Patient Name:
MRN:

Nemours
Informed Consent for
Participation in a Research Study
Nemours IC Template July 2021

You have been asked to consent to be in a research study. This form explains the research, your rights as a research participant, and any responsibilities that you may have as a result of your participation. You should understand the research study before you agree to be in it. ***You will receive a copy of this form. Read this form carefully. You may also talk with your family or friends about it. A research team member will answer any questions you have before you make a decision.***

1. WHAT IS THE TITLE OF THE STUDY?

Title of Study: A randomized controlled trial of eSCCIP: An eHealth psychosocial intervention for English and Spanish speaking parents of children with cancer

Key Information for You to Consider
• **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation. • **Purpose**. The purpose of this research is to learn if the Electronic Surviving Cancer Competently Intervention Program (eSCCIP) can help decrease symptoms of distress, anxiety, and stress in parents and caregivers of children with cancer. • **Duration.** It is expected that your participation will last no more than 3-months. • **Procedures and Activities.** You will be randomly assigned (as in the flip of a coin) to either the eSCCIP program or an electronic education program. If randomly assigned to eSCCIP you will be asked to complete four online intervention sessions, each consisting of approximately 30 minutes of self-guided content, and three 15-30 minutes of telemedicine follow-up calls. If you are in the education program, you will have access to a website with resources about coping. You will be asked to complete three sets of online questionnaires: one close to the time you sign this consent, another after the final telehealth meeting, and a final one at the three-month follow-up. Questionnaires will take between 20 and 30 minutes to complete. • **Risks.** The risks for participating in this study are minimal and are described down below. Some risks may include: feeling upset by some of the content and the potential that personal information will be disclosed.

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- **Benefits**. We hope that, by participating in this study, you will benefit psychologically by learning coping skills and ways to support all family members. The education materials offered in the comparison group may also help you cope and support others. Future patients may benefit from what is learned. There may be no direct benefits for you in this study.

- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

If interested, please continue to the detailed consent.

2. WHO IS IN CHARGE OF THE STUDY AT NEMOURS?

If you have a question, complaint, or problem related to the study, you can call the investigator anytime at the numbers listed below.

	Nemours - WIL
Principal Investigator	Kimberly Canter, Ph.D.
Co-Investigator(s)	Anne Kazak, Ph.D., ABPP Aimee Hildenbrand, Ph.D. Karen Wohlheiter, Ph.D. Steven Reader, Ph.D.
Study Coordinator(s)	Gabriela Vega, M.S. Angel Munoz Osorio, B.S. Alejandra Perez, B.A.
Address	Center for Healthcare Delivery Science 1600 Rockland Rd. Wilmington, DE 19803
Daytime Phone After Hours Phone	**302.651.4000**
Long Distance	1-800-SOS-KIDS (1-800-767-5437)

3. WHO SHOULD RESEARCH PARTICIPANTS CONTACT ABOUT THEIR RIGHTS?

If you have questions about your rights as a research participant, what to do if you are injured, if you would like to offer input or obtain information, or if you cannot reach the investigator or want to talk to someone else who is not involved with this research, you may contact the persons listed below.

Chairperson, Nemours IRB 302 690-8728
Director, Nemours Office of Human Subjects Protection at 302-298-7613
Email address: NOHSP@nemours.org

You may also contact the IRB office of MD Anderson Cancer Center (the IRB overseeing the research) at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

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- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

4. WHAT IS THE PURPOSE OF THE STUDY?

The goal of this research study is to learn if the Electronic Surviving Cancer Competently Intervention Program (eSCCIP) can help decrease symptoms of distress, anxiety, and stress in parents and caregivers of children with cancer. eSCCIP aims to deliver content to help parents and caregivers of children with cancer through online modules and telehealth follow-ups with a therapist.

5. WHO IS SPONSORING OR PAYING FOR THE STUDY?

The National Institute of Health is the Sponsor of this study and will pay Nemours for its costs in conducting this study.

6. WHO CAN BE IN THE STUDY?

You can be in this study if all of the following criteria are true:

- You have a child with cancer who is between the ages of 0 and 17.
- Your child with cancer currently receives care at Nemours Children's Hospital, Delaware.
- You can speak and read English/Spanish
- You have a place where you can comfortably complete the online modules and telehealth visits.
- You have reliable internet access through a device like a computer, tablet, or smartphone. We can help you access the study materials if you do not have reliable internet access or a device.

7. HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?

Up to 420 individual participants (representing 350 families) will be enrolled in this multicenter study. Up to 95 individuals will take part at Nemours.

8. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

Participation in this study will end after the 3-month follow-up.

If you are randomly assigned to eSCCIP, your participation is expected to take between 5-10 hours over a month-long period. There will be four online intervention sessions, each consisting of approximately 30 minutes of self-guided content, and three 30-minute telehealth follow-ups.

If you are randomly assigned to the education program, you can look over these materials at any time according to your own schedule.

All participants will complete three online sets of questionnaires. The questionnaires will ask about topics like your stress levels, mental health, and coping abilities. The questionnaires will take between 20 and 30 minutes to complete.

9. WHAT ARE THE RESEARCH PROCEDURES?

If you agree to take part in this study, you will be randomly assigned (as in the flip of a coin) to either the eSCCIP program or an electronic education program. If two caregivers from the same family participate, both will be assigned to the same program. This is done because no one knows if one group is better, the same, or worse than the other group.

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If you are assigned to the eSCCIP program, you will complete up to four online modules and three telehealth follow-ups over 1 month. Each module will take about 30 minutes to complete.

- Core 1 will help identify and discuss issues and beliefs about cancer and its impact on the family. In Core 1, you will also review the overall module goals and provide the therapist with information about yourself (such as your first name and your child's first name).
- Core 2 is designed to help recognize and change distressing beliefs that may lead to future problems.
- Core 3 will help you identify and discuss beliefs about the future of the family and help the family imagine a life after cancer treatment ends.
- Core 4 will be a summary of what you learned in the other cores and provide access to multiple resources that you may access at any time following completion of the program.

Each module is a unique mix of original video content and interactive activities. Cores 1 through 3 are paired with brief telehealth follow-up meetings performed by a therapist. At these follow-ups, you will review the skills you learned and discuss how these can be applied to your own life. If you complete the intervention with a second parent or caregiver (for example, your spouse), you will have the option of completing the follow-ups individually or together.

Telehealth follow-up meetings will be audio-recorded to help make sure that the meeting leaders are covering all of the important topics planned. 15% of the recordings will be reviewed for this purpose. The audio-recordings will be labeled with the study identification number only and sent via encrypted e-mail to the fidelity consultant at Nemours Children's Health. Recordings will then be transferred to a secure, internal, password-protected electronic drive at Nemours Children's Health. After the audio check is complete, recordings will be deleted from the computer.

The module and follow-ups will be done by 1 or 2 parents and/or caregivers per family, but the module content is made to apply to the whole family.

If you are assigned to the education program, you will be given access to a website with resources about coping with cancer (for example, stress management and recognizing symptoms of traumatic stress). You can look over these materials at any time according to your own schedule.

All participants will complete questionnaires online at 3 time points: at baseline, which is close to the time you sign this consent form and before Core 1; after the final telehealth meeting; and at the three-month follow-up. The questionnaires will ask about topics like your stress levels, mental health, and coping abilities. Questionnaires will take between 20 and 30 minutes to complete. Answers will not be shared with the healthcare team or other caregivers/parents, including the second caregiver from the same family

Optional Procedure #1: After completing the 3-month follow-up surveys, you may be asked if you would like to participate in an interview. If you agree, you will take part in an interview to learn more about your experience with eSCCIP, including how the strategies learned through the modules were used and possible costs and savings of using a program like eSCCIP. You will complete the interview via phone or in person sometime after completing the 3-month follow-up surveys. The interview will be audio-recorded and transcribed (written down) for research purposes. No identifying participant names will be included. Once the audio recordings have been transcribed and identifying information is removed, the recording will be deleted. The interview is expected to take about 45 minutes.

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One parent or caregiver can choose to participate in the interview, even if the second parent chooses not to participate. Parents/caregivers will be interviewed individually. Please note, if you agree to the interview, you may or may not be contacted, depending on when enough interviews have been completed to meet study goals.

10. WHAT ARE POSSIBLE RISKS OF BEING IN THIS STUDY?

Any research has some risks (things that could make you sick, feel uncomfortable, or hurt). The risks with the most chance of happening to someone in this study are listed below. Also, there is a chance of other risks that almost never happen, or unknown risks. The risks for participating in this study are minimal. There is a risk of emotional discomfort when completing study questionnaires that ask you about how you are feeling. Similarly, there is a risk of experiencing emotional discomfort while participating in the program, because it will address coping with your child's cancer treatment. You may refuse to answer any question. If you have concerns after completing the questionnaire(s), you are encouraged to contact your doctor or the study chair.

If the study coordinator thinks that you may be experiencing high levels of distress while taking part in the study, they will tell the study doctor. You will then be referred to a licensed social work counselor or psychologist for additional help. If needed, the study doctor will follow up with you at the next scheduled telehealth meeting.

Researchers will take appropriate steps to keep your information private. However, there is no guarantee of absolute privacy.

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this CoC cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below).

The CoC cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation. You should understand that a CoC does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to.

Optional Procedure Risks

There is a risk of emotional discomfort when completing the optional interview. You may refuse to answer any question. If you have concerns after completing the interview, you are encouraged to contact your doctor or the study chair.

Researchers will take appropriate steps to keep your information private. However, there is no guarantee of absolute privacy.

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You do not have to agree to the optional procedures in order to take part in this study. There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedure.
This study may involve unpredictable risks to the participants.

11. WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?

Participants may benefit psychologically by learning coping skills and ways to support all family members during this study. The education materials offered in the comparison group may also help you cope and support others. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including potential costs and time commitment. Participants may not wish to participate in the study, because thinking about and talking about coping with childhood cancer may feel difficult at times. To take part in this study, you will need to have internet access through an electronic device such as a tablet or computer.

There will be no cost to you for taking part in this study. You may choose not to take part in this study.

12. WHAT HAPPENS IF A PROBLEM OR INJURY RESULTS FROM THE RESEARCH PROCEDURES?

Nemours will assure that your child receives treatment, if needed, for study-related injuries. Neither Nemours nor the study doctor has a program to pay for medical care provided to treat the injury. If you have health insurance, it may, or may not, pay for the cost of treatment resulting from a study-related injury.

If your insurance does not pay, or if you do not have insurance, you understand that you may be responsible for paying for the cost of treatment.

If you think that your child has been injured while in this study or has a problem related to the study, you should tell one of the study doctors as soon as possible. The study doctor or research staff will tell you what you should do. The study doctor(s)' names and phone numbers are on the first page of this form.

The study staff is available Monday - Friday from 8:00am to 4:00pm. During these hours, you should call Angel Munoz Osorio with any questions or concerns about the study. Angel will direct your call appropriately.

During evenings, weekends, and holidays, you should call 302.651.4000 if you need immediate psychosocial assistance. You will reach the Nemours operator. Ask to page the Psychologist or Psychiatrist on call. In the event of a life-threatening psychosocial emergency, you should call 911.

13. IS BEING IN THE STUDY VOLUNTARY?

Being in this study is totally voluntary. Anyone who takes part in the study can stop being in it at any time. There will be no change to your usual medical care if you decide not to be in the study or decide to stop being in the study. No one will be angry with you, or treat you any differently than before you were asked to be in the study.

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In the event that you withdraw from the study, the study doctor may ask your permission to continue study follow-up, and all clinical data related to the study may continue to be collected from your medical records.

You may ask the researcher to destroy your information or samples. Your request must be in writing. The researcher will tell you if this is possible. There may be legal reasons for keeping your information or samples.

14. WHAT OPTIONS ARE AVAILABLE OTHER THAN BEING IN THIS STUDY?

You can decide to not participation in this study. There may be other research or treatment choices that could be considered. If you decided against being in this study, you can still get social and emotional support during your child's treatment at Nemours. The study doctor can provide detailed information about the benefits and risks of the various treatment options available. You should feel free to discuss these alternatives with the study doctor or your personal physician.

15. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?

The researchers would only remove someone from the study if they asked to be removed from the study, or if they did not complete the intervention according to the predetermined timeline. If a participant does not complete portions of the intervention, three attempts to contact them will be made by study personnel before they are removed from the study.

16. WHAT ARE THE COSTS OF BEING IN THIS STUDY?

There is no direct cost to you for being in this study. The possible added time on the days of the intervention may lead to other costs such as child care, etc., but the study has no funds to pay for such costs.

17. WILL I BE PAID FOR BEING IN THIS STUDY?

You will receive a $30 reloadable gift card once you complete the questionnaire after your last telehealth meeting. An additional $10 will be added to the gift card after you complete the 3-month follow-up questionnaires.

Optional Procedure #1: If you choose to participate in the interview, you will receive an additional $30 gift card.

No arrangement exists that would allow participants to share in any profit generated from this study or future research.

18. WILL I BE TOLD OF ANY NEW INFORMATION THAT MIGHT AFFECT MY WILLINGNESS TO STAY IN THE STUDY?

Any new information that may change your mind about participation in this study will be given to you. A committee called the Institutional Review Board (IRB) will review this study at least once per year. If the IRB finds that there is new information that you should know about while you are taking part in this study, it will ask the study doctor to tell you about it. You may be asked to sign a new version of this form after discussing the new information with a member of the research team.

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.

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19. WHAT INFORMATION ABOUT ME WILL BE USED OR DISCLOSED? (AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION)

Limited identifiable health information about you will be used by Nemours researchers and may be given to people outside of Nemours for this research. This is done to conduct the research study, to monitor the safety of research participants and for auditing. Federal law requires us to tell you about, and get your approval for, research use and disclosure of health information that includes "identifiers" that can connect the health information to you. (Names, initials, date of birth, addresses, phone numbers, and social security numbers are examples of identifiers.) This Identifiable health information is called Protected Health Information (PHI).

Your name, address, and date of birth will be given to Greenphire so that you can be paid for your participation in this study. Greenphire is a company working on behalf of Nemours to support the process of paying participants. You will be issued a Greenphire ClinCard, which is a debit card that your payment will be loaded onto and can be used as you wish. In order to assign a ClinCard to you and load payment onto the ClinCard, Greenphire will need your name, address, and date of birth.

Use of Health Information by Nemours Staff

The health information that will be used within Nemours includes all data collected for this study, as described in this form.

Your identity will be protected as much as possible. Nemours protects your health information by storing records in files or computers that can only be used by authorized Nemours staff. All hard-copy study materials, such as consent forms like this one and the surveys that you complete, will be stored in locked file cabinets located at Nemours Children's Hospital, Delaware. Electronic data will also be stored on secure, password protected computer servers connected to the Nemours internal network. These data files will identify participants by code numbers, and names or other identifying information will not be used. There will only be one document connecting participants to their unique code numbers, used for tracking purposes, and this document will be password-protected and stored on a password-protected computer connected to the Nemours internal network.

The people within Nemours that may use this health information include:

- The investigators listed on the first page of this consent form and their staff;
- The Nemours Institutional Review Board (IRB). (The IRB is a group of people that reviews research activities. The IRB is responsible for the safety and rights of research participants), and;
- Nemours internal audit staff.

Disclosure of Health Information to Others

Limited information from this research study will also be contained in your Nemours' medical record along with the information about your regular office visits. This will help other doctors to know about the research study you are in and give them extra information from the research that might help them take better care of you. The same information might also be seen by anyone who can look at your medical records, such as your insurance company.

Identifiable health information will be disclosed (given) to the following individuals or groups:

- National Institute of Health (NIH) who is a sponsor of this study
    - Health information in your child's medical record shared with the NIH or their agent is limited to information directly related to this research study.

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- De-identified data will be shared with researchers at MD Anderson Cancer Center, the Children's Hospital of Los Angeles, the Rector and Visitors of the University of Virginia, the University of Southern California, the Hospital for Sick Children, and New York University.
- Other: Study monitors and auditors who verify the accuracy of the information and individuals who put the study information together in report form

The PHI that will be disclosed (given) to people or groups outside of Nemours for research purposes are listed in the table below:

Type of Identifiable Health Information:	**Disclosed:**
History and Physical	☒
Demographics (information about race, ethnicity, gender, age)	☒
Questionnaires	☒

Limits on Protection of Privacy and Confidentiality
Only health care organizations have to follow laws and rules about protecting the privacy of health information. If health information containing peoples' identities is given to other kinds of companies or organizations, they are not required by law to safeguard the privacy and confidentiality of that information. Nemours expects these companies and organizations to protect the privacy and confidentiality of research participants, but it is not possible for Nemours researchers to assure that this happens.

Government agencies that may look at records for this research study, including the above health information, include:

- The U.S. Food and Drug Administration
- The U.S. Department of Health and Human Services
- Other agencies of State and local government as required by law

The research results may be presented at scientific meetings or in print. Participants' identities will not be disclosed in those presentations.

20. SIGNATURES:
I am making a decision whether or not to participate in this study. I have read this form, or had it read to me in a language that I understand. I have been given enough time to make this decision. I have asked questions and received answers about things I did not understand. I willingly consent to participate in this study. By signing this form, I am not giving up any rights to which I am entitled under law.

I understand that:

- I can withdraw consent for participation in this study and for the use and / or disclosure of my PHI by contacting the person in charge of the study listed on the first page of this form.
- The use and / or disclosure of my PHI will stop after Nemours receives the withdrawal notice. Information that is used or disclosed before the withdrawal may still be used.
- Unless I withdraw consent, the use and / or disclosure of my PHI described in this form will not have an expiration date.
- My PHI may be disclosed again by the person or organization (other than Nemours) that receives it. If this happens, Federal or state law may not protect the information.
- I have the right to refuse to sign this consent form.

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- If I refuse to sign this consent form, I will not be allowed to be in this research study.
- I have the right to ask Nemours to tell me who has received my protected health information.
- I have the right to revoke my authorization for the use and disclosure of my health information at any time, which would end my participation in this study.
- I will receive a signed and dated copy of this form.

My signature indicates that:

- I give my consent to participate in the research study described in this form.
- I give the researchers and Nemours authorization to use and /or disclose my individually identifiable health information for this research study as described in the section on use and disclosure of PHI.

Name of Participant (**Print**)	Participant Date of Birth
Signature of Participant	Date

I, the undersigned, certify that to the best of my knowledge the participant signing this consent had the study fully and carefully explained and that she / he understands the nature, risks and benefits of his / her participation in this research study.

I, the undersigned, certify that the participant completed no research procedures for this study prior to signing this consent.

Name of Person Obtaining Consent (**Print**) (Investigator or Designee)	
Signature of Person Obtaining Consent (Investigator or Designee)	Date

A copy of the signed form was provided to Participant ☐