Official Study Title: SOCIAL EMOTIONAL DEVELOPMENT IN YOUNG CHILDREN WITH CANCER

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Informed Consent for Research (Non-therapeutic)

SOCIAL EMOTIONAL DEVELOPMENT IN YOUNG CHILDREN WITH CANCER

***NOTE:** When we say "you" in this document, we mean "you or your child."*

1. Why am I being asked to take part in this research study?

You are invited to take part in this research study because you are a child between the ages of 4 and 6 who has completed therapy for a brain or solid tumor. This consent form gives you information about the study which will be discussed with you. Please take your time making a decision and feel free to discuss it with your friends, family and St. Jude staff. Before agreeing to take part in this research study, it is important that you read this consent form that describes the study. After you understand the study, and if you agree to take part, you will be asked to sign this consent form. You will be given a copy to keep.

2. Why is this study being done?

With this research study we plan to learn about social functioning in preschool aged children with brain and solid tumors. We want to know how these skills develop in children with cancer over time.

3. What are my rights in this study?

- Whether or not you take part in this study is entirely up to you.
- If you decide not to be in the study or to leave the study at any time, you are still eligible for care at St. Jude.
- This study is being sponsored by the Department of Psychology and Biobehavioral Sciences at St. Jude Children's Research Hospital and the American Cancer Society.
- The sponsor will get information about you related to the study.
- The principal investigator (researcher) in charge of this study is Dr. Heather Conklin, who can be reached at 901-595-3585 if you have questions or concerns about this research.

4. What will be done in this study?

The parts of this study are:

1. An initial study visit during which you will complete an assessment of social and cognitive functioning, including attention, memory, executive function (e.g., higher order cognitive skills, including planning, organization, and behavior regulation), processing speed, and social skills like problem solving and facial expression recognition. Your parent/legal guardian will complete questionnaires about your social, emotional, behavioral, and executive functioning. Your assessment will take about 90 minutes for you to complete. Your parent's/legal guardian's questionnaires will take about 60 minutes to complete.

2. During the initial study visit, we will ask you to identify another adult that sees you on a regular basis (that is, a teacher or daycare employee). With your permission, we will contact that person and ask him/her to complete questionnaires about your social and behavioral functioning. The questionnaires will take about 20 minutes to complete. This part of the study is optional. If you do not wish to identify another adult, you can still take part in the study.

3. A follow-up study visit will occur about two years later in which you and your parent/legal guardian will complete the same study measures that you completed during the initial study visit, plus a few additional measures. We will also again ask your permission to contact your teacher/caregiver to fill out questionnaires about you.

All procedures listed above are done solely for research purposes (in other words, would not happen if you were not in this study).

5. What are my other choices if I do not take part in this study?

Your participation in this study is voluntary. You may choose not to take part in this research study. If you decide not to be in the study, or to withdraw from the study at any time, you will not lose any of the benefits of the routine medical care received at St. Jude Children's Research Hospital.

6. How many people will take part in this study?

Up to 124 children and their parents will take part in this study at St. Jude.

7. How long will I be in this study?

You will be in the study for about two years. During this time, you will complete one 90-minute study visit at the time of enrollment and a repeat 90-minute study visit about two years later.

8. What risks can I expect from taking part in this study?

These are the main risks of this study:

- Surveys, interviews, questions: You may become upset by some of the questions or not want to answer them. If you do not want to answer a question for any reason, please tell us, and we will skip it. If you become upset, study staff will be there for you to discuss your feelings. You may stop the study at any time.
- Loss of privacy: Very rarely, personal information from your records could be given out by accident. This might make you upset, embarrass you or affect your ability to get insurance. To stop this from happening, we:
  - Store records apart from names or other personal information
  - Only allow members of the study team to see the records
  - Store electronic data only on computers protected with a password and encryption software
  - Report study results on the whole group and never identify one single person in any reports

9. What are the possible benefits of the study?

You probably will not benefit personally from taking part in this study. However, the information we learn from this study may help other children in the future.

10. Can I stop taking part in this study?

If you leave the study, you will still have the same services and care you normally would have.

11. Can I be taken out of the study without my consent?

You may be taken out of the study without your consent for these reasons:

- The researcher decides that staying in the study would harm you.
- You miss so many appointments that we cannot use your data in the study.
- You do not follow the instructions given to you by the study team.
- The study sponsor, St. Jude Children's Research Hospital, Department of Psychology and Biobehavioral Sciences, decides to end the study.

12. Will I be paid for my time or expenses?

You and your parent will each receive a $10.00 gift card for your time and effort after completing each study visit ($20.00 total). We will ask for your Social Security number and address before you are paid for taking part in the study.

13. How will new findings related to this study be shared with me?

We will tell you anything we learn during the study that might change your mind about staying in the study.

14. How will I find out the results of this study?

The researcher will give you information about the overall results of this study. St. Jude researchers share information with people in studies in many ways, including:

- articles on www.stjude.org
- in newsletters
- in medical or scientific journals
- in the media

Published research results will only describe groups of people who took part in the study. Information that points out a single person will not appear in research journals or other reports.

15. Who will see my research records and medical information?

As part of the study, Dr. Heather Conklin and her study team may share the results of your study and parts of your medical record with the groups named below. These groups may include people from St. Jude Children's Research Hospital and the American Cancer Society. These groups are required to make sure your protected health information (PHI) is kept private.

We will keep your medical records private to the degree allowed by law. St. Jude may give your health data, without identifiers, to other researchers or use it for other approved research projects not listed in this form.

The sponsor, St. Jude, Dr. Conklin and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

We will not identify you in any publication or presentation about this study. Only information needed for this study is recorded.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will also be kept for an unknown length of time.

SUMMARY OF RESEARCH AND PRIVACY RIGHTS
Minimal Risk Non-therapeutic Research

The following statement describes your rights as a research participant in this study:

1) You may refuse to be in this research study or stop at any time. This decision will not affect your care or your relationship with your doctor or St. Jude. If available, you may receive routine medical care at St. Jude Children's Research Hospital.

2) If you have insurance, TennCare or Medicaid, or other health care coverage such as an employer-sponsored benefit plan, they will be billed for many of the services we provide. However, we do not bill patients or their families for the cost of medical care not covered by their health plans. This includes research costs.

3) Your samples and information may be used to develop a new product or medical test, which may be sold. If this happens, you will not receive any payments for these new products.

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

5) A decision to take part in this research means that you agree to let the research team use and share with other researchers your health information, also called protected health information (PHI), for the study explained above. This information will be kept indefinitely. You have the right to see, copy, and ask for changes to your protected health information that will be used or given out. However, research information may not be seen until the end of the study.

6) When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI may be used or given to someone outside the hospital. You have the right to read the Notice of Privacy Practices before you sign this form. It may have changed since you first registered at St. Jude. You can find it at the bottom of every page on the St. Jude Internet website: *www.stjude.org*.

7) Federal agencies such as the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), the National Institutes of Health (NIH), and St. Jude Children's Research Hospital Institutional Review Board (IRB), your insurance company or other health benefits plan (if charges are billed to these plans), as well as other regulatory agencies, committees, or persons involved in overseeing research studies may review your research and medical record.

8) Information about you that may be given out includes your complete medical records, including details about diagnosis, illness, treatment, and information that may be recorded about past diagnosis or treatment and information taken as a part of this research study as explained in this informed consent.

9) After your records are given to or used by others, St. Jude Children's Research Hospital cannot promise that information will not be given out again. Also, the information given out may no longer be protected by federal privacy laws.

10) St. Jude uses reasonable safeguards and means to protect your private information. However, St. Jude cannot guarantee the security and confidentiality of e-mail, text messages, fax communications or mail.

11) Researchers and study staff are required by law to report suspected child abuse, threat of harm to self or others, and certain diseases that spread from person to person.

12) Your permission to use and give out your child's protected health information will end when your child turns 18 years of age. At that time, we may contact your child for his or her permission to continue using it.

13) You may take back permission for your records to be used or given out at any time, for any reason, except when that information has already been given out or used for the study based on your permission. To take back your permission, please fill out a form called a Revocation of Release of Authorization. You may ask for this form by calling the St. Jude Privacy Officer at 901-595-6141. You must mail the form or hand it to:

    HIPAA Privacy Officer
    St. Jude Children's Research Hospital
    262 Danny Thomas Place, Mail Stop 280
    Memphis, TN 38105

14) You can get more details about your rights as a research participant by calling the St. Jude Institutional Review Board at 901-595-4357 or the Research Participant Advocate at 901-595-4644. If you are outside of the Memphis area, please call toll-free 1-866-583-3472 (1-866-JUDE IRB).

15) The St. Jude Research Participant Advocate is an individual who is not part of the research study team and is available to you to discuss problems, concerns, and questions. The Advocate can help you obtain information and can relay any input you may have concerning the research to the research study team. You can reach the Advocate by calling 901-595-4644, or if you are outside of the Memphis area, call toll free at 1-866-583-3472 (1-866-JUDE-IRB).

16) You will be given a copy of this <u>signed</u> consent form.

PARENT/GUARDIAN STATEMENT (Required for participants younger than 18 years): I have read this document or it was read to me. I have been encouraged to ask questions and all my questions have been answered. I give permission for my child to be in this research study.

___________________________________	_______________	___________AM/PM
Parent/Legal Guardian Signature	Date	Time (circle one)

ASSENT DISCUSSION (Required for participants 7–13 years old):

☐ The research was explained to the minor participant in age-appropriate terms and the minor verbally agreed to take part in the study.

☐ Minor declined to take part in the study. The minor declined for the following reason(s):

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☐ An assent discussion was not initiated with the minor for the following reason(s):

☐ Minor is under 7 years of age.
☐ Minor is incapacitated.
☐ Minor refused to take part in the discussion.
☐ Other____

RESEARCHER/DESIGNEE STATEMENT: I have explained the research to the participant and his/her parent(s) or legal guardian(s). The research participant and parent(s)/guardian(s) were encouraged to ask questions and all questions were answered to their satisfaction. A copy of this form has been given to the participant or his/her representative.

___________________________________	_______________	___________AM/PM
Researcher/Designee Signature	Date	Time (circle one)

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Print Name

PLEASE FAX CONSENT FORM TO PROTOCOL OFFICE #6265