Official Study Title: SOCIAL EXPERIENCES OF ADOLESCENTS AND YOUNG ADULTS WITH CANCER

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SOCIAL EXPERIENCES OF ADOLESCENTS AND YOUNG ADULTS WITH CANCER

NOTE: When we say "you" in this consent, we mean "you or your child." When we talk about research, it can be called a clinical trial, research study or research protocol.

Key Information

To start we want to highlight the **risks and study requirements** that we think you should know before deciding if you want to take part in this research study. If you're still interested, we'll then get into more detail.

A. Why are you being asked to volunteer in this study?

You are being asked to take part in this clinical trial, a type of research study, because we want to learn more about the social experiences of youth your age who are being treated or have been treated for cancer.

B. What is the usual approach to this condition?
Most of the research done about this topic has been focused on youth who have completed treatment for cancer.

C. Why is this study being done?
We want to learn more about how the treatment of your cancer affects your relationships with others. In this research study, we will use questionnaires and interviews to learn about how you view your relationships and interact with others. We will also ask you about activities you take part in and which ones you want St. Jude to offer to patients like you.

D. What will happen if you decide to take part in this study?

You will answer questions that take about 90-120 minutes to complete. You may also be asked to do an interview that takes about 20-30 minutes. Once you are done, you are done with the study.

E. What are the research risks and benefits of taking part in this study?
Risks are small, like possible upset when answering the questions. There may be no direct benefits to you.

F. How many people will take part in this study?
200 adolescents and young adults.

G. What are your options?
   a. Taking part in this research study is completely your choice.
   b. If you decide to take part in this study, you can change your mind and stop at any time.
   c. If you decide not to take part in this study, you may still able to receive care at St. Jude.
   d. You may choose no treatment or to seek treatment somewhere else.

If you are still interested in taking part in the CONNECT research study, more detail will be provided in the following pages.

Table of Contents

1. Why are you being asked to volunteer for this research study?

You are being asked to take part in this clinical trial, a type of research study, because we want to learn more about the social experiences of youth your age who are being treated or have been treated for cancer. Because of your age, diagnosis, and treatment history, you can be a part of this study. Please take your time in deciding and feel free to discuss it with your family, friends and St. Jude staff. Before agreeing, 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. Who is sponsoring this study?

St. Jude Children's Research Hospital, Department of Psychology, Phone: 901-595-3300

3. What is the purpose of this study?

We want to learn more about how the treatment of your cancer affects your relationships with others. In this research study, we will use questionnaires and interviews to learn about how

you view your relationships and interact with others. We want to allow you to share your opinions and experiences so that we can learn about what is important to you and activities and programs you would like to see offered by St. Jude.

4. What will be done in this study?

You will answer questions that take about 90-120 minutes to complete. These questions will cover topics like social competence, attachment, and connectedness. We will also ask questions about your interest in types of activities and programs that St. Jude could offer patients your age. You may also be asked to do an interview that takes about 20-30 minutes in which we will talk about your cancer experience and how it has affected your friendships. These activities can be completed in person in a private room in the Psychology Clinic or in medical clinics/inpatient rooms, or remotely by mail, email, phone, and/or using a video call application. With your permission, we will ask if your caregiver wants to answer questions. If so, these can be done in person at the same time, through an emailed link, or over the phone. Once you are done with the questions, you are done with the study.

5. What are the risks and benefits of taking part in this study?

a. <u>Risks</u>

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 or embarrass you.
  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

b. <u>Benefits</u>

There may be no direct benefits to you for taking part in this study. However, the information we learn from this study may help other patients in the future.

6. What are the risks to pregnancy, to an unborn child and to the ability to have children when taking part in this study?

There are no risks to males or females.

7. Can you stop taking part in this study?

a. You may refuse to be in this research study or stop at any time. There are no consequences; you will simply no longer be a part of the study. The 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.

b. **Can you be taken out of this study without your 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 do not follow the instructions given to you by the study team.
- The study sponsor, St. Jude Children's Research Hospital, Department of Psychology, decides to end the study.

8. What are your other options?

You may take part in other studies offered to you at St. Jude.

9. How much will it cost you?

There are no costs to you for taking part in this research study.

10. Will you be paid for your time or expenses?

You will be paid for your time or expenses. You will receive a $20 gift card for completing questionnaires. If you complete the interview, you will be given an additional $10 gift card. If your caregiver takes part in this study, he/she will receive $10 gift card.

11. What if there is a problem?

If you have any questions about this study or if you are injured because of this study, contact Dr. Sarah Daniels, at 901-595-3300 immediately. If you are injured from being in this research study, St. Jude will offer you reasonable and necessary medical treatment for that injury. If you need more care than St. Jude can provide or if you prefer to seek treatment elsewhere, we will help you find medical care somewhere else. St. Jude may bill your insurance company or other third parties, if appropriate. It is not the hospital's policy to provide payment for other types of costs, such as lost wages, disability, or discomfort if you are injured from being in this study. You are not giving up any of your rights by signing this consent form.

12. How will new findings related to your participation in this study be shared with you?

The researcher will tell you of any new information learned during your study participation which might cause you to change your mind about continuing the study.

13. How will you find out the results of this study?

The researcher will give you information about the overall results of this study. Whether you will know your personal test results will be discussed in another part of this document. 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 be in research journals or other reports.

14. What about privacy and confidentiality?

Privacy

When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI (protected health information) 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.

A decision to take part in this research means that you agree to let the research team use and share your PHI with other researchers for purposes of 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.

These groups, agencies or people may view your information from your research and medical records:

- Food and Drug Administration (FDA)
- Office of Human Research Protections (OHRP)
- National Institutes of Health (NIH)
- Other government agencies
- Your insurance company and other health benefits plan
- St. Jude Children's Research Hospital Institutional Review Board (IRB)

- Other committees or people involved in overseeing research studies

Confidentiality

As part of this study, the research team will store records apart from names or other personal information. We will only allow members of the research team to see data records. Data will be stored on a secure server and downloaded to a study-specific database on a weekly basis. Medical data from the participant's record will be entered directly into a secure study-specific database. We will store electronic data only on computers protected with a password and encryption software. Study results will be reported on the whole group and never identify one single person in any reports.

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.

15. Permission to Use Your Data/Information: Permission/HIPAA

If you sign this document, you give permission to all researchers and their staff at St. Jude Children's Research Hospital to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or release for this research includes:

Information in your medical record, as well as the information you provide in the study questionnaires and interviews.

St. Jude Children's Research Hospital is required by law to protect your health information. By signing this document, you give St. Jude Children's Research Hospital permission to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

If you sign this document, you give St. Jude permission to share your information for future research studies and for the placement of information on databases as described in #14 of this consent form. By signing, you will also give St. Jude permission to put your research information, including testing, imaging, genomic and genetic information, other information and studies, and other sensitive information in your medical record (unless the research information is from a research-only laboratory). Any information placed in the medical record becomes a permanent part of your medical record and is not protected by the Certificate of Confidentiality discussed in #14 of this consent form, but is protected like any other part of your medical record as described in the Notice of Privacy Practices.

The following entities will disclose information:

- Data coordinating centers that will receive and process PHI
- Sponsors who want access to PHI or who will actually own the research data; and/or
- Institutional Review Boards or Data Safety and Monitoring Boards

You do not have to sign this document and give your permission, but if you do not, you may not receive research-related treatment.

Please note that you may change your mind and revoke (take back) this permission at any time. Even if you revoke this permission, St. Jude Children's Research Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this permission, you must write to:

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

Memphis, TN 38105

This permission expires at the end of this research study.

16. Further Information and Contact Details for Questions about This Research Study

You are encouraged to ask any questions you wish, before, during or after your participation in this study. If you have any questions about the study, please speak to the study team, who will be able to provide you with up-to-date information. If you wish to read the research on which this study is based, please ask the study team.

If there is anything you do not understand, or have any other questions, please contact the researcher listed below.

IF AT ANY TIME DURING THE STUDY YOU EXPERIENCE ANY DISCOMFORT OR UNUSUAL SYMPTOMS, OR SIDE EFFECTS, PLEASE CONTACT ANY OF THE DOCTORS LISTED BELOW.

Principal Investigator, Researcher:
Dr. Sarah Daniels
St. Jude Children's Research Hospital
262 Danny Thomas Place
Memphis, TN 38105
Tel: (901) 595-3300

If you require any medical or surgical treatments outside of St. Jude such as with your local doctor or another hospital during this study, your researcher and their team would need to be informed.

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 or 901-595-1139. The 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. If you are outside of the Memphis area, please call toll-free 1-866-583-3472 (1-866-JUDE-IRB).

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

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)

RESEARCH PARTICIPANT STATEMENT (14-17 years old and Adult Participants 18 years and older):

I have read this document or it was read to me. I have been encouraged to ask questions and all my questions were answered. I agree to take part in this study.

_____	_____	_____AM/PM	
Research Participant Signature	Date	Time	(circle one)

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	
Research/Designee Signature	Date	Time	(circle one)

_____

Print Name

PLEASE SEND COMPLETED CONSENT FORM TO CLINICAL TRIALS OPERATIONS:

- SCAN and E-MAIL to: (preferred)
protocoleligibilityoffice@stjude.org<mailto:protocoleligibilityoffice@stjude.org
- Or FAX to: (901) 595-6265