

ASSENT FORM FOR OLDER TEENS (2/20/04)**ChildrensHospitalLosAngeles***International Leader in Pediatrics*

Childrens Hospital Los Angeles
ASSENT¹ TO PARTICIPATE IN A RESEARCH STUDY

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

Subject's Name: _____
_____ Birth Date: _____

- **INTRODUCTION**

You are being asked to participate in a research study 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. You have been asked to participate in this study because you have expressed an interest in being involved in one of the online support groups offered by The Wellness Community for teens with cancer or parents of children 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 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 volunteer to participate in this study, we would ask you to do the following things:

1. Before you begin participation in an online support group, you 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 convenience. These questionnaires will ask about your

¹ This form will also serve as the "Consent/Permission for Child to Participate in Research" form for the parents to read and sign. In this case, "You" refers to "your child."

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symptoms, mood, how you have coped with the illness, your level of distress, and how your family and friends have reacted to the cancer experience.

2. Twelve weeks, six months, and one year after you join your online support group, we will ask you 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 time to complete this second set of questionnaires.
3. Ask your doctor to fill out a form to confirm your diagnosis of cancer.

- **POTENTIAL RISKS AND DISCOMFORTS**

The risks of participating in this study are unknown, but are likely to be minimal. The questionnaires are routinely asked of cancer patients, but you might find some of the questions too personal and/or uncomfortable. You are free to decline to answer any questions you do not wish to answer or to leave The Wellness Community program at any time.

If you do not wish to participate in this study now or at any point during the course of the study, you 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 to be involved in these activities will be in no way hindered by your decision to withdraw participation in this study.

- **ANTICIPATED BENEFITS TO SUBJECTS**

Participation in the current study is unlikely to provide direct benefit to you.

- **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 do not wish to participate in this study, you may elect to remain involved in an online support group without completing any of the questionnaires involved in this study. You will have complete access to all TWC programs conducted by the centers, including support groups, participation in TWC community and all their educational activities.

- **PAYMENT FOR PARTICIPATION**

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

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- **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 will know that you are a research subject. All results will be kept confidential. If while participating in this research study it becomes apparent to the research team that you may have a serious desire to cause harm to yourself, the research team will attempt to contact your parent or guardian 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 rights or welfare (for example, if you express a serious desire to cause harm to yourself); or
- if required by law (i.e., child abuse,).

Authorized representatives of the Department of Health and Human Services and the CHLA Committee on Clinical Investigations may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this research is VOLUNTARY. Whether or not you choose to participate will have no affect on your care, services or benefits at Childrens Hospital Los Angeles, the Wellness Community, or your health care facility. If you agree to participate, but later decide to withdraw from the study, you may do so without affecting your rights to healthcare, services or other benefits at Childrens Hospital Los Angeles, the Wellness Community, or your health care facility.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

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

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• **IDENTIFICATION OF INVESTIGATORS**

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

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 doctor is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You are not under any obligation to participate in a research study conducted by your doctor.

• **RIGHTS OF RESEARCH SUBJECTS**

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

SIGNATURE OF RESEARCH SUBJECT

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 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

Signature of Subject and Date

SIGNATURE OF PARENT(S)/GUARDIAN

Your signature below indicates that you have read this document; understand its meaning; have had a chance to ask questions; have had these questions answered to your satisfaction; and agree to your child's participation in this research study. You have been given a signed copy of this assent/permission form and of the *Experimental Subject's Bill of Rights*.

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Name(s) of Parent(s)/Guardian

Signature of Parent (Guardian) and Date

Signature of Parent (Guardian) and 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.

Name of Investigator

Signature of Investigator and Date

Please sign two copies of this form. Keep one copy for your self and mail the other copy with the form filled out by your doctor to:

Mitch Golant, Ph.D., The Wellness Community
2716 Ocean Park Blvd. Suite 1040
Santa Monica, CA 90405-5211
ATTN: Group Loop

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