

**Official Study Title:** ChronCan (Chronicling Cancer): PILOTING A NOVEL WRITING INTERVENTION WITH ADOLESCENTS AND YOUNG ADULTS WITH CANCER

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**ChronCan (Chronicling Cancer):**

**PILOTING A NOVEL WRITING INTERVENTION WITH ADOLESCENTS AND YOUNG ADULTS WITH CANCER**

**Note:** When we say “you” in this informed consent document, we mean “you or your child.” When we talk about research, it can be called a clinical trial, research study (study), or research protocol.



**Key Information**



To start, we highlight here the risks, benefits 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 details.

**A. Why are you being asked to voluntarily take part in this study?**

You are being asked to take part in this research study, because you are an adolescent or young adult patient being treated for cancer at St. Jude Children’s Research Hospital.

**B. Why is this study being done?**

Young people with cancer have difficult experiences and writing exercises may help improve their well-being. However, very few studies have examined how a creative writing activity might be useful for young people with cancer. In this pilot study, we hope to explore whether teenagers and young adults with cancer want to participate in a writing exercise and whether they find it to be valuable.

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

We will invite patients to participate in an activity where they are given the opportunity to write about their experiences with cancer, with support and guidance from an expert writer (Dr. Paul). Patients will meet briefly with the expert at the start of the exercise, and they can choose to meet 1-3 additional times with the expert over the next 2 months to receive further support if they wish. After completing the writing exercise, patients will do an informal interview to share their thoughts about whether the experience of writing felt helpful or not.

**D. What are the research risks and benefits of taking part in this study?**

Participants may find it emotional or stressful to write about their experiences, but risks are minimal because participants can choose not to participate at any time and/or not to answer any of the writing prompts or interview questions that they do not feel comfortable with. There will be no direct benefits to participants in the study, although the potential benefit to future patients, parents, and clinicians will inform the development of further writing interventions

**E. How many people will take part in this study?**

Approximately 20 people

F. What are your options?

- 1) Taking part in this research study is completely your choice.
- 2) If you decide to take part in this study, you can change your mind and stop at any time.
- 3) If you decide not to take part in this study, you will still be able to receive care at St. Jude.

If you are still interested in taking part in this research study, ChronCan, more detail is provided below in the following pages.

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Study Contact Details and Further Information



You are encouraged to ask any questions you wish, before, during or after your participation. If you have any questions about the research study, please contact the study PI Trisha K. Paul, MD (trisha.paul@stjude.org). If there is anything that you do not understand, or if you have any other questions, please contact any of the people below.

<u>Who to talk to for...</u>	<u>You can contact...</u>	<u>At...</u>
<ul style="list-style-type: none"><li>• Any new or unexpected symptoms, side effects or discomforts</li><li>• General study questions</li><li>• Any medical or surgical treatments done outside of St. Jude such as with your local doctor or another hospital during this study</li></ul>	<p><b>Your St. Jude Doctor</b> 262 Danny Thomas Place Memphis, TN 38105</p>	901-595-3300 (Main Hospital Number)
<ul style="list-style-type: none"><li>• Your rights as a research participant</li><li>• Any research concerns or complaints</li></ul>	<p><b>Institutional Review Board (IRB)/Research Participant Advocate</b></p> <ul style="list-style-type: none"><li>* IRB is a group of scientists and community members who make sure research meets legal and ethical standards</li><li>* Research Participant Advocates are individuals who are not part of the research study team and are available to you to discuss problems, concerns and questions. The Advocate can help you obtain information and can relay any input you</li></ul>	901-595-4644 or 901-595-1139

	may have concerning the research to the research study team and the IRB.	
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### 1. Why are you being asked to voluntarily take part in this research study?

You are being asked to take part in this study because you are an adolescent or young adult being treated for cancer at St. Jude Children's Research Hospital. Taking part in this study is completely your choice. 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 informed consent document (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?

The study is sponsored by St. Jude Children's Research Hospital. The study doctor is Dr. Trisha Paul who can be reached at 901-595-3300.



### 3. What is the purpose of this study?

Young people with cancer have difficult experiences and writing exercises may help improve their well-being. However, very few studies have examined how a creative writing activity might be useful for young people with cancer. In this pilot study, we hope to explore whether teenagers and young adults with cancer want to participate in a writing exercise and whether they find it to be valuable.



### 4. What will be done in this study?

We will invite patients to participate in an activity where they are given the opportunity to write about their experiences with cancer, with support and guidance from an expert writer (Dr. Paul). Patients will meet briefly with the expert at the start of the exercise, and they can choose to meet 1-3 additional times with the expert over the next 2 months to receive further support if they wish. Copies of the written narratives will be collected by the study team. After completing the writing exercise, patients will do an informal interview to share their thoughts about whether the experience of writing felt helpful or not.



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

#### a. Risks

This study will pose minimal risks to you. The study will collect personal information that you choose to disclose, which may cause a loss of privacy. Very rarely, personal information from your records could be given out by accident. This might make you upset or embarrass you. It is possible that this research study also involves risks that we currently do not know about.

To prevent this, we:

- Store research records apart from names or other personal information.
- Remove your name and other identifiers from the information collected.
- Only allow members of the study team to see the records.
- Store data only on computers that are protected with a password and special software.

Also, patients or parents may find it stressful or emotional to talk about their diagnosis and future. The study team will take numerous steps to protect you from any distress. If you feel upset, you may stop the interview at any time. Participants can choose not to participate at any time and/or not to answer any of the writing prompts or interview questions that they do not feel comfortable with. You also may talk about your feelings with a member of the research team or contact any other supportive individual. You can talk to your social worker, psychologist, chaplain, or other clinicians if this might be helpful.

#### **b. Benefits**

There may not be any direct benefit to you personally, although the potential benefit to future patients, parents, and clinicians as this study will inform development of further writing interventions for AYA patients with cancer.



#### **6. Can you stop taking part in this study?**

##### **a. Can you change your mind about participating in this research study?**

You may change your mind about taking part in this research study and stop at any time. You may continue to receive routine medical care at St. Jude or participate in another study. This decision will not affect your relationship with your doctor at St. Jude.

If you change your mind about participating in this study, information that has already been given to or used by researchers will not be returned or removed.

##### **b. Can you be taken out of this study without your consent?**

Yes, you can be taken out of this study without your consent. Participants will be taken out of the study if the Study Doctor decides that continuing in the study would be harmful to you.



**7. What are your other options and can you have other treatments while taking part in this study?**

**a. Other Treatment Options**

You have the option to not take part in this research study.

**b. Can you participate in other research studies at the same time?**

You may participate in other research studies at the same time. Please check with your study doctor before thinking about taking part in any other research.



**8. How much will it cost you to take part in this study?**

There is no cost to participating in this study.



**9. Will you be paid for your time or expenses while taking part in this study?**

You will not be paid for your time or expenses.



**10. What if there is a problem while taking part in this study?**

If you have any questions or concerns about this study, contact Dr. Trisha Paul, at 901-595-3300



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

St. Jude researchers share information with people in studies in many ways including:

- Articles on [www.stjude.org](http://www.stjude.org)
- In newsletters
- In medical or scientific journals
- In the media
- A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by the 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.

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.



**12. What about identifiable private information and identifiable biospecimens (blood, tissue, urine, cells, and any type of data and/or samples) obtained from you during the study?**

If you choose to take part in this study, your data will be used to answer the research question(s) and to publish the findings of this study. 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. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially. There is no plan to share any money with you.

St. Jude's researchers and their collaborators will store the data collected in this study in electronic databases and other locations and will store specimens in the biorepository or other locations. They may use the data collected in this study for future research purposes and may share some of the data with others without seeking further consent from you. You may not receive results from that future research.

Sharing data is part of research. It may increase what can be learned from this study and future studies. Often data sharing is required as a condition of funding or for publishing study results. It is also needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared with government agencies, research collaborators, and other researchers and organizations conducting research that may not be related to this study. There is no time-limit on sharing of information.

This future research may be unrelated to the current study and may include outside researchers and organizations from around the world. These organizations may include for-profit companies conducting medical research. We or others who distribute data or samples may be paid for data or samples, including yours. You will not receive payment if this happens.

St. Jude will do its best to protect and maintain your data and in a safe way. One of the ways we protect your data is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data sharing agreements and review by oversight groups within St Jude. Often the data and specimens may be coded to protect your identity before they are shared, and we will keep the key to the code in a secure way.

If data is used or shared with any information that may be likely to identify you, such as your name, address, or medical record number, further institutional review and approval would be required. In these cases, we will review whether additional consent from you is required.

Generally, if your data and are used and shared without any personal identifiers or only with information that is less likely to identify you, further review and approval is not needed, and you will not be contacted.

Data sharing could change over time and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. The purpose of research is to learn and discover new information to make improvements to patient care and/or treatments. To make these improvements, research results must be shared with others. By agreeing to take part in research studies, you are agreeing for your information or data to be used and shared with others. If you are generally not comfortable with the use and sharing of your data in future research as explained this consent, you should talk with your doctor before agreeing to take part in this study.



**13. What about permission to use your data/information (HIPAA Privacy Rule), privacy and confidentiality?**

**Permission to Use Your Data/Information- HIPAA Privacy Rule and Privacy**

The HIPAA Privacy Rule defines the situations in which PHI (protected health information) may be used or given to someone outside of the hospital to be used or released for research and other purposes. PHI includes information such as your name, MRN, date of birth, or other identifying information, including research information placed in your medical record.

To do this research, St. Jude Children's Research Hospital (St. Jude) will need to collect, use, and share your private health information. St. Jude is required by law to protect your health information. By signing this consent form, you give St. Jude permission to use and/or release (share) your private 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 consent form, you give permission to all researchers and their staff involved in the study at St. Jude to use or release (share) your health information that identifies you for the research study described in this document.

The health information that we may use or release includes demographics that you choose to disclose such as age, gender identity, and cancer diagnosis.

If you sign this consent form, you give St. Jude permission to share your information for future research studies about disease or advancing science and for future unspecified research.

When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI, including research information placed in your medical record, may be used or given to someone outside of St. Jude. You have the right to read the Notice of Privacy Practices before you sign this consent form. It may have changes 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](http://www.stjude.org)

The people who may view, request, receive, or use your private health information include St. Jude researchers and their staff, and other doctors, nurses, and staff members. Additionally, St. Jude may share your information with other people or groups of people. These include:

- St. Jude Children's Research Hospital Institutional Review Board (IRB)
- Other committees or people involved in overseeing research studies

You do not have to sign this consent form which gives your permission. Please note that you may change your mind and take back (revoke) this permission at any time. Even if you take back 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 take back this consent form/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 does not have an expiration date.

### **Confidentiality**

All electronic files containing personal identifiers will be stored only on a St. Jude Children's Hospital file server located behind a firewall and assessable to only research team through user/password protections. Non-electronic files will be kept in a locked file cabinet in your doctor's office in an access-controlled area. Audio recordings will be reviewed only by research staff and erased following data analysis. We will protect the confidentiality of your information to the extent reasonably possible.

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.

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If you decide you would like to take part in this research study, please ask any questions you have, and read and sign this consent form. You will be given a copy of it to keep. A copy of this consent form will also be put in your patient notes, one will be put 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 informed consent document and to consider taking part in this study.

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#### 14. Signatures

**PARENT/Legal GUARDIAN STATEMENT** (Required for participants younger than 18 years):

I have read this consent form or it was read to me. I have been encouraged to ask questions and all my questions have been answered. I give my permission for my child to be in this research study.

\_\_\_\_\_  
Parent/Legal Guardian Signature      Date      Time      AM/PM  
(circle one)

**ASSENT DISCUSSION (Required for participants 15-17 years old)**

Minor Age 15 to 17 years old Assent Signature:

I have read this consent form or it was read to me and discussed in a way that I could understand. I have been encouraged to ask questions and all of my questions were answered. I agree to take part in this research study.

\_\_\_\_\_  
Minor Assent Signature      Date      Time      AM/PM  
(circle one)

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

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

Minor refused to take part in the discussion.

Other \_\_\_\_\_

**RESEARCH PARTICIPANT STATEMENT (Age 18 years and older):**

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

\_\_\_\_\_  
Research Participant Signature      Date      Time      AM/PM  
(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 consent form has been given to the participant or his/her representative.

\_\_\_\_\_  
Researcher/Designee Signature \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_ AM/PM  
(circle one)

\_\_\_\_\_  
Researcher/Designee Print Name \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Interpreter (if needed) Signature \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_ AM/PM  
(circle one)

For non-English speaking participants, an interpreter is required. The interpreter may serve as the research participant advocate unless mandated otherwise by the IRB.

**PLEASE UPLOAD COMPLETED CONSENT FORM TO EPIC.**