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UNIVERSITY OF WASHINGTON

PATIENT CONSENT FORM

Enhancing Connections: Helping Your Child

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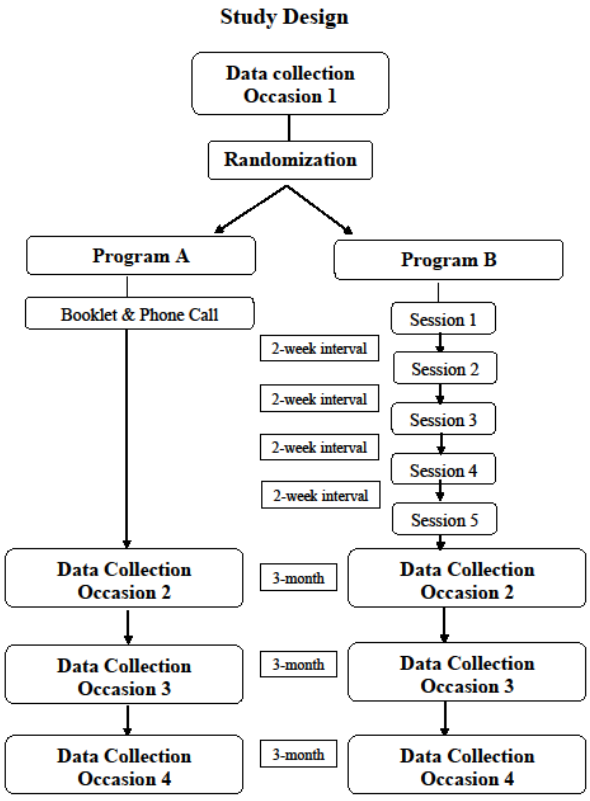
We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study. Your participation in the study is voluntary.

PURPOSE OF THE STUDY

The purpose of this study is to test the usefulness of two educational programs for parents with late-stage cancer who have a 5 - 17 year old child. The programs are designed to enhance the quality of the parent-child relationship and add to the parent's confidence in managing the impact of their cancer on their child. We are recruiting parents and their partners or parent surrogates into this study. Before sharing the programs with others, we want to make sure they are helpful to parents like you and your child. The feedback you give us will be used to change and strengthen the programs so that we can assist other parents with cancer and their children.

STUDY PROCEDURES



You will be asked to complete a set of 7 questionnaires at the beginning of the study and then again at 3, 6, and 9 months following entry into the study. You will be sent a copy of the study questionnaires. A trained phone worker will ask you to complete the questionnaires over the telephone each time (at beginning of study, 3, 6, and 9 months) and will enter your responses into a data base. You can choose not to answer any questions you do not want to answer. The study questionnaires will take about 35-45 minutes to complete with the phone worker.

(It is possible, if after multiple attempts to reach you by telephone we are unable to connect with you, study questionnaires will be mailed to you to complete and return by mail.)

These questionnaires will help us judge the quality of the program and how things have gone for you and your child. Examples of the most sensitive items on the questionnaires include:

• How often have you felt this way during the past week? -- I was bothered by things that usually don't bother me

[rarely to most or all of the time].
-- I felt I could not shake off the blues even with help from my family or friends [rarely to most or all of the time] • I feel frightened [not at all-very much so].

You are free not to answer any questions you do not want to answer.

Once you and your co-parent have completed the first set of questionnaires, you will be randomly selected (like flipping a coin) to one of two programs. We will send you a letter to tell you about your assigned program. We will send a second mailing that includes either the booklet or workbook for your program. A patient educator will call you within 2 weeks of the first letter to set up an appointment for your program participation.

If you are randomly selected to receive Program A, you will be mailed carefully selected educational material that discuss ways to talk about your cancer with your child. You will receive a phone call from a specially trained patient educator who will teach you ways to best use the printed materials to help your child. The phone call will last about 20-30 minutes.

If you are randomly selected to receive Program B we will ask you to participate in a 5-session Enhancing Connections Program with a patient educator about ways to help you talk to and support your child. All 5 sessions will be delivered by telephone every two weeks. Each session will last approximately 1 hour (5 hours total). Sessions will be scheduled at a time convenient to your schedule. These sessions will include short activities for you to do with your child. You will be taught about these activities by the patient educator. Your participation in the study will last approximately 9 months.

We ask your permission to digitally record your sessions with the patient educator. These recordings will not include any personal identifiers other than study participant code number and will be retained indefinitely, based on signed consent, for educational purposes.

RISKS, STRESS, OR DISCOMFORT

There is a risk of emotional distress or discomfort as a result of personal and possibly sensitive questions, or as a result of talking about your cancer. This distress is usually short-lived, but should you want assistance in dealing with these feelings, we will gladly assist you in getting a referral to an appropriate resource. Your permission must be given before a referral is made because all information you share with us is kept strictly confidential within the limits of the law.

Information collected from or about you during this study, including your cancer diagnosis and information we collect about your family/child, could be accidentally disclosed outside of the research. We will do our best to protect your confidentiality, but it cannot be guaranteed.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You may also work with a counselor or social worker who help parents with skills in talking with their child about the cancer.

BENEFITS OF THE STUDY

We do not know if this study will benefit participants. We hope the information we gain will help parents in the future who have cancer talk with their child.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from The National Institute of Nursing Research.

CONFIDENTIALITY OF RESEARCH INFORMATION

We will keep a link between your information and the study data indefinitely. The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. In addition, we will also report any observed instances of child abuse or neglect.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We have a Certificate of Confidentiality from the federal National Institute of Nursing Research. This helps us protect your privacy. The Certificate means that we do not have to give out information or documents that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- State authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is March 31, 2027. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this consent form.

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive a copy of this consent form.

Is it OK if someone contacts you in the future to ask about your responses to the *Enhancing Connections study?*

(circle one)

YES **NO**

Is it OK if your de-identified data is stored and made available to researchers in the future who may want to do further analysis of the data?

(circle one)

YES **NO**

I voluntarily consent to have the session(s) audio recorded. Only members of the research team will be able to listen to the recordings unless Dr. Lewis gives permission for others to listen to the recordings.

☐ Yes, I agree to be audio recorded as part of this research.

☐ No, I do not want to be audio-recorded as part of this research.

Printed name of subject Signature of subject Date

Copies to: Researcher
Subject
Subject's Medical Record (if applicable)