University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: December 14th, 2020
IRB Study # 19-1468
Title of Study: The FAMILY Study: A Pilot Program for Families Affected by Parental Cancer
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CONCISE SUMMARY

Most parents' primary goal – the wellbeing of their children – is not addressed in standard cancer care. We have developed a new program to help with cancer-related parenting concerns. The program was developed with input from patients who are parents, their partners, and healthcare providers (such as oncologists, social workers, and therapists). The purpose of this study is to pilot test the program.

The study will last about 3 months. You and your partner will be asked to participate in 2-3 visits together with a trained facilitator. You will be asked to complete a survey after each visit, and participate individually (without your partner or partner) in a feedback interview at the end. There is an optional additional feedback interview 6 months after your last visit. Visits can take place at the North Carolina Cancer Hospital, at home (if you live within 75 miles of the Hospital), or virtually by video conferencing.

The benefits to you from being in this study may be the potential to reduce parenting concerns about your children and to help your family feel better prepared to cope with any current or future cancer-related changes. The risks of participating could be loss of privacy, loss of confidentiality, and temporary emotional discomfort. You will receive compensation for your participation (described later in this form).

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people

in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

Most parents' primary goal – the wellbeing of their children – is not addressed in standard cancer care. There are also no programs or psychosocial interventions that have been proven to address the unique needs of parents with advanced cancer and their partners. The study team has developed a new program with a panel of patients who are parents, their partners, and healthcare providers (such as oncologists, social workers, and therapists). The goal of the program is to help parents address cancer-related parenting concerns.

The purpose of this study is to pilot test the new program. Feedback from parents in the study will help the study team refine the program and make sure it is feasible and acceptable.

Are there any reasons you should not be in this study?

You should not be in this study if you are unable to participate in study visits due to illiteracy, inability to speak English, or other causes. You should not participate if you are not willing to be audio recorded during the study visits and during the feedback interview. You should not participate if you live more than 75 miles away from the UNC Cancer Hospital and cannot attend study visits at the Hospital or by video conferencing. You should not participate if you are unwilling to conduct virtual visits by video conferencing during UNC-CH mandated restrictions on in-person research activities during the COVID-19 pandemic.

If you live more than 75 miles away from the UNC Cancer Hospital and are willing and able to attend study visits at the Hospital or by video conferencing, you are still eligible for the study.

How many people will take part in this study?

There will be approximately 20 people (10 couples) in this research study.

How long will your part in this study last?

Depending on your preferences for scheduling, your participation in the study will last between 6 and 16 weeks. We expect the duration of your participation to be 3 months.

What will happen if you take part in the study?

Baseline survey

One questionnaire lasting approximately 10-15 minutes. The survey can be done in person, over the phone, or with an email link. You can complete the survey at any time before your session. The survey contains questions about your demographic information (such as gender and age),

your thoughts and feelings about parenting and cancer, and any parenting concerns you might have.

Study visits
Both parents will participate in 2 sessions together with the facilitator (Visits 1 and 2). If you wish, an optional third session is available (Visit 3). You can choose to have the visits virtually by video conferencing, at the North Carolina Cancer Hospital or, if you live within 75 miles of the Hospital, at your home. The visits are expected to last between 1 hour and 1.5 hours. Study visits will be scheduled approximately 2-5 weeks apart if possible, but can be scheduled up to 7 weeks apart if needed or if that is your preference. For quality assurance and to determine the acceptability of the sessions, visits will be audiotaped and transcribed.

Post-visit surveys
You will be asked to complete a brief questionnaire after each session. You can choose to complete the questionnaire in person after the session, by telephone, or by an email link. The survey can be completed up to 7 weeks after your visit, or before your next visit (whichever comes first).

Feedback interview
After the study sessions, you will be asked to participate in an interview individually (separate from your partner) to give feedback on the program. You can do the interview in person or over the phone, and the interview is expected to take 30-45 minutes. The feedback interview will also be audiotaped and transcribed.

Optional – 6 month follow-up interview
If you are willing, the study team would like to follow up with you 6 months after you finish the study sessions. You would be asked to participate in an additional interview individually (separate from your partner). The interview is expected to take 20-30 minutes, and can be done in person or over the phone. This interview will also be audiotaped and transcribed. Participation in the 6-month follow-up interview is completely optional.

Please initial your choice below:

_____ Yes, I am willing to participate in the optional 6-month interview.

_____ No, I am NOT willing to participate in the optional 6-month interview.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be the potential to reduce parenting concerns about your children and to help your family feel better prepared to cope with any current or future cancer-related changes.

Other research has shown that parents with cancer want more information and support for themselves and their family members. Parents participating in this pilot study may directly

benefit from the opportunity to communicate their concerns with a trained facilitator and each other. A panel of parents with cancer and their partners have reported that the study content and study materials were helpful to them.

What are the possible risks or discomforts involved from being in this study?
The primary risks in this study are loss of privacy, loss of confidentiality, and risk of emotional distress.

Loss of privacy
Approaching patients about studies in the clinic poses a risk to privacy, although we expect this risk to be low. To protect against loss of privacy, all study-related interactions will be conducted in private areas at UNC Hospitals, in your home, or by telephone or video conferencing after confirming that you are in a private location.

Loss of confidentiality
Loss of confidentiality could occur if the study database were to be breached. To protect against this risk, only the study team will have access to the study database or your identifiable information. The database will be password-protected and stored on a secure server. For analysis, you will be assigned a unique, random study code. All information will be associated with this code. The transcripts of all study visits and the feedback interview will also be coded. All audiotapes will be stored on a secure, password-protected server and destroyed within 2 years of study completion.

Risk of emotional distress
There is risk for temporary emotional discomfort or distress due to this study. Questions about quality of life, prognosis, and parenting concerns may be temporarily uncomfortable or distressing. We expect the risks of discomfort or distress to be moderate relative to the overall distress that patients and their families experience on a day-to-day basis due to their illness.

We have successfully conducted studies about emotional distress and supportive care needs with patients and families. Prior participants with a wide range of educational backgrounds, illness severity, and emotional needs have described our study practices as appropriate and acceptable. Additionally, all intervention materials were developed with extensive review by a panel of patients, their partners, and healthcare providers (such as oncologists, social workers, therapists, and nurses).

There may be uncommon or previously unknown risks. You should report any problems to the study team.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
You will not be identified in any report or publication about this study. The data from this study

will not be used for future research without your consent, and your information will not be used or distributed for future research studies.

The study database will be password-protected and stored on a secure server. For analysis, you will be assigned a unique, random study code. All information will be associated with this code. The transcripts of all study visits and the feedback interview will also be coded. All audiotapes will be stored on a secure, password-protected server and destroyed within 2 years of study completion.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States (for example, a court subpoena) unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the

right to stop your participation at any time. This could be because you have had an unexpected problem, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw before completing Visit 2, you may still choose to participate in the feedback interview if you wish to give feedback on your experience in the study. This is completely optional.

Will you receive anything for being in this study?

You will receive up to $125 for taking part in this study. Any payment provided for participation in this study may be subject to applicable tax withholding obligations.

You will receive a $25 gift card after finishing each post-visit survey. You will receive an additional $50 after completing the feedback interview.

There is not additional compensation if you choose to participate in the 6-month follow-up interview, but participation in this activity is completely optional.

If you choose to complete a study visit at the Hospital, you will be given a parking voucher for the day of your visit.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent