protected health information.

14) You may take back permission for your records to be used or given out at any time, for any reason, except the following:
- When that information has already been given out or used based on your permission
- When the information is needed to maintain the integrity of the study

15) 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 the:

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

16) If you have more questions about this study you can call the Principal Investigator of this study, Dr. Leslie Robison, at 901-595-3300.

17) You can get more details about your rights as a research participant by calling the chairman of the 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).

The staff will give you a copy of this statement.

RESEARCH PARTICIPANT STATEMENT

I have read (or have had read to me) the contents of this document and have been encouraged to ask questions. I have received answers to my questions. I give consent to take part in this research study and authorize the disclosure and use of my/my child's protected health information for the purposes of that research. I voluntarily and freely donate my cell sample to the Long-Term Follow-up Study and relinquish all my property rights and interests in the sample.

Sign Here

_____ Research Participant

_____ Date

Fill in Date

Please! Do not mark below this line

INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRE

Please follow these rules in completing this questionnaire. If you have any questions about completing this questionnaire, please call 1-800-775-2167.

1. Use a black ballpoint pen or a number 2 black pencil. Do not use a felt-tip or roller-ball pen. These may cause smudging. If you must erase answers, erase them completely.
2. When marking boxes, make an x inside the box (see examples below).
3. Make no stray marks of any kind. Please keep the form as clean as possible.
4. Written responses must stay within the boxes provided:

CORRECT

Grape

INCORRECT

MARKING EXAMPLES

Below are some examples of how to fill out this questionnaire. Please look these over before you begin.

Example 1

1. During the past month, did you participate in any physical activities or exercises such as running, calisthenics, golf, gardening, bicycling, swimming, wheelchair basketball, or walking for exercise?

☐ No ☒ Yes

Example 2

2. Have you ever taken. . .

	No	Yes	Not sure	If yes, age at first use (years)
a. BIRTH CONTROL PILLS such as Demulen, Lo-Ovral, Loestrin, Norinyl, Norplant, Ortho-Novum, Ovral, Triphasil----------	☒	☐	☐	
If yes, specify the name of the drug(s) or indicate you do not know the specific name				
b. MEDICATIONS TO LOWER CHOLESTEROL OR TRIGLYCERIDES, such as Zocor, Pravachol, Lipitor, Colestid (colestipol), Tricor, Lescol, Lopid (gemfibrozil), Mevacor, niacin, or Lorelco----------	☐	☒	☐	34
If yes, specify the name of the drug(s) or indicate you do not know the specific name				

mevacor

Example 3

3. When was this condition diagnosed?

Month (mm)	Year (yyyy)
04	1995

Please! Do not mark below this line

In the past we have asked you questions similar to those below. We would like to update this information.

A1. What is your current height without shoes?

☐☐ Feet ☐☐ Inches

A2. What is your current weight without shoes?

☐☐☐ Pounds

MEDICAL CARE

The next questions are about health care received during the 2 year period between September 2010 and September 2012.

B1. During this two year period, which of the following health care providers (excluding dentists) did you see or talk to for medical care? This includes routine and sick care. ***(Mark all that apply)***

- ☐ None → *Go to Question C1.*
- ☐ Physician (including Osteopath)
- ☐ Nurse Practitioner/Physician's Assistant
- ☐ Nurse
- ☐ Chiropractor
- ☐ Physical therapist
- ☐ Other

If Other, please describe.

B2. Where did you receive your health care? ***(Mark all that apply)***

- ☐ Doctor's office
- ☐ Oncology (cancer) center or clinic
- ☐ Other type of clinic
- ☐ Hospital
- ☐ Emergency room or urgent care center
- ☐ Long-term follow-up clinic
- ☐ Other

If Other, please describe.

B3. When was your MOST RECENT routine check-up where a doctor examined you and did tests to see if you had any health problems from your cancer or your cancer treatment?

- ☐ Less than 1 year ago
- ☐ 1-2 years ago
- ☐ More than 2 years but less than 5 years ago
- ☐ 5 or more years ago
- ☐ Never

Continue on next page.

C1. Please indicate all medicines/drugs you took regularly during the two-year period between September 2010 and September 2012.

- We are only asking about medicines/drugs which you took consistently for more than one month, or for 30 days or more in a year.

- Please list only drugs prescribed by a doctor and filled by a pharmacist. Include pills, syrups, injections, patches, or creams.

- Please do NOT include medicines/drugs that you bought without a prescription (over-the-counter drugs).

	No	Yes	Not sure	If yes, age at first use	If yes, are you currently taking? No	If yes, are you currently taking? Yes
1. PILLS OR INSULIN FOR DIABETES such as Glucophage (metformin), Glucotrol (glipizide), Glynase (glyburide), Prandin, Amaryl, Avandia, Actos, or insulin injections (such as Humulin, Novolin, Lantus)----------	☐	☐	☐	☐☐ years	☐	☐
If yes, specify the name of the drug(s) or indicate you do not know the specific name						
2. MEDICATIONS FOR HIGH BLOOD PRESSURE OR HYPERTENSION such as hydrochlorothiazide (HCTZ), Dyazide (triamterene/HCTZ), Tenormin (atenolol), Lopressor (metoprolol), Zestril or Prinivil (lisinopril), Vasotec (enalapril), Cozaar, Hyzaar, Diovan, or others----------	☐	☐	☐	☐☐	☐	☐
If yes, specify the name of the drug(s) or indicate you do not know the specific name						
3. MEDICATIONS TO LOWER CHOLESTEROL OR TRIGLYCERIDES such as Lovastatin, Zocor (simvastatin), Pravachol (pravastatin), Crestor, Lipitor, Zetia, Tricor, Vytorin, gemfibrozil----------	☐	☐	☐	☐☐	☐	☐
If yes, specify the name of the drug(s) or indicate you do not know the specific name						
4. MEDICATIONS FOR HEART CONDITIONS, INCLUDING ANGINA, CORONARY ARTERY DISEASE, CONGESTIVE HEART FAILURE, OR IRREGULAR HEART BEAT----------	☐	☐	☐	☐☐	☐	☐
If yes, specify the name of the drug(s) or indicate you do not know the specific name						
5. OTHER PRESCRIBED DRUGS----------	☐	☐	☐	☐☐	☐	☐
If yes, specify the name of the drug(s) or indicate you do not know the specific name ***and*** specify the reason the drug was prescribed.						

Please! Do not mark below this line

Medical Conditions

The next series of questions relate to medical conditions that you have ever had. You may have previously told us about some of these conditions. We are asking again to make sure our records are current and to capture occurrences of new medical conditions.

Please indicate, by marking the box (either "No", "Yes", or "Not sure") if a doctor or other health care professional has told you that you have or have had any of the following conditions. If you answer "yes", please give your age when the condition first occurred. (If more than one occurrence, please give age at first occurrence.)

Because we need definite responses, it is very important to mark an answer for each question, even if you have never had that condition. Please do not leave any questions blank (unmarked).

URINARY SYSTEM

Have you ever been told by a doctor or other health care professional that you have, or have had. . .

	No	Yes, but the condition is no longer present	Yes, and the condition is still present	Not sure	If yes, age at first occurrence (years)
D1. Kidney stones?	☐	☐	☐	☐	
D2. REPEATED (more than 3 in any 12 month period) kidney or bladder infections?	☐	☐	☐	☐	
D3. Dialysis?	☐	☐	☐	☐	
D4. Any other kind of kidney, bladder or urinary tract disorder?	☐	☐	☐	☐	

If yes, describe this problem.

HORMONAL SYSTEMS

	No	Yes, but the condition is no longer present	Yes, and the condition is still present	Not sure	If yes, age at first occurrence (years)
E1. Diabetes that can be controlled with diet?	☐	☐	☐	☐	
E2. Diabetes controlled with pills or tablets?	☐	☐	☐	☐	
E3. Diabetes controlled with insulin shots?	☐	☐	☐	☐	

DIGESTIVE SYSTEM

Have you ever been told by a doctor or other health care professional that you have, or have had. . .

	No	Yes, but the condition is no longer present	Yes, and the condition is still present	Not sure	If yes, age at first occurrence (years)
F1. Hepatitis?	☐	☐	☐	☐	

If yes, what type(s)? ***(Mark all that apply)***

- ☐ Hepatitis A
- ☐ Hepatitis B
- ☐ Hepatitis C
- ☐ Don't know
- ☐ Other

	No	Yes, but the condition is no longer present	Yes, and the condition is still present	Not sure	If yes, age at first occurrence (years)
F2. Cirrhosis of the liver?	☐	☐	☐	☐	
F3. Fatty liver?	☐	☐	☐	☐	
F4. Any other liver trouble?	☐	☐	☐	☐	

If yes, describe.

Continue on next page.

Please! Do not mark below this line

5958631333

It is very important that you mark an answer for each of the following questions, even if you have never had that condition.

HEART AND CIRCULATORY SYSTEM

Have you ever been told by a doctor or other health care professional that you have, or have had. . .

	No	Yes, but the condition is no longer present	Yes, and the condition is still present	Not sure	If yes, age at first occurrence (years)
G1. Congestive heart failure or cardiomyopathy (weak heart muscle)?	☐	☐	☐	☐	☐☐
G2. A myocardial infarction (heart attack)?	☐	☐	☐	☐	☐☐
G3. Coronary heart disease?	☐	☐	☐	☐	☐☐

If yes, describe this problem.

	No	Yes, but the condition is no longer present	Yes, and the condition is still present	Not sure	If yes, age at first occurrence (years)
G4. Hypertension (high blood pressure) requiring medication?	☐	☐	☐	☐	☐☐

If yes, do you currently take hypertension medication?
☐ No ☐ Yes

	No	Yes, but the condition is no longer present	Yes, and the condition is still present	Not sure	If yes, age at first occurrence (years)
G5. Angina pectoris (chest pains due to lack of oxygen to the heart requiring medication such as nitroglycerin)?	☐	☐	☐	☐	☐☐
G6. Does exercise cause severe chest pain, shortness of breath, or irregular heart beat?	☐	☐	☐	☐	☐☐
G7. High cholesterol (or triglyceride) requiring prescription medication?	☐	☐	☐	☐	☐☐

If yes, do you currently take medication for this?
☐ No ☐ Yes

SURGICAL PROCEDURE

Please indicate if you have ever had the following surgical procedure done.

	No	Yes	Not sure	If yes, age at first occurrence (years)
H1. Kidney transplant?	☐	☐	☐	☐☐

Continue on next page.

Please! Do not mark below this line

9505631335

Do you have an email address we could use to contact you?

☐ No ☐ Yes

Your Email Address

Please give us your correct address or location and also cell phone number:

Address		
City	State	
Zip Code	Home Phone Number	Cell Phone Number

Please provide the name and address of someone who could give us your new address should you move. We will contact this person only if we are unable to reach you at your home address.

Name	
Address	Relationship to you
City	State
Zip Code	Phone Number

Continue on next page.

We are always interested in your input in the follow-up study.
Use this space for any additional comments you may have:

When you have completed this questionnaire please return it to us in the enclosed envelope.

Mail to:

LONG-TERM FOLLOW-UP STUDY
St. Jude Children's Research Hospital
Department of Epidemiology
Mail Stop 735
262 Danny Thomas Place
Memphis, TN 38105-3678

Thank you!

Please! Do not mark below this line