



ChildrensHospitalLosAngeles

International Leader in Pediatrics

PERMISSION FORM (11/13/03)

Childrens Hospital Los Angeles

CONSENT/PERMISSION FOR CHILD TO PARTICIPATE IN RESEARCH

**EVALUATION OF ONLINE SUPPORT FOR TEEN SURVIVORS OF CANCER
AND PARENTS OF CHILDREN WITH CANCER**

Subject's Name:	_____	
CHLA#:	_____	Birth Date: _____

• INTRODUCTION

Your child is asked to participate in a research study conducted by conducted by Ernest Katz, Ph.D., from the Department of Pediatrics at Childrens Hospital Los Angeles, and Mitch Golant, Ph.D. from The Wellness Community. This research is sponsored by Amgen. Your child has been asked to participate in this study either you or your child has expressed an interest in your child becoming involved in one of the online support groups offered by The Wellness Community for teens with cancer. Participation in this study is completely voluntary. Please read the information below, and ask questions about anything you do not understand, before deciding whether or not to allow your child to participate. If you decide to participate, **please complete this form and fax it to The Wellness Community at 614-413-3400.**

• PURPOSE OF THE STUDY

The purpose of this study is to evaluate whether using online support groups is helpful to teens with cancer or parents of children with cancer.

• PROCEDURES

If you allow your child to volunteer to participate in this study, we would ask your child to do the following things:

1. Before your child begins participation in an online support group, he or she will be asked to fill out a series of questionnaires that will take approximately 1 to 1-1/2 hours to complete. These may be completed on our website at your child's convenience. These questionnaires will ask about your child's symptoms, mood, how your child has coped with the illness, your child's level of distress, and how your child's family and friends have reacted to the cancer experience.

Date of Preparation:

CHLA CCI#:

Protocol Expiration Date:

2. Twelve weeks, six months, and one year after your child joins the online support group, we will ask your child to complete another set of questionnaires on our website. These questionnaires will be similar in content to the first set of questionnaires but will not take as long to complete. It will take approximately 45 minutes of your child's time to complete this second set of questionnaires.

- **POTENTIAL RISKS AND DISCOMFORTS**

The risks of participating in this study are unknown, but are likely to be minimal. The questionnaires are routine and have not elicited adverse reactions among the hundreds of cancer patients or children previously studied, but your child might find some of the questions too personal and/or uncomfortable. Your child is free to decline to answer any questions he or she does not wish to answer or to leave The Wellness Community program at any time.

If you or your child does not wish to participate in this study now or at any point during the course of the study, you and your child will have complete access to all The Wellness Community programs conducted by the centers, including support groups, participation in The Wellness Community and all their educational activities. Your eligibility and your child's eligibility to be involved in these activities will be in no way hindered by your (or your child's) decision to withdraw participation in this study.

- **ANTICIPATED BENEFITS TO SUBJECTS**

Because this research involves only the completion of questionnaires, there are no known benefits thought to be associated with participation in this study.

- **ANTICIPATED BENEFITS TO SOCIETY**

This research will help the researchers to determine whether or not the use of online support groups is helpful to teens with cancer or parents of children with cancer. At the conclusion of this study, the results will be used to develop more effective support services and to better address quality of life concerns in survivors of childhood cancer and their family members.

- **ALTERNATIVES TO PARTICIPATION**

If you or your child does not wish to participate in this study, you may continue to participate in the online support group without being involved in the research study. You will also have complete access to all TWC programs conducted by the centers, including support groups, participation in TWC community and all their educational activities. You may also contact the American Psychosocial Oncology Society for additional, confidential referrals to support services in your area at the toll-free number 1-866-276-7443 (1-866-APOS-4-HELP).

- **PAYMENT FOR PARTICIPATION**

After completing each set of the online questionnaires, the investigators will provide your child with a promotional code that will be valid for five free music downloads from the Apple iTunes website.

Date of Preparation:

CHLA CCI#:

Protocol Expiration Date:

- **FINANCIAL OBLIGATION**

This research study is funded by Amgen. Participants and their families are not responsible for any of the costs involved in this study. Neither you nor your insurance company will be billed for your participation in this research.

- **PRIVACY AND CONFIDENTIALITY**

Members of the research team and, if appropriate, your physicians and nurses will know that your child is a research subject. All results will be kept confidential, but may be made available to you, and/or your child's physician if you wish. If while participating in this research study it becomes apparent to the research team that your child has a serious desire to cause harm to himself/herself, the research team will attempt to contact you immediately. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except:

- if necessary to protect your child's rights or welfare (for example, if he/she is injured and needs emergency care, or if he/she expresses a serious desire to cause harm to himself/herself); or
- if required by law (i.e., child abuse, reports of certain infectious diseases).

⇒ When the results of the research are published or discussed in conferences, no information will be included that would reveal your child's identity.

- **PARTICIPATION AND WITHDRAWAL**

Your child's participation in this research is VOLUNTARY. Your choice about whether or not to participate will have no affect on your child's care, services or benefits at Childrens Hospital Los Angeles or any other health-care facility. If you agree to participate, but later decide to remove your child from the study, you may do so without affecting you or your child's rights to health care, services or other benefits at Childrens Hospital Los Angeles or any other health-care facility.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw your child from participating in this research if necessary to protect your child's health or if other situations arise that make it necessary to do so. The investigator, Dr. Ernest Katz, will make the decision and let you know if it is not possible for your child to continue. The decision may be made either to protect your child's health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

- **HOW TO OBTAIN INFORMATION**

In the event of a research related injury or if you experience side effects, please immediately contact one of the investigators listed below.

Date of Preparation:

CHLA CCI#:

Protocol Expiration Date:

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call Dr. Katz at (323) 669-5922 or Dr. Mitch Golant at (310) 314-2565.

• **FINANCIAL INTEREST OF THE INVESTIGATOR**

Funding for this research study is provided by Amgen. The funding is used to support the development of the online support groups and the evaluation of their helpfulness to patients. Compensation is not based upon the number of research subjects enrolled. If your child’s physician is an investigator for this study s/he is interested in both your child’s healthcare and the conduct of this research. Your child is not under any obligation to participate in a research study conducted by his or her doctor.

• **RIGHTS OF RESEARCH SUBJECTS**

You may withdraw your permission for your child’s participation at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your child’s participation in this research study. If you have questions regarding your child’s rights as a research subject, you may contact the CHLA Office for Human Subjects Protections at 323/669-2265.

SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

Your signature(s) below indicate

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent to your child’s participation in this research study; and
- You will be given a copy of the signed permission form and of the *Experimental Subject’s Bill of Rights*.

Name of Subject

Name(s) of Parent(s)/Guardian

Signature of Parent (Guardian)

Date

Signature of Parent (Guardian)

Date

SIGNATURE OF INVESTIGATOR

I have explained the research to the subject’s parent(s)/guardian and answered all of his/her questions. I believe that he/she understands the information described in this document and freely gives permission for his/her child to participate.

Date of Preparation:

CHLA CCI#:

Protocol Expiration Date:

Name of Investigator _____

Signature of Investigator _____

Date (must be the same date as subject's) _____

SIGNATURE OF WITNESS

My signature as witness certified that the parent(s)/guardian signed this permission form in my presence as his/her voluntary act and deed.

Name of Witness

Signature of Witness

Date (must be the same date as subject's)

Add, if applicable:

Please check appropriate box and sign below.

Investigator's Statement of Certification for Subjects less than Seven Years of Age (Assent)

The undersigned investigator, [*Name*], hereby certifies that he/she has discussed the information contained in the study consent to the subject, including any risks that may reasonably be expected to occur. The undersigned further certifies that the subject was encouraged to ask questions, that all questions were answered, and that assent was obtained.

Assent was not obtained for a subject under 18 years of age. (*Please state the reason. Examples include: child is an infant; child is comatose; child lacks cognitive abilities to understand the information.*)

Date: _____

Time: _____

Signature _____

Routing of signed copies of the consent form:

- 1) Give to parent
- 2) Place in the CHLA Medical Record
- 3) Place in the Principal Investigator's research file.

Date of Preparation:

CHLA CCI#:

Protocol Expiration Date: