Building Evidence for Effective Palliative/End of Life Care for Teens with Cancer

NCT#02693665

April 5, 2016

Informed Consent Form and Informed Assent Form

CHILDREN'S NATIONAL MEDICAL CENTER

Division of Adolescent and Young Adult Medicine
111 Michigan Avenue, NW
Washington, DC 20010
(202) 476-5000

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY AND AUTHORIZATION TO USE PROTECTED HEALTH INFORMATION

TITLE OF STUDY: FAmily CEntered Advance Care Planning: Teen Living with Cancer (FACE-TC)

PRINCIPAL INVESTIGATOR: Maureen E. Lyon, Ph. D., Clinical Psychologist, Division of Adolescent and Young Adult Medicine

"You" refers to "You" or "Your Child" throughout this document

INTRODUCTION: We would like to invite you to be part of a research study at Children's National Medical Center. Before you decide if you would like to participate, we want you to know why we are doing the study. We also want you to know about any risks (anything unexpected that might happen) and what you will be expected to do in the study.

This form gives you information about the study. Your doctor will talk to you about the study and answer any questions you have. We encourage you to discuss this study with your family and anyone else you trust before making your decision. We will ask you to sign this form to show that you understand the study. If your child is fourteen years old or older, we may talk to your child about the study and ask your child to sign a form like this one but shorter. We will give you a copy of this form to keep. It is important that you know:

- You do not have to join the study;
- You may change your mind and stop being in the study any time you want.
- If we make any important change to the study we will you about it and make sure you still want to be in the study.

A. PURPOSE OF STUDY

1. The first purpose of the study is to look at the attitudes of adolescents with cancer about discussing their wishes about life-prolonging treatments with their physician or other health care providers in an outpatient clinic at Children's Hospital. This is also known as an advance directive or a living will. We want to know what you want. Although we know what adults think about these issues, no one has ever asked teenagers what they think. We want to find out what teenagers want and need, so that we can be more useful and sensitive to the needs of all teenagers who are living with life-threatening illness and their families.
2. A second purpose of this study is to help you and your family talk about your wishes for end of life care and make a plan for yourself for the future that you can share with your doctor.
3. You qualify for this study because you are between the ages of 14 and 20 or you are the legal guardian of an adolescent aged 14 to 17 or the chosen surrogate of an adolescent aged 18 to 20.

B. PROCEDURE

This is a standard of care comparison study to see if FAmily CEntered Advance Care Planning for Teens with Cancer (FACE-TC) is helpful to adolescents and their families. We will divide the adolescents and their parent or guardian in the study into two groups (like flipping a coin so you have an equal chance of being in any group). We will give one group the Family Centered Advance Care Planning intervention. The other group will receive standard of care or usual care.

The Family Centered Advance Care Planning Intervention will have three sessions:

1. In Session One, you will be asked to answer 30 questions about your attitudes concerning end-of-life care and death and dying. For example, would you want to be involved in these decisions or would you rather have your physician and family make these decisions for you? We just want to know what you think about these issues. We will ask your permission to share your wishes with your family and with your doctor. We will also ask your legal guardian or surrogate the same questions.

2. In Session Two, we will tell you the ways in which you and your family had the same or different attitudes. We will help you make a plan for the future, if you wish. In this session you will complete the Statement of Treatment Preferences.

3. In Session Three, if you want to, you and your family can complete an Advance Directive called the Five Wishes. The Five Wishes is a research document, as well

as a medical directive document. With your permission, it will be placed in your medical record along with a copy of the Statement of Treatment Preferences and a copy given to you and to your primary health care provider. Sessions 1, 2 and 3 will be scheduled one week apart.

If you are in the comparison group, you will receive your usual care in the clinic. You will complete questionnaires at six points in time over 18 months. (Time 1, Time 3, Time 5, Time 6, Time 7, Time 8). Time 2 and Time 4 are for intervention participants only.

If there is a change of surrogate or revoking of surrogate status by a patient 18 years of age or older, the planned intervention and/or follow-up visits will not take place with the original surrogate.

We want your opinion and we want to test that the questions we ask make sense to you should take about 30 to 90 minutes to answer the questions. We will be happy to answer any questions you have. The questions will be asked in a private office.

We will divide the responses of the teenagers and those of their parent (or surrogate) to compare answers and evaluate the differences**.**

C. POTENTIAL RISKS/DISCOMFORT

Potential risks are minimal. However, some people feel that this is an uncomfortable topic, even though most people do have thoughts about it. If you should find the questions upsetting, we will be available to talk to you and/or make referral to a counselor.

D. VOLUNTARY PARTICIPATION

There will be no penalty or loss of benefits to which you are otherwise entitled if you decide to withdraw from the study.

E. POTENTIAL BENEFITS

1. One benefit for you is that participation may increase your knowledge about end-of-life decision making. It might also make it easier for you to discuss these issues with your physician. Beginning at the age of 18, whenever teenagers come to the hospital to stay, he/she will be given a form asking you questions about end-of-life decision making, even to have their tonsils taken out.

2. You will be making a contribution to the care of all adolescents with a life-threatening illness by increasing health care professionals' sensitivity and knowledge of teenagers' wishes, as well as the wishes of their parents.

F. ALTERNATIVES TO PARTICIPATION

The alternative would be not to participate in this study and to continue your regular care as previously done.

G. QUESTIONS – WHO TO CALL

We want you to ask questions about any part of this study or consent form either now or at any time in the future. If you have research or medical questions about this study, call the Principal Investigator, Maureen Lyon, PhD, at 202-476-5442. If you believe you have been injured as a result of being in this study, you should call the Principal Investigator, Maureen Lyon, PhD, at 202-476-5442. If you have any questions or concerns about your rights in this research study at any time, please call Children's Hospital's Manager of Customer Relations, or the Chair of the Institutional Review Board, or the Chief Academic Officer of the Children's National Medical Center. All parties may be reached at (202) 476-5000.

H. CONFIDENTIALITY

We will keep the records of this study confidential. Only the people working on the study will know your name. The federal government can review the study records and medical records to make sure we are following the law and protecting the children in the study and to make sure our results are correct. Your child's medical record is confidential, but just like any medical record; there are some exceptions under state and federal law. No published or unpublished report or visual or speaking presentation about this study will include any material that will identify you as a participant in this study. You will be assigned an identification number, which will be used on all study-specific forms. Your name/identity will not be put on any answers. Only the research staff at the clinical site, and whomever else you decide to tell, will know that the special number is linked to you. They will not tell anyone about the linking number and they will not tell anyone that you have participated in the survey. The information linking your name to the special ID number will be kept in a double-locked area of the clinical site.

In certain circumstances, Children's Hospital Institutional Review Board (IRB) may request a copy of your records. The job of the IRB is to make sure that volunteers in studies are protected. If they ask for a copy of your records, we will give it to them.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA). This privacy law protects your individually identifiable health information (Protected Health Information or **PHI**). The privacy law requires you to sign an agreement so researchers can use or share your PHI for research purposes. This describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully and ask a member of the research team to explain anything you do not understand.

I authorize Dr. Maureen E. Lyon, Ph. D. and her research staff to create, access, use, and disclose my PHI for the purposes described below.

Protected Health Information that may be used and shared includes:

x☐ Information that identifies you such as name, address, telephone number, date of birth, Social Security number, and other details about you
x☐ Information that relates to your health or medical condition from your medical records
x☐ Information obtained from the study procedures outlined in this consent form, for example: the results of intelligence testing, and any other medical information we learn from you about your health history and family history
x☐ Laboratory results in your medical chart obtained on specimens collected from you (blood)
x☐ Questionnaires or surveys you complete
x☐ Interviews conducted with you by members of the research team
x☐ Audio/ video recordings
x☐ Other *[please specify]: ethnicity, education

The Researchers may use and share my Protected Health Information with:

- The Principal Investigator, other Investigators, Study Coordinators, and all administrative staff in charge of doing work for the study;
- Government agencies that have the right to see or review your PHI, including but not limited to the Office of Human Research Protections and the Food and Drug Administration;
- Children's National Medical Center Institutional Review Board;
- Audit Committee of the Children's National Medical Center Institutional Review Board;
- Quality Improvement Program Coordinator and other staff in the Office for the

Protection of Human Subjects at Children's National Medical Center.

In addition to the above people and organizations, the Researchers may also use and share my Protected Health Information with:

X☐ Doctors and staff at other places that are participating in the study. The name(s) of the other place(s) that are participating in this study are Saint Jude Children's Research Hospital and Akron Children's Hospital

X☐ The Sponsor of the study and people that the Sponsor may contract with for the study.
The name of the Sponsor is the National Institute of Nursing Research/National Institutes of Health
X☐ The Safety Monitoring Committee (a group of people who examine the medical information during the study)
X☐ The Medical Monitor for the Study (a person who reviews medical information during the study)
X☐ The Patient Advocate or Research Ombudsman (person who watches out for your best interest)
☐ Any other outside entity who will receive health information
Please list: None

Also, your primary physician will be contacted if during the course of the study the researcher learns of a medical condition that needs immediate attention.

Should your health information be disclosed to anyone outside of the study, your information may no longer be protected by HIPAA and this Authorization. However, the use of your health information will still be regulated by applicable federal and state laws.

Storage of PHI in a Database:

We would like to store personal health information collected from you in this study in a database for future research. The database is maintained by Children's National Medical Center, Center for Health Services and Community Research.

Please indicate your approval of any or all of the following by initialing next to the statement:

My personal health information may be stored in the above named database for future analysis related to this study. ☐ Yes ☐ No _____ initials

My personal health information may be stored in the above named database for future analysis related to FAmily CEntered (FACE) Advance Care Planning, FACE-TC. ☐ Yes ☐ No _____initials

My personal health information may be stored in the above named database. Researchers may contact me to request my authorization for future studies that are not related to this study or the disease named above.

☐ Yes ☐ No _____ initials

My personal health information may be stored without any of my identifying information for use in other studies of other diseases. ☐ Yes ☐ No _____ initials

If you agree to participate in this research study, the research team, the research sponsor (when applicable) and the sponsor's representatives, may use Personally Unidentified Study Data. The Personally Unidentified Study Data does not include your name, address, telephone, or social security number. Instead, the researcher assigns a code to the Personally Unidentified Study Data. Personally Unidentified Study Data may include your date of birth, initials, and dates you received medical care. Personally Unidentified Study Data may also include the health information used, created, or collected in the research study. The research team or the research sponsor may share the Personally Unidentified Study Data with others to perform additional research, place it into research databases, share it with researchers in the U.S. or other countries, or use it to improve the design of future studies. They may also publish it in scientific journals, or share it with business partners of the sponsor and to file applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

You do not have to sign this Consent/Authorization. If you decide not to sign the Authorization, you will not be allowed to participate in the research study.

After signing the Consent/Authorization, you can change your mind and:

- Revoke this Authorization. If you revoke the Authorization, you will send a written letter to: Maureen E. Lyon, Ph. D. to inform her of your decision.
- If you revoke this Authorization, researchers may only use and disclose the PHI that was collected for this research study before you revoked the Authorization.
- If you revoke this Authorization your PHI may still be used and disclosed if you should

have an adverse event (unexpected side effect).

- ♦ If you change your mind and withdraw the Authorization, you will not be allowed to participate in the Family Centered Advance Care Planning for Teens with Cancer (FACE-TC) study.

You will not be allowed to review the information collected for this research study until after the study is completed. This Authorization expires on March 31, 2020.

If you have not already received a Notice of Privacy Practices from Children's National Medical Center, you may request a copy and will be given one. If you have any questions or concerns about your privacy rights, you may contact the Children's Hospital Privacy Officer at 202-476-4550.

I. COMPENSATION

We cannot promise that the risks we have told you about or other unknown problems will not happen. If you think that something bad happened because your child was in the study, please call the Chief Academic Officer of the Children's National Medical Center at (202) 476-5000. We will give your child any emergency treatment needed.

YOUR CONSENT

- The study doctor may need to take you off the study without your permission if:
- The study is canceled by the Institutional Review Board (IRB). (An IRB is a committee that watches over the safety and rights of research subjects.)
- You are not able to attend the study visit as required by the study.
- You cannot complete the study requirements.
- Your doctors decide that participation in the study is not in your best interest.

COSTS OR PAYMENTS

You will not have to pay for study visits, examinations or laboratory tests which are required as part of the study. Medical costs for treatments, examinations or laboratory tests outside of the study will be charged to you or your health insurance company as would normally be done for your medical care. You will not receive any medications through this study. You will each receive a cash voucher for your on-study visit in the amount of $25 for Baseline (Time 1); $25 for assessments at Time 2 (intervention group only), Time 3, Time 4 (intervention group only); $25 each for 3 month follow-up assessment (Time 5); $25 each for 6 month follow-up assessment (Time 6); $30 each for 12 month follow-up assessment (Time 7); and $30 each for 18 month follow-up

assessment (Time 8). We will provide a voucher or tokens/metro cards for you on the day of your on-study visits and for babysitting as needed.

CONSENT/AUTHORIZATION:

I am the participant or I am authorized to act on behalf of the participant. I have read this information and will receive a copy of this form after it is signed.

By signing this form, you agree that you have talked to your doctor about the study and understand it, and you want to be in the study. You agree that we have talked to you about the risks and benefits of the study, and about other choices. You may decide to stop being in this study at any time and no one will mind and nothing will change about your medical care other than not being in the study. Copies of this form will be:

(1) Kept in the study file by the Principal Investigator;
(2) Put in your medical record; and
(3) Given to you to keep.

Please call the Principal Investigator, Maureen E. Lyon, Ph. D., at 202-474-5442, if you have any questions.

Printed Name of Participant: _____
Medical Record Number: _____
Printed Name of Parent(s)/Guardian(s): _____

Signature of Participant: _____Date:_____
(Participant must be 18 years of age or older)

Signature of Parent(s)/Guardian(s): _____Date:_____

*[Note: Signature of both parents required if more than minimal risk **and no direct benefit**, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child]*

Signature of 2nd Parent/Guardian: _____Date: _____
(ONLY when applicable)

Witness (to signatures): _____ Date: _____
(may be investigator)

Translator's Signature (if, applicable): _____
Language: _____

AFFIDAVIT OF PERSON OBTAINING CONSENT: I certify that I have explained to the above individual(s) the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised.

Printed Name of Individual Obtaining Consent: _____

Title: _____ Signature: _____ Date: _____

CHILDREN'S NATIONAL MEDICAL CENTER

Division of Adolescent Medicine
111 Michigan Avenue, NW
Washington, DC 20010
(202) 476-5000

ASSENT (AGES 12 to 17) TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

TITLE OF STUDY:	**Family Centered Advance Care Planning: Teens Living with Cancer**
PRINCIPAL INVESTIGATOR:	Maureen E. Lyon, Ph. D., Clinical Psychologist Division of Adolescent and Young Adult Medicine

INTRODUCTION: We would like to invite you to be part of a research study at Children's National Medical Center. Before you decide if you would like to participate, we want you to know why we are doing the study. We also want you to know about any risks (anything unexpected that might happen) and what you will be expected to do in the study. You can only be in the study if your parent(s) or legal guardian agree(s).

This form gives you information about the study. Your doctor or a research staff member will talk to you about the study and answer any questions you have. We encourage you to discuss this study with your family before making your decision. We will ask you to sign this form to show that you understand the study. We will give you a copy of this form to keep. It is important that you know:

- You do not have to join the study;
- You may change your mind and stop being in the study any time you want and no one will mind.
- If we make any important change to the study we will tell you about it and make sure you still want to be in the study.

A. WHAT IS THE REASON FOR THE STUDY?

The first purpose of the study is to look at the attitudes of adolescents with cancer about discussing their wishes about life-prolonging treatments with their physician or other health care providers in an outpatient clinic at Children's Hospital. This is also known as advance directives or a living will. We want to know what you want.

Although we know what adults think about these issues, no one has ever asked teenagers what they think. We want to find out what teenagers want and need, so that we can be more useful and sensitive to the needs of all teenagers who are living with a life-threatening illness and their families.

A second purpose of this study is to help you and your family talk about your wishes for end of life care and make a plan for yourself for the future that you can share with your doctor.

You qualify for this study because you are between the ages of 14 and 20.

B. WHAT WILL HAPPEN IN THE STUDY?

This is a standard of care comparison study to see if Family Centered Advance Care Planning is helpful to adolescents and their families.

We will divide the adolescents and their parent or guardian in the study into two groups (like flipping a coin so you have an equal chance of being in any group). We will give one group the Family Centered Advance Care Planning intervention. The other group will receive standard of care or usual care.

The Family Centered Advance Care Planning Intervention will have three sessions:

Session One

1. In session one, you will be asked to answer 30 questions about your attitudes concerning end-of-life care and death and dying. For example, would you want to be involved in these decisions or would you rather have your physician and family make these decisions for you? We just want to know what you think about these issues.
2. Next, we will also ask your parent or proxy the same questions.
3. We will ask your permission to share your wishes with your family and with your doctor.
4. It should take about 30 to 90 minutes to answer the questions. We will be happy to answer any questions you have.
5. The questions will be asked in a private office before or after your outpatient visit.
6. We will divide the responses of the teenagers and those of their parents (or surrogate) to compare answers and evaluate the differences.

Session Two

1. In session two, we will tell you the ways in which you and your family had the same or different attitudes.
2. We will ask your guardian to join you for an interview so that you can share in decision making about advance care plans.

Session Three

1. In session three, if you want to, you and your guardian can complete an Advance Directive called the Five Wishes. The Five Wishes is a research document, as well as a medical directive document.
2. With you and your guardian's permission, it will be put in your medical record and a copy will be given to you and to your health care provider.

Sessions 1, 2 and 3 will be scheduled one week apart (for intervention group only).

The first four visits will be one week apart from each other (Time 1, Time 2, Time 3, and Time 4) for the intervention group. The comparison group will only meet at Time 1 and Time 3. All participants, regardless of group assignment, will meet again in 3 months (Time 5), 6 months (Time 6), 12 months (Time 7) and 18 months later (Time 8.)

C. WHAT POSSIBLE UNEXPECTED THINGS COULD HAPPEN?

Potential risks are minimal. However, some people feel that this is an uncomfortable topic, even though most people do have thoughts about it. If you should find the questions upsetting, we will be available to talk to you and/or make referral to a counselor or chaplain.

D. WHAT POSSIBLE GOOD THINGS COULD HAPPEN?

One benefit for you is that participation may increase your knowledge about end-of-life decision making. It might also make it easier for you to discuss these issues with your physician. Beginning at the age of 18, whenever teenagers come to the hospital to stay, he/she will be given a form asking you questions about end-of-life decision making, even to have their tonsils taken out.

You will be making a contribution to the care of all adolescents with a life-threatening illness by increasing health care professionals' sensitivity and knowledge of teenagers' wishes, as well as the wishes of their parents.

E. WHAT OTHER CHOICES DO YOU HAVE IF YOU DO NOT WANT TO BE IN THE STUDY?

If you do not want to be in this study, you can continue your regular care, as you have always done.

F. HOW WILL WE KEEP YOUR RECORDS PRIVATE?

We will keep the records of this study confidential. Only the people working on the study will know your name. They will keep this information in case we have to find you later to let you know of any new information that may affect your health.

G. PAYMENTS

You will receive a cash voucher for your on-study visit* in the amount of:

- $25 for Baseline (Time 1);
- $25 for assessments at Time 2*, Time 3, Time 4* (scheduled one week apart);
- $25 each for 3 month follow-up assessment (Time 5*);
- $25 each for 6 month follow-up assessment (Time 6*);
- $30 each for 12 month follow-up assessment (Time 7*); and
- $30 each for 18 month follow-up assessment (Time 8*).

**Visits marked with an * are for the intervention group only.*

We will provide a meal voucher for you on the day of your on-study visit, pay for your parking if you drive, or if needed, provide transportation for you (taxi, bus tokens, or a Metro pass) to and from your visit. We will also pay for a babysitter, if that is needed.

ASSENT

By signing this form, you agree that you have talked to your doctor about the study and understand it, and want to be in the study. You also agree that you have been told about the risks (unexpected things) and benefits (good things) of the study, and about other choices. You may stop being in the study at any time and no one will mind and nothing will change about your medical care other than not being in the study. Please call the Principal Investigator, Maureen E. Lyon, Ph. D., at 202-476-5442 if you have any questions.

Printed Name of Participant: _____

Medical Record Number: _____

Signature of Participant: _____

Witness (to signature): _____ Date: _____
(may be investigator)

Translator's Signature (if, applicable): _____ Date: _____

Language: _____

AFFIDAVIT OF PERSON OBTAINING ASSENT: I certify that I have explained to the above individual(s) the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised.

Printed Name of Individual Obtaining Consent: _____

Title: _____ Signature: _____ Date: _____