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Official Study Title: Optimizing Fertility Preservation and Decision Quality in Male AYA With Cancer: A Family-centered Intervention

NCT04268004

Informed Consent Form (ICF)

Date of the document: December 16, 2021

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

STUDY TITLE: Optimizing Fertility Preservation and Decision Quality in Male AYA with Cancer: A Family-centered Intervention

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

STUDY TITLE: Optimizing Fertility Preservation and Decision Quality in Male AYA with Cancer: A Family-centered Intervention

PRINCIPAL INVESTIGATOR: Leena Nahata, MD

CONTACT TELEPHONE NUMBER: (614) 722-2828 (9am-5pm, Monday-Friday)

STUDY SPONSOR: National Institute of Health (NIH)

PARTICIPANT'S NAME: _____ DATE OF BIRTH: _____

NOTE: The words "you" and "your" are used in this consent form. These words refer to the study volunteer whether a child or an adult.

Key Information About This Study
The following is a short summary of this study to help you decide whether or not to participate. More detailed information follows later in this form.

Very little is known about how we can help adolescent and young adults (AYAs) and their caregivers make decisions about fertility preservation (sperm banking) before beginning cancer treatment. The purpose of this study is to see if having a guided conversation about fertility preservation increases preservation rates and/or satisfaction with the decision among AYA males with cancer.

Study participation: Everyone will be asked to complete questionnaires. Families will then be randomized to either standard care or a brief guided conversation about fertility preservation. Half of AYAs and caregivers will be asked to complete a questionnaire about demographic information only. The other half will be asked to complete questionnaires about demographics and about fertility preservation and participate in a discussion about those questions with a trained interventionist. Both groups will be asked to complete additional questionnaires and participate in a brief, audio-recorded interview about 1 month from now and again at 1 year.

Study visits: You will be asked to take part in 3 study visits. The first one will happen today. The second one will happen about month from now. The third one will happen about a year from now. Each one will take about 30 minutes. See a more detailed discussion later in this form.

The main risk of the study is that you could feel irritated or upset when answering questions, but it may be more likely that you find them a little boring. Other risks are listed later in this form.
Although there may be no benefit to you from being in this study, we hope to learn something that could help others.

If you are interested in learning more about this study, please continue reading below.

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1) INTRODUCTION

We invite you to be in this research study. Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. By signing this form, you agree to be in this study. If you do not want to be in this study, all regular and standard medical care will still be available to you here at Nationwide Children's Hospital. Participation is voluntary. You can leave this study at any time.

You will be given a signed and dated copy of the consent and the assent forms.

2) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at Nationwide Children's Hospital. We hope to enroll 40 families of AYAs recently diagnosed with cancer.

3) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

To determine whether our survey questions and discussion help increase fertility preservation/sperm banking rates, we need two groups of AYA males with cancer. Both groups will be asked to answer demographic questions. One group will also be asked to answer questions about their (or their son's) goals and feelings about parenthood and sperm banking and discuss their answers with an interventionist.

To determine which group you are in, families will be randomized to one of two groups. Randomized means that each participant will be picked by chance, like flipping a coin or drawing straws to get either the demographic questions and standard care or the demographic and fertility preservation questions plus the guided discussion. Each participant has a 1 in 2 chance of being assigned to the guided discussion.

This study will last about 1 year. It will include study activities now, in about 1 month, and about 1 year from now. Each of these meetings will last about 30 minutes. These activities we do at these meetings include answering survey questions, having a guided discussion, and completing a brief audio-recorded interview.

Visit 1:
Everyone will be asked to complete a demographic questionnaire.

Patients and caregivers who are randomized to the guided discussion group will also be asked to complete an additional questionnaire regarding goals and feelings about parenthood and sperm banking. Caregivers will be asked to complete questionnaires about both their own and their son's goals and feelings. This questionnaire should take about 10 minutes for patients and caregivers to complete. The guided discussion should take about 20 minutes.

In addition, study staff will review medical records to obtain information about your diagnosis, treatment, and sperm banking decision. This information will be used in the study to examine the importance of medical factors in understanding decision making and satisfaction.

Visits 2 and 3: After about one month and after about one year, study staff will contact you to complete another questionnaire about family communication and how you feel about your decision. You will also be asked to complete a brief audio recorded interview. The interview will ask more about your decision about fertility preservation, how you feel about that decision, and how being in this study has impacted you. The questionnaire and interview should take about 30 minutes to complete.

4) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

We believe that there is very little chance that bad things will happen as a result of being in this study. It is possible that you could feel irritated or upset when answering questions, but it may be more likely that you find them a little boring. If you do find any of the questions upsetting or don't want to answer a question, you don't have to, and the study staff will be available to discuss this with you further. You can also take breaks while completing the questionnaires. There may be other risks that are not known at this time.

Although we will take every precaution, there is a small chance of loss of confidentiality of your study information.

5) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

Although there may be no benefit to you from being in this study, we hope to learn something that could help others.

6) WHAT ARE THE COSTS AND REIMBURSEMENTS?

It will not cost you anything to participate in this study. For your time and inconvenience, each person will receive $10 for the first visit paid on a debit card designed for clinical research. You will receive $20 for the second visit, and $30 for the third visit. When a study visit is completed, funds will be approved and automatically loaded onto your card. If the card is lost or stolen, please call the study coordinator for a replacement card.

If you receive $600 or more in a calendar year from participating in research studies, you will be issued a 1099 IRS Form to file with your income taxes.

7) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

We believe that there is very little chance that injuries will happen as a result of being in this study.

8) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?

It is your choice to be in this study. You may decide to stop being in this study at any time. If you decide to stop being in this study, call the study team at the number on page 1 of this form to see if there are

any medical issues about stopping. If you stop being in the study, there will be no penalty or loss of benefits to which you are otherwise entitled.

If at any time the Principal Investigator believes that this study is not good for you, the study team will contact you about stopping. If the study instructions are not followed, participation in the study may also be stopped. If unexpected medical problems come up, the Principal Investigator may decide to stop your participation in the study.

9) OTHER IMPORTANT INFORMATION

If you are an employee of Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, your job or performance review will not be affected in any way if you decline to participate or withdraw your consent to participate in this study.

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.

The final study results will not be shared with you individually. However, at some time, a final study summary will be available on the ClinicalTrials.Gov (http://clinicaltrials.gov) website.

The Principal Investigator is an employee of The Research Institute at Nationwide Children's Hospital and The Ohio State University and is being paid for her time and knowledge needed to do this study.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will enable us to learn and provide the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decline to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

10) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?

Information collected for this study includes information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to this study team to collect, use, and share your PHI for this research study. Information collected is the property of Nationwide Children's Hospital, its affiliated entities, and/or the sponsor.

Some of the information collected as part of this study will be sensitive, such as information relating to your cancer treatment.

PHI that may be used or shared will include: complete address, telephone number, dates (treatment dates, birth date), email address, medical record number, and voice recordings.

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People or Companies authorized to use, share, and receive PHI collected or created by this research study:

- PI and study staff
- The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
- Nationwide Children's Hospital internal auditors
- National Institute of Health (NIH)
- The Office for Human Research Protections (OHRP) (the federal government office that oversees human subject research)

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may be further shared by them and no longer be protected by federal privacy rules.

Reason(s) why the use or disclosure is being made: We will record and use/share your PHI to keep track of participants in the research and contact you in the future about progress of the study and other possible chances for involvement in research. This information will also be used to describe the diagnostic and treatment characteristics of the group of participants and evaluate whether outcomes vary for kids with different levels of medical risk.

You may decide not to authorize the use and disclosure of your PHI. However, if it is needed for this study, you will not be able to be in this study. If you agree to be in this study and later decide to withdraw your participation, you may withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator at Nationwide Children's Hospital, 700 Children's Drive, Columbus, OH 43205. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

PHI will only be shared with the groups listed above, but if you have a bad outcome or adverse event from being in this study, the study team or other health care providers may need to look at your entire medical records.

The results from this study may be published but your identity will not be revealed.

The PHI collected or created under this research study will be used or shared as needed until the end of the study. The records of this study will be kept for an indefinite period of time and your authorization to use or share your PHI will not expire.

11) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about anything while on this study or you have been injured by the research, you may contact the Principal Investigator at (614) 722-2828, Monday – Friday, between 9-5 pm.

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If you have questions, concerns, or complaints about the research; if you have questions about your rights as a research volunteer; if you cannot reach the Principal Investigator; or if you want to call someone else, call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (the committee that reviews all research involving human subjects at Nationwide Children's Hospital).

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Signature Block for Children ☐ N/A, Adult Participant

Your signature documents your permission for the named child to take part in this research.

_____
Printed name of child

_____ _____
Signature of parent or individual legally authorized to consent to the child's general medical care Date & Time AM/PM

_____
Printed name of parent or individual legally authorized to consent to the child's general medical care

_____
Relationship to Participant

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact Legal Services if any questions arise.

_____ _____
Signature of second parent or individual legally authorized to consent to the child's general medical care Date & Time AM/PM

_____
Printed name of second parent or individual legally authorized to consent to the child's general medical care

_____
Relationship to Participant

If signature of second parent not obtained, indicate why: (select one)

- Not required by IRB
- Second parent is deceased
- Second parent is unknown
- Second parent is incompetent
- Second parent is not reasonably available
- Only one parent has legal responsibility for the care and custody of the child

_____ _____
Signature of person obtaining consent Date & Time AM/PM

_____
Printed name of person obtaining consent

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Assent

_____ _____
Signature of subject Date & Time AM/PM

❑ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

☐ N/A, Witness not required

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____ _____
Signature of witness to consent process Date & Time AM/PM

_____
Printed name of person witnessing consent process

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Signature Block for Adult Participation ☐ N/A, Pediatric Participant

Your signature documents your permission to take part in this research.

Signature of subject	Date & Time AM/PM
Printed name of subject	
Signature of person obtaining consent	Date & Time AM/PM
Printed name of person obtaining consent	

☐ N/A, Witness not required

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date & Time AM/PM
Printed name of person witnessing consent process	